

Organ Transplantation in Malaysia: A Socio-Legal Study

Anisah Che Ngah

Faculty of Law

Universiti Kebangsaan, Malaysia

ABSTRACT

Kidney and corneal transplants have been undertaken since the seventies although other forms of organ transplantation were lesser known. To date more than 1000 kidney transplants, the majority from living related donors have been performed. Nevertheless heart, lung and liver transplant only had an impact in the nineties. The main reason being, the lack of cadaveric donors, which has hampered the development of organ transplantation in Malaysia. It is instructive to note that the Malaysian society has been rather conservative when it comes to organ transplantation. This is compounded by the Asean culture and value system, which are directly derived from our historical background and religious convictions. However attempts had been made by various organisations such as The Malaysian Society of Transplantation, which was set up in 1994 to create greater awareness on organ donation & transplantation amongst both the healthcare professionals and the public.



1.0 INTRODUCTION

Organ Transplantation was relatively lesser-known in Malaysia till the nineties although tissue transplantation such as corneal transplants have been undertaken since the late sixties with a total of 1,231 reported to date.¹ Donation of tissues from a living person includes regenerative tissues like blood and bone marrow. Blood transfusion is the most common type of exchange and is used in many operations and accident emergencies. In December 1975, the first kidney transplant was carried out when a Sarawakian businessman obtain his kidney from his brother. Since then a total of 1,005 renal transplants have been carried out in the country. Bone marrow transplant service was first started in University Hospital Kuala Lumpur for paediatric patients in 1987 and later for adults. In March 1995, the first liver transplant was carried out in a private institution and recently in May 2002, the first Liver Transplant centre was set up in a government hospital to treat patients requiring liver transplants. Until then, such transplants were only available in private hospitals or overseas at a significantly higher cost. In December 1997,² the first heart transplant was carried out successfully in the National Heart Institute of Malaysia and since then, 15 heart transplantations have been done.

From the time of the first corneal transplant until 31 December 2003, a total of 7,671 organ and tissue transplants have been performed in the country. These included 4,170 tissue graft, 1,267 cornea, 1,007 kidney, 634 bone marrow, 483 bone, 45 liver, 43 heart valve, 15 heart and 7 skin transplants.³

2.0 ORGAN AND TISSUE TRANSPLANTATION

Since then, progress has been made and numerous non-governmental organisations had been set up to cater for these needs. The Malaysian Liver Foundation (MLF) is a national, voluntary, non-profit, charitable organisation dedicated to the prevention, treatment and cure of liver, gallbladder and pancreatic diseases through education, training and research. Activities of MLF include, organising public awareness campaigns on liver conditions such as hepatitis, creating educational forums and events for doctors, dealing with research into liver diseases, and providing laboratory services to test patients for liver conditions.

¹ See the National Transplant Registry at <http://www.crc.gov.my/ntr> (21 April 2005)

² The heart recipient unfortunately passed away a year after the historic transplant took place.

³ Extracted from the speech of the Hon. Dato' Chua Jui Meng, the then Minister of Health Malaysia, at the launch of the certificate in medical law and the book entitled "Issues in medical law and ethics", in Kuala Lumpur, on 13 March 2004 .

The National Transplant Resource Centre (NTRC) at Hospital Kuala Lumpur was set up in November 1997. This was a one-stop information centre with toll-free lines and manned by trained paramedical personnel to answer to queries on organ donation and transplantation. Administrative mechanism was in place to ensure smooth pledging of organ donation. Its success was followed with the establishment of similar regional centres throughout the country to carry out organ donation and transplantation awareness programmes.

The National Transplant Registry (NTR) was set up in 2003 to collect information about patients who had undergone organ or tissue transplantation. This is considered vital to estimate the magnitude of transplant activity in the country. It is also useful in assisting the Ministry of Health (MOH), the Non-Governmental Organizations, private providers and industry in the planning and evaluation of transplant services. Till date, The NTR receives data on organ/ tissue transplantation from individual doctors who provide transplantation services and also patients who voluntarily report data to the NTR. Data collection are obtained from six main types of transplantation services namely ; Blood and marrow Transplant, Heart and Lung Transplant, Liver Transplant, Renal Transplant, Cornea Transplant and Bone / Tissue Transplant. The NTR is sponsored by the MOH through its various agencies namely;

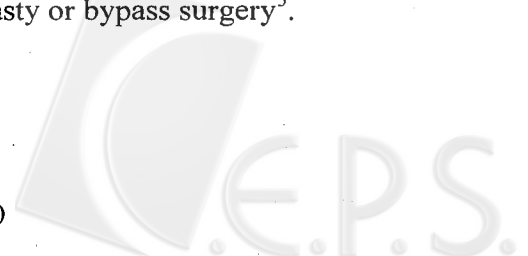
- (a) National Transplant Coordinating Committee, MOH
- (b) The Medical Development Division, MOH
- (c) The Malaysian Society of Transplantation
- (d) Clinical Research Centre (CRC) of Kuala Lumpur Hospital.

The NTR has formulated a number of clinical registry forms for various types of organ transplantations. One of those is for liver transplantation⁴ to ensure that proper monitoring and counselling for both donors and recipients are taken care of.

In May 2000, Hospital Selayang (government Hospital) successfully carried out the world's first paediatric, whole arm transplant between 2 identical twin babies, the donor having died from a severe, congenital brain abnormality. In September 2003, Malaysia, recorded its first successful stem cell transplant to treat severe heart disease. The transplant, performed on one Allagara Arumugam, 60 years of age, by surgeons from the National Heart Institute and the Kuala Lumpur Hospital was a breakthrough for patients unable to undergo conventional angioplasty or bypass surgery⁵.

⁴ See Appendices 1 & 2

⁵ See the NSTP online at <http://www.nst.com.my> (3 May 2005)



When it comes to regenerative tissues, we have got two tissue banks in Malaysia. One of those is MINT (Malaysian Institute for Nuclear Technology Research) under the auspices of the Ministry of Science, Technology and Innovation.⁶ MINT Tissue Bank produces biomaterials for clinical uses. This tissue bank produces bone and tissue grafts already used by local hospitals. The other is The Tissue Bank Unit, School of Medical Sciences, situated in University Science Malaysia which serves as an academic as well as a service oriented unit in the production of tissue allografts and xenografts. The unit was established in July 1991 and is playing a national role in tissue banking research and services. The tissue grafts are used in the field of burn management, orthopedic surgery, neurosurgery, maxillofacial surgery, dental surgery, paediatric surgery and otorhinolaryngology. The grafts are used as biological wound dressings in the management of burns or as tissue replacement substitutes in reconstructive surgery.⁷

On April 11, 2005, in a show of solidarity 150 people took part in the Malaysian Transplant Games. They were from different races and walks of life. Among them were a retired clerk, a former minister and a lorry driver. Yet, they had something in common – all were organ recipients.⁸ In fact the Association would be sending a contingent to the World Transplant Games in Canada from July 16 to July 24 this year.

3.0 THE BACKGROUND

An average of 2000 organs were needed per year however the total amount of donation was only at an average of 30-40 organs.⁹ Donation was done amongst related relatives of the patient. This had been an ongoing process for the past 20 years, mostly depending on living donors. Live donors can be parents, siblings or close relatives who are genetically related to the recipients; or spouses and very close friends who are “emotionally related” to the recipients. They are collectively known as “live related donors”. However in recent years, there were cases where live unrelated donors had also donated with prior permission from the Ministry of Health.

3.1 THE LIVING DONOR

To date, there is no legislation to monitor the conduct of living donors in Malaysia. As such, the author based it on recent practices done in Malaysia, under the auspices of the Ministry of Health. Policies and guidelines pertaining to this matter have been randomly issued as and when it becomes necessary to do so. From the practices, these

⁶ See MINT online at <http://www.mint.gov.my> (15 April 2005)

⁷ See USM online at <http://www.usm.my/usm/misc/usmlink/v2n2/m5.html> (15 April 2005)

⁸ The Star Online (<http://thestar.com.my>) 12 April 2005

⁹ Islam dan pemindehan organ (Islam and organ transplantation) IKIM, Malaysia 1998, pg. iii

are the common elements, which can be translated into criteria for organ transplantation for both regenerative as well as non-regenerative organ.

Conditions:

(i) Adult- Competent organ donors

An adult is according to law, a person who has reached the age of majority. In Malaysia the age of majority is 18 years old.¹⁰ Legally speaking, an adult person must be 18 years and above to be deemed competent unless proven otherwise.

(ii) Free, voluntary and informed consent

The competent donor will then be informed of all material facts relating to the operation, which would enable a reasonable person to weigh the risk, benefits and other possible side effects before arriving at a decision whether or not to undergo the operation. The donation must be made voluntarily. In other words there must not be an unfair pressure upon the donor, which induces him to consent despite his misgivings. As such, when a person signed his name for organ donation then he is considered voluntarily and freely making his decision to donate his organ.

(iii) Operation must be therapeutic.

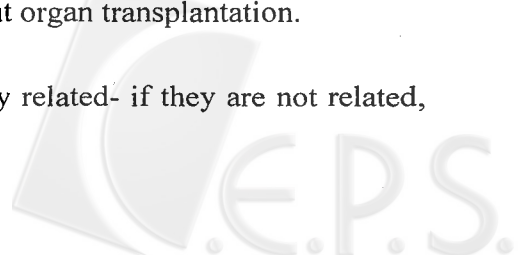
The word 'therapeutic' means that the operation is the only alternative to save the patient's (recipient) life. The success rate of this kind of operation ought to be arguably high. Apart from obtaining the consent of the donor, there must also be acceptance on the part of the recipient. Both must be prepared to accept the inevitable outcome.

(iii) Operation performed by a medically qualified person.

Section 14(1)(2) (3) of the Medical Act 1971 states that 'a person is a qualified doctor if he or she fulfils the following requirements namely; holds a qualification specified in the schedule of the said Act or a qualification in medicine and surgery approved by the Minister of Health and able to produce evidence that he or she has completed the 1 year requirement engaging in employment in a resident medical capacity to the satisfaction of the Medical Qualifying Board unless exempted'. In other words, the person must be a skilled specialist in order to carry out organ transplantation.

(iv) Involve a donor or recipient who are genetically related- if they are not related, the

¹⁰ Age of majority Act 1971



donation must be approved by the regulatory authority.

In Malaysia, we did not have a specific regulatory body to accommodate these needs, however, it comes within the purview of the Ministry of Health. (MOH) As such, the MOH will issue permission when it involves a donor or recipients who are not genetically related. In the recent liver transplant cases, parents usually are the ones to donate part of the liver, however there were cases where the donors were –not genetically related. The potential donors have to undergo a donor medical assessment to consider whether they are suitable for the transplant.

3.2 INCOMPETENT LIVING DONOR

(a) Adult/children

To date there is never a case where an incompetent adult or child has donated any part of his or her body to another recipient. However in May 2000, a whole arm transplant between 2 identical twin babies were carried out, the donor (twin A) having died from a severe, congenital brain abnormality. Parental consent was given in this case. In recent cases, adult donors gave part of their livers to children who needed liver transplants.

3.3 THE DEAD DONOR/ CADAVERIC TRANSPLANT

Cadaveric organ donation is the donation of organs after the death of an individual. However, death is not defined in the Act, (Human Tissues Act 1974) as such there was a question whether Malaysia should follow the traditional criteria of death namely the heart-lung orientated death or the contemporary standard of brain-death to establish death. Traditionally, death was defined in terms of cessation of cardiovascular function, namely the person has no pulse and the heart stops breathing.

However in 1992, the MOH formed a committee consisting of various medical experts and health professionals to consider the brain-stem death criteria, which were then accepted worldwide. They finally conclude that the said guidelines could be used because the principles would not go against the basic tenets of Islam, as such the guidelines were then disseminated to various government and private medical centres. Since Malaysia is predominantly a Muslim country where 60% of the population profess Islam, it is only appropriate to view the brain death criteria according to the Muslim faith.¹¹ Prior to 1992, the National Fatwa Council¹² issued a fatwa (religious

¹¹ Annual report of the Department of Statistics, Malaysia, 2000. Malaysia is a developing country with a population of 24 million. The predominant ethnic race consists of Malays who are Muslim, Chinese who practice Taoism, Confucianism, Buddhism and Christianity; and Indians who practice Hinduism.

¹² Highest Islamic Authority in Malaysia consisting of religious experts.

ruling) accepting the concept of 'brain-death' in 1989 and again reiterating its stand in 1992.

Input from various non-governmental organisations on religions had supported the idea that all religions in the country accepted organ transplantation if it is done to save the lives of patients. As such, a consensus was reached that permits organ donation and transplantation but prohibits the sale and purchase of organs. Such rulings allow transplants of organs as long as the following conditions are satisfied namely;¹³

- i) the transplant is the only form of treatment available;
- ii) the likelihood of success of the transplant is high;
- iii) the consent of the donor or next of kin is obtained;
- iv) death of the donor has been fully established by a doctor of repute
- v) the recipient has been informed of the operation and its implications.

It is instructive to note that there is an Act, which makes provisions with respect to cadaveric organ donors, as such it is only fair to consider some of the pertinent issues according to the Act.

4.0 LEGAL STATUS

4.1 Human Tissues Act 1974 (Act 130)¹⁴

The preamble of the Act provides " An act to make provision with respect to the use of parts of human bodies of deceased persons for therapeutic purposes and for purposes of medical education and research.

The Act came into force on 1st January 1975 throughout Malaysia to facilitate the donation of organs for therapeutic purposes, research and medical education after the patient (donor)'s death. There are only five sections in the HTA 1974.

There are two methods that the law allows for the removal of organs from dead bodies namely :

- (i) at the request of the donor (Section 2(I))

The request may be given at any time in writing or may be stated orally during the deceased's last illness in the presence of two witnesses. This is known as the "opting in", method which is widely practised in this country, whereby a person states his intention to donate his organs when he is alive and this is recorded. The practice

¹³ Konsep asas Rawatan pemindahan Organ menurut Islam (Basic concept on organ transplantation according to Islam) Dr Abdul Monir Yaacob & Mohd Fauzi Mustaffa, IKIM, Malaysia, 1998, pg.48

¹⁴ See Appendix 3

nowadays is to submit a form to the NTRC ¹⁵ where it is recorded and a donor card issued.

(ii) with the consent of the relatives, provided the donor has not expressly objected to his organs being donated. (Section 2(2))

The person lawfully in possession of the body (usually a doctor/transplant surgeon) is under a duty to take all reasonable steps to find out if the deceased had any objection and to obtain consent from the next-of-kin.

Section 3(2) of the HTA 1974 provides that “ no such removal shall be effected except by a medical practitioner fully registered under S.14 of the Medical Act and who together with at least one other fully registered medical practitioner have satisfied themselves by personal examination of the body that life is extinct.”

In other words, the doctors must be highly qualified to perform the operation. In the country apart from several government hospitals, there are only a handful of private medical centres, which provide these services. Although the concept of brain death is yet to be formally adopted (either through legislation or the courts) however by and large doctors have adopted the brain-death criteria guidelines issued by the MOH.

Section 4 provides that ‘in the case of a body of a deceased person lying in a hospital and unclaimed the person having the control and management of the hospital or any other person authorised by him shall be deemed for the purpose of this Act to be a person in lawful possession of the body”.

In practice, the Director of the Hospital will delegate this function to the Head of the transplant team to consider whether it is feasible to remove any parts of the body according to the administrative mechanism that was in place. An example would be the Malaysian Society of Nephrology (MSN), which had established a committee, which was tasked to initiate the development of a national organ-sharing network. The network was referred as the Malaysian Organ Sharing System or MOSS. MOSS in fact has come out with published criteria concerning the eligibility for transplantation, and a ranking system to determine who among the eligible patients should receive transplantation first, based on the principles of utility, justice and autonomy.

The HTA 1974 was based primarily on the UK 1961 Human Tissues Act. With the passage of time and rapid advancements in transplantation technology, shortcomings in the HTA Act 1974 have become evident. Accordingly, the Ministry of Health is

¹⁵ See Appendix 1

now in the final stages of reviewing the Act to address these shortcomings and bring it up to date.¹⁶

5.0 SOCIAL, CULTURAL AND RELIGIOUS ASPECTS

Up until the end of 2003, slightly more than 75,000 persons in the country have pledged their organs, with the Chinese making up the majority (67%), followed by the Indians (22%) and Malays (8%). Women (54%) slightly outnumber men.¹⁷ It is interesting to note that 'to save lives' and 'for the benefit of others' are universal values, which cut across all religions. The Chinese who are mainly Buddhists believe that giving organs was clearly an act of compassion as well as an act of generosity. Likewise in Islam, Christianity and Hinduism.

A local media had posed the germane question of 'WHAT exactly hinders Malaysian Muslims from organ donation?' Muslims prefer to donate during their lifetime rather than afterlife although the National Fatwa Council had issued the ruling that organ transplantation is permissible, however the main cultural and religious belief is the fear that the act of transplantation itself would hurt the dead body (donor). Perhaps it is fair to say that apart from the educated masses, the majority would still abide to the traditional and cultural belief rather than go along with the recent religious ruling.

It is instructive to note that lack of awareness amongst society, be him a Muslim, a Buddhist, a Hindu or a Christian, is still the dominant reason as to the scarcity of organ donation. In a way, this again relates back to inadequate information. The organ donation campaign is not widespread throughout the country. Those who are directly or indirectly involved (example a loved one who needs a new kidney, a diseased liver perhaps?) will definitely have the knowledge but still, the message did not really get through the masses.

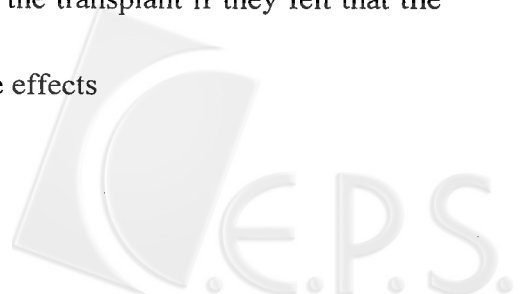
Even doctors themselves find it difficult to explain to relatives of the patient (the would be donors) on the possibility of organ donation especially when they are in grief losing a loved one.

Some other reasons for the shortage of cadaveric donors are as follows:

- (a) The next-of-kin refused to donate
- (b) Doctors did not proceed with the transplant if they felt that the donor was forced to donate
- (c) Donor was worried of the side effects

¹⁶ *ibid*, fn 3

¹⁷ *ibid*



6.0 CONCLUSION

Some of the ethical problems that need to be solved for live donations are questions of consent, whether they were given freely and not under duress, whether the risks were explained to the donors, and ensuring that no payments were involved in the procurement of the tissues and organs.

By and large, doctors accept the notion of brain death. However, the pronouncement of brain death should be done using very strict criteria and performed by doctors who are independent of both the transplant team and the team looking after the recipient.

Further there are various shortcomings in the Act, which need further explanations. For example who are 'deemed to be the next-of-kin'. The current Act does not ban the sale or purchase of organs and there is also no provision for any sanction in the event of a breach of any section. There is also no definition of death in the current Act. There is presently no legislation in the country governing the removal of organs from live donors. In the absence of any clear legal authority, it is presumed that live donations are legally permissible by way of valid consent obtained from the donor. These are some of the legal problems, which need to be addressed immediately.

Further to safeguard the public interest and to maintain a safe and equitable transplantation program, transplant hospitals and private medical centres should be gazetted so that there is proper monitoring of all activities relating to organ transplantation. The administrative mechanism to provide these services must be properly maintained and be made transparent so that the masses will have confidence to donate their organs.