Proposed Amendments to the Human Organ Transplant Act

Public Consultation Paper

2008
EXECUTIVE SUMMARY

The Ministry of Health (MOH) is proposing three amendments to the Human Organ Transplant Act (HOTA) to help raise our organ transplant rate:

a. Increase the number of cadaveric donors by lifting the upper age limit for cadaveric organ donation;
b. Facilitate living donor transplants by allowing donor-recipient paired matching for exchanges of organs;
c. Support the welfare of living donors by allowing them to be compensated according to accepted international practices.

In addition, to protect donors and recipients from exploitation by middlemen, MOH is also proposing to increase the penalties for syndicated organ trading.

Currently, HOTA limits cadaveric donors to those below 60 years of age. With improved health and longer expectancy of life, some older persons can be suitable donors. The removal of the age limit is also in line with international practice.

Paired matching is a way of matching living donors with compatible recipients across two or more donor-recipient pairs who are incompatible within the pair. It involves an arrangement for a willing donor who is medically incompatible with the intended recipient, to be matched to a suitable recipient who has a medically incompatible donor. The recipients essentially exchange donors so that each recipient can receive a medically suitable organ.
In line with international ethical recommendations, the amendment will allow organ donors to be compensated for direct costs incurred as a result of the donation and indirect losses such as loss of earnings and future expenses due to the donation. HOTA will continue to prohibit the buying and selling of organs. To further deter syndicated organ trading, we propose to raise the penalties against it. This aims to protect donors and recipients from exploitation by unscrupulous middlemen.

MOH would like to seek your views on the above proposed amendments to HOTA so that we could work together to help more organ failure patients.

INTRODUCTION

1. The altruistic organ transplant rate in Singapore is not low. However, compared to Spain and Norway which are almost self-sufficient in kidney donation, there is scope to further increase our organ transplant rate and save more lives.

2. To do so, MOH proposes to amend the Human Organ Transplant Act (HOTA) to:
   a. Increase the number of cadaveric donors by lifting the upper age limit for cadaveric organ donation;
   b. Facilitate living donor transplants by allowing donor-recipient paired matching for exchanges of organs;
   c. Support the welfare of living donors by allowing them to be compensated according to accepted international practices.
3. In addition, to protect donors and recipients from exploitation by middlemen, MOH is also proposing to increase the penalties for syndicated organ trading.

4. MOH would like public feedback on the proposed amendments (see Annex for the relevant sections of HOTA to be amended), which are aimed at saving more organ failure patients.

ORGAN DONATION LEGISLATION

5. HOTA allows for the removal of kidneys, liver, heart and corneas upon death for transplant purposes, unless the individual has registered an objection. The Act applies to all Singapore Citizens and Permanent Residents (PRs) who are between 21 and 60 years old.

6. Persons not covered under HOTA who wish to donate their organs can do so under the Medical (Therapy, Education and Research) Act (MTERA). MTERA allows individuals to pledge their bodies, organs or tissues for use for treatment, education or research purposes after their death. The family members of the deceased may also choose to donate the body, organs or tissue of the deceased if he or she had not pledged under MTERA while alive.

ORGAN TRANSPLANT SITUATION IN SINGAPORE

7. Transplantation is the best treatment option for organ failure patients. For patients with heart or liver failure, an organ transplant is life-saving. For patients in need of corneas, the restoration of sight through cornea transplantation can be life-changing. For kidney failure patients, transplantation offers greater chances of survival and overall improved quality of life.
8. HOTA was enacted in 1987 to set up an opt-out cadaveric kidney donation system for non-Muslims who die from accidental causes. From 1987 to mid-2004, 222 patients with kidney failure benefited from cadaveric kidney transplants under HOTA — an average of 13 per year compared with 5 before HOTA. In mid-2004, HOTA was amended to cover all causes of death and to include the liver, the heart and the cornea. As a result, from then till end-June 2007, the average number of patients who benefited from cadaveric kidney transplants increased to 49 per year, totalling 148 patients. In the same period, an additional 285 patients benefited from the cadaveric transplants of 17 livers, 14 hearts and 254 corneas. HOTA was further amended to include Muslims with effect from 1 August 2008.

9. Despite the increase in organs available as a result of the previous HOTA amendments, the growth in demand for organs for transplant continues to outstrip the supply, especially for kidneys. In 2006, 22 organ failure patients died while waiting for an organ. As of 31 Dec 2007, there were 563 patients on the transplant waiting list for kidney, 25 for cornea, 9 for liver and 7 for heart. (The relatively short waiting lists for liver and heart transplants are due to the fact that these patients usually do not survive long without a transplant.)

10. To address the growing problem of organ shortage, there is a need to increase the yield of cadaveric organs as well as to facilitate living organ donation.
LIFTING OF UPPER AGE LIMIT

11. Whether a person is suitable to be an organ donor depends on his health rather than his age. The upper age limit of 60 years was used as a proxy indicator of a person’s health in the identification of suitable donors. In practice, deceased persons above 60 years old are able to donate their organs for transplantation as long as they are assessed to be medically suitable. Countries such as Norway, Spain, UK and US do not set age limits for cadaveric organ donation. Currently, for a deceased person above 60 years old to donate his organs in Singapore, he needs to have pledged his organs for donation under MTERA during his lifetime, or his family members need to give consent upon his death. In the past 10 years, there were 13 donors above 60 years of age who had donated their kidneys under MTERA for transplantation.

12. As the life-expectancy and health of the population continue to improve with higher standards of living and medical care, the age limit of 60 years set in 1987 as a marker of a person’s health in relation to his suitability as a donor is no longer appropriate. MOH proposes to amend HOTA to lift the upper age limit for cadaveric organ donation under HOTA. With the amendment, persons above 60 years of age, who are Singapore citizens and PRs, who are of sound mind, and who have not registered an objection, would also be included under the Act. The proposed amendment could provide up to 10-12 additional organ donors per year (yielding as many as 24 kidneys, 12 livers, 12 hearts and 24 corneas).
13. Currently, kidney failure patients are removed from the waiting list for transplant when they reach 60 years of age. MOH will remove the upper age limit for patients to be placed on the waiting list. However, as organs retrieved from older persons are usually more suitable for transplant into older recipients, the MOH Transplant Advisory Committee will refine its organ allocation criteria to ensure maximum benefits to patients on the waiting list. It is anticipated that more elderly organ failure patients will benefit from this amendment.

14. MOH will take steps to inform persons of the older age-group who could be implicated by the lifting of the age limit. They will be able to opt-out if they wish to, by registering their objection in their lifetime.

ALLOWING PAIRED MATCHING

15. Paired matching is a way of matching living donors with compatible recipients across two or more donor-recipient pairs who are incompatible within the pair. It involves an arrangement for a willing donor who is medically incompatible with the intended recipient, to be matched to a suitable recipient who himself has a medically incompatible donor. The recipients essentially exchange donors so that each recipient can receive a medically suitable organ. An illustration of paired matching involving 2 donor-recipient pairs is shown below.

Diagram 1: Illustration of Paired Matching

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Recipient 1
Medically incompatible e.g. blood type
Donor 1

Recipient 2
Medically incompatible e.g. blood type
Donor 2
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16. By matching two or more donor-recipient pairs to create matches that would otherwise not have occurred, more patients can receive organs. In addition, paired matching also has the potential to create donor-recipient matches which are more medically compatible for improved transplant outcomes.

17. HOTA currently prohibits the giving or acceptance of organs under a “contract or arrangement”. The prohibition was intended to preclude organ trading. However, an unintended consequence of the prohibition is that it disallows paired matching, which involves an arrangement where a donor gives his organ subject to the promise of a "return" in the form of an organ for his recipient. MOH proposes to amend HOTA so that contracts may be established to facilitate paired matching while the prohibition against organ trading remains.

**PROTECTING THE WELFARE OF LIVING DONORS**

18. There is a need to protect the welfare of living donors. In their altruistic act of organ donation, living donors undertake significant short- and long-term risks for the benefit of others. Therefore, it is only appropriate to have measures in place to ensure that their welfare is not compromised. These could include the following:
   a. A donor registry to track the long-term outcomes of donors;
   b. Long-term medical follow-up and care;
   c. Short-term life insurance coverage for risks associated with surgery;
   d. Adequate compensation for the expenses incurred and loss of earnings and time; and
   e. Priority for receiving an organ for transplant if the donor develops any organ failure later.
19. HOTA currently prohibits the payment of any “valuable consideration” to organ donors. MOH will need to amend HOTA to allow donors to be compensated with the objective of protecting their welfare.

20. The international ethics community is against organ trading but has clarified that compensation and reimbursement to donors not amounting to inducement are ethically permissible.

21. The World Health Organization’s Guiding Principles on Human Cell, Tissue and Organ Transplantation recognize the need to compensate donors for the costs of making donations, including medical expenses and lost earnings.

   Extracts from the WHO’s Guiding Principles:
   “The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income … This Principle permits compensation for the costs of making donations (including medical expenses and lost earnings for live donors), lest they operate as a disincentive to donation.”

22. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism includes a recommendation to ensure the protection and safety of living donors, and appropriate recognition for their heroic act, including the comprehensive reimbursement for donors. Providing reasonable compensation serves to cover losses incurred, or anticipated to be incurred, by the donor, and is not the same as paying donors for their organs.

   Extracts from the Declaration of Istanbul:
   “Comprehensive reimbursement of the actual, documented costs of donating an organ does not constitute a payment for an organ, but is rather part of the legitimate costs of treating the recipient.”
23. Singapore’s National Medical Ethics Committee (NMEC) has similarly suggested compensation to ensure that donors do not bear the burden of losses suffered as a result of their altruism. It has suggested compensation for direct expenses incurred as a result of the donation (e.g. transport and accommodation), and indirect losses (e.g. loss of earnings and time) and future expenses (e.g. anticipated costs of medical follow-up, costs of long-term care of the donor, and life insurance coverage) due to the donation.

Extracts from the NMEC’s Press Release on Altruistic Living Kidney Donation for Transplantation:
“Comprehensive reimbursement of costs of donating a kidney should be a financially neutral process to the donor, and would include any costs that the donor would otherwise not have incurred but for the transplant.”

24. MOH supports the recommendations adopted by the international community and the NMEC. The amendment will allow these recommendations to be implemented.

25. Hospital Transplant Ethics Committees will continue to assess applications for living donor organ transplants. These Committees shall (a) ensure that donors fully understand the risks and implications of their decisions, and (b) determine that there is no financial inducement or undue influence on the donors, before approving these applications. MOH will formulate relevant guidelines for these Committees to comply.

26. HOTA will continue to prohibit organ trading. However, MOH empathizes with the plight of sellers, driven by their circumstances, and that of buyers, motivated by their basic instinct to try to live. In syndicated organ trading, these donors and recipients are themselves exploited by unscrupulous middlemen who profit from the transaction.
27. The current penalties in HOTA (a fine not exceeding $10,000, or imprisonment not exceeding 12 months, or both), make no distinction between the liabilities of the seller, the buyer and the middleman in the offence of organ trading. MOH proposes to make a distinction by amending HOTA to raise the penalties for organ trading syndicates and middlemen to a fine not exceeding $100,000, or imprisonment not exceeding 10 years, or both. This aims to deter organ trading syndicates and unscrupulous middlemen.
THE MINISTRY WELCOMES YOUR VIEWS AND FEEDBACK

28. MOH would like to seek your views and feedback on the proposed amendments to HOTA. In particular, we would like to obtain your feedback on the below questions, which can also be found on the e-consultation page at the Ministry’s website.

   a. Should HOTA be amended to increase the number of cadaveric donors by lifting the upper age limit for cadaveric organ donation?

   b. Should HOTA be amended to facilitate living donor transplants by allowing donor-recipient paired matching for exchanges of organs?

   c. Should HOTA be amended to support the welfare of living donors by allowing them to be compensated according to accepted international practices?

   d. Should HOTA be amended to protect donors and recipients from exploitation by middlemen by increasing the penalties for syndicated organ trading?

29. Replies should reach the Ministry by **15 Dec 2008**.

   All feedback and comments should be addressed to:

   “Feedback on Proposed Amendments to HOTA”
   Ministry of Health
   College of Medicine Building
   16 College Road
   Singapore 169854
   Email: MOH_HOTA@moh.gov.sg
   Fax: 6325 1686

   *This document is also available on the MOH website: http://www.moh.gov.sg*
(I) Lifting The Upper Age Limit For Cadaveric Organ Donation Under HOTA

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<td>5. —(1) The designated officer of a hospital may, subject to and in accordance with</td>
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<td>this section, authorise, in writing, the removal of any organ from the body of a</td>
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<td>removal of the organ from his body after his death;</td>
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<td>(b) who is neither a citizen nor a permanent resident of Singapore;</td>
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<td>(c) who is below 21 years of age unless the parent or guardian has consented to such</td>
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<td><strong>(d) who is above 60 years of age;</strong></td>
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<td>(e) whom the designated officer, after making such inquiries as are reasonable in the circumstances, has reason to believe was not of sound mind, unless the parent or guardian has consented to such removal.</td>
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(II) Allowing Donor-Recipient Paired Matching For Exchanges Of Organs

(III) Allowing Compensation For Living Organ Donors under HOTA

(IV) Increased Penalties For Syndicated Organ Trading

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<td>14. —(1) Subject to this section, a contract or arrangement under which a person agrees, for valuable consideration, whether given or to be given to himself or to another person, to the sale or supply of any organ or blood from his body or from the body of another person, whether before or after his death or the death of the other person, as the case may be, shall be void.</td>
<td>14. —(1) Subject to this section, a contract or arrangement under which a person agrees, for valuable consideration, whether given or to be given to himself or to another person, to the sale or supply of any organ or blood from his body or from the body of another person, whether before or after his death or the death of the other person, as the case may be, shall be void.</td>
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<td>(2) A person who enters into a contract or arrangement of the kind referred to in subsection (1) and to which that subsection applies shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 12 months or to both.</td>
<td>(2) A person who enters into a contract or arrangement of the kind referred to in subsection (1) and to which that subsection applies shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 12 months or to both.</td>
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<td>(2A) Any person who – (a) gives or offers to give valuable consideration for the sale or supply of, or for an offer to sell or supply, any organ from the body of another person other than for the purpose of transplantation to his body; (b) receives valuable consideration for the sale or supply of, or for an offer to sell or supply, any organ from the body of another person; (c) offers to sell or supply any organ from the body of another person for valuable consideration; (d) initiates or negotiates any contract or arrangement for the sale or supply of, or for an offer to sell or supply, any organ from the body of another person for valuable consideration other than for the purpose of transplantation to his body; or (e) takes part in the management or control of a body corporate or body unincorporated whose activities consist of or include the initiation or negotiation of any contract or arrangement referred to in paragraph (d),</td>
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| (3) Subsection (1) shall not apply to or in relation to —
(a) a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of any organ or blood in accordance with the provisions of any other written law; *and*  
(b) any scheme introduced or approved by the Government granting medical benefits or privileges to any organ or blood donor and any member of the donor’s family or any person nominated by the donor. | *shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $100,000 or to imprisonment for a term not exceeding 10 years or to both.*  
[Source: section 32(1) UK Human Tissue Act 2004]  
(3) Subsection *(1), (2) and (2A)* shall not apply to or in relation to —  
(a) a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of [deleted] blood in accordance with the provisions of any other written law; [deleted]  
(b) any scheme introduced or approved by the Government granting medical benefits or privileges to any organ or blood donor and any member of the donor’s family or any person nominated by the donor, *and*  
(c) *a contract or arrangement providing only for* — |
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<td>(4) The Minister may, by notification in the Gazette, declare that subsection (1) shall not apply to the sale or supply of a specified class or classes of product derived from any organ or blood that has been subjected to processing or treatment.</td>
<td>(i) defraying or reimbursing such costs or expenses as may be reasonably incurred by a person in relation to the removal, transport, preparation, preservation, quality control or storage of any organ;</td>
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<td>(ii) compensation in money or money’s worth for such costs, expenses or loss of earnings as may be incurred by a person so far as are reasonably or directly attributable to his supplying any organ from his body; and</td>
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<td>(iii) the payment in money or money’s worth of the costs or expenses of making adequate provision for the short-term and long-term medical care, and insurance protection, of a person which is or may reasonably be necessary as a consequence of his supplying any organ from his body.</td>
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<td>[Source: section 32(7) UK Human Tissue Act 2004]</td>
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(5) A person who as vendor or supplier enters into a contract or arrangement for the sale or supply of a product derived from any organ or blood that has been subjected to processing or treatment, other than such a product which is of a class declared under subsection (4), shall be guilty of an offence if the organ or blood from which the product was derived was obtained under a contract or arrangement that is void by reason of subsection (1), and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 12 months or to both.

(6) Nothing in this section shall render inoperative a consent or authority given or purporting to have been given under this Act in relation to any organ or blood from the body of a person or in relation to the body of a person if a person acting in pursuance of the consent or authority did not know and had no reason to know that the organ or blood or the body was the subject-matter of a contract or arrangement referred to in subsection (1).

(7) For the purposes of this section, the donation by a living donor (“Donor A”) of any organ from his body in consideration of —
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<td>(a) a donation of an organ from another donor for the purpose of the transplantation of the organ to the body of a recipient of Donor A’s choice (“recipient A”); or</td>
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<td>(b) priority in the selection of recipient A as a recipient of any organ, whether removed pursuant to section 5 or otherwise, shall not, of itself, constitute valuable consideration if the donors have given their consent and the provisions of Part IVA (as applicable) are complied with.</td>
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