GUIDELINE OF
THE MALAYSIAN MEDICAL COUNCIL

MMC GUIDELINE 006/2006

ORGAN TRANSPLANTATION

Malaysian Medical Council

PRELUDE

This Guideline complements, and should be read in conjunction with the Code of Professional Conduct of the Malaysian Medical Council (MMC) and the Report of the Committee on Organ Transplantation, Ministry of Health.

In this Guideline, the words "doctor", "physician", "medical practitioner" and "practitioner" are used interchangeably, and refer to any person registered as a medical practitioner under the Medical Act 1971. The words "hospital" and "healthcare facility and service" are used interchangeably and refer to any premises in which members of the public receive healthcare services. Words denoting one gender shall include the other gender. Words denoting a singular number shall include the plural and vice versa.

Adopted by the Malaysian Medical Council on 14 November 2006

FOREWORD

The Malaysian Medical Council, with the objective of ensuring that registered medical practitioners are fully aware of the codes of professional medical practice, issues directives and guidelines from time to time. The purpose of these codes, guidelines and directives is to safeguard the patient and members of the public, to ensure propriety in professional practice and to prevent abuse of professional privileges.

The Guidelines are designed to complement, and should be read in conjunction with, the Medical Act Regulations, Code of Professional Conduct of the Malaysian Medical Council and other Guidelines issued by the Council or nay related organisation, as well as any statute or statutory provisions in force and all related statutory instruments or orders made pursuant thereto.

This Guideline on **Organ Transplantation** has been prepared with careful attention to details, cognisant of the prevailing current international stand on the subject. The Draft has been reviewed numerous times by the Malaysian Medical Council and includes valuable response from individuals, organisations and professional bodies in the country, before formal adoption by the Council.

The Guideline is available in the printed form as well as in the MMC website. Registered medical practitioners are advised to familiarise themselves with the contents, as they will serve as documents to refer to or to seek clarifications from, when practitioners need guidance on matters of professional ethics, codes of professional conduct and medical practice in general.

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ORGAN TRANSPLANTATION

SUMMARY

Organ transplantation has in the last few decades become an effective form of treatment for end stage heart, liver and kidney failure, and the technical skill and knowledge for transplantation of other organs like the lung and pancreas are being continuously developed.

Our ability to control the transplant patient's immune response and the side effects of immunosuppressive regimens has reduced the incidence of acute graft loss. This has given greater confidence among transplant surgeons who now believe that, with the fine-tuning of skills and technique, organ transplantation should no more be reserved for life-threatening organ failure but should also be available for structural non-life threatening defects.

Ethical issues in organ transplantation relate to organ donation and organ allocation. Along the way, issues relating to live donors, particularly in liver transplantation, have also emerged in the context of non-maleficence of live donors who run the risk of mortality and physical and psychological morbidity.

Moral issues of organ allocation to recipients, the shortage of organs available for transplantation, the commercialisation of organ donation and the consent for, and religious beliefs in, cadaveric organ donation are also dealt with in this Guideline.

Organs obtained from non-human donors (xeno-transplantation), and human cloning for organ harvesting are already becoming exciting but contentious issues.

1. INTRODUCTION

The last fifty years have seen major advances in the field of medical research, many of which were translated into clinical applications. In general these applications have brought immense benefits to patients. As many of these new clinical applications are quite radical and often controversial, they inevitably challenge conventional ethical principles.

Solid organ transplantation is one such advance which has generated and continues to generate issues involving ethics, law and morality. Organ transplantation has become an effective form of treatment particularly for end stage heart, liver and kidney failure. Except for kidney failure, organ transplantation is the only form of possible treatment for the other organ failure states, like the heart or the liver.

The success rate in solid organ transplantation generally has improved since the first heart transplant 40 years ago, and this is as a result of our ability to control the transplant patient's immune response. This has reduced the incidence of acute graft loss and the side effects of immunosuppressive regimens and given greater confidence among transplant surgeons who now believe that organ transplantation should no more be reserved for life-threatening organ failure but should also be available for structural non-life threatening defects. Thus we have increasingly seen hand transplants, laryngeal transplants along with knees, nerves, flexor tendon apparatus of the hand. But these are reconstructive transplants and need to be differentiated from the more complex organ transplantation.

From the beginning, issues involving ethics have dominated the field of organ transplantation. This is not surprising as transplantation involves the use of human donors who may be alive or dead. Further the persistent shortage of organs in relation to the number of patients needing transplantation has led to problems of allocation. The success

of transplantation, as measured by survival of the transplanted organs, has improved considerably in recent years. But the continued shortage of organs for transplantation has led to an unsavoury aspect of transplantation, that of trafficking in organs, with all the attendant social, moral and ethical issues.

Ethical issues in organ transplantation can be broadly categorised into issues relating to organ donation and those that relate to organ allocation.

2. ETHICAL ISSUES IN ORGAN DONATION

Organ donors can be classified as live or cadaveric. Live donors can come from family members when they are known as "live related" donors (LRD) or from close friends, relatives or spouses, when they are known as "emotionally related" donors (ERD). As mentioned above there are also donors who sell body parts, and they are called "commercial" donors.

Ethical issues in live organ donation

The ethical issues of live organ donation should be considered in the light of the four basic principles of biomedical ethics:

- respect for autonomy
- non-maleficence
- beneficence
- justice.

No one would argue against a parent's decision to donate a kidney or part of a liver to his/her child. It is seen as a selfless, altruistic and noble act. On the other hand the actions of doctors, nurses and other allied health staff to fulfil the parent's wishes may on surface appear to violate the basic principles of medical practice and ethics, which is *primum*

non nocere or "first do no harm". However all clinicians involved in transplantation and the public have accepted live donor transplantation for kidneys as the risks involved are minimal and the benefits to the recipient are enormous.

Respect for Autonomy

Since the beginning of organ transplantation, clinicians have emphasised altruism as the basis for organ donation. The element of a freely given consent without any duress is central to the altruistic act. Transplant teams clearly appreciate that live donors will have to make the decision to donate voluntarily without any duress if the principle of autonomy is to be respected. One justification for living organ donation is that it is an exercise of individual autonomy and in practice most donors have made the decision on their own free will. Clinicians practising organ transplantation using live donors are cognisant of the fact that despite their best efforts, there are instances when donors have donated organs under subtle forms of coercion. Relatives who are economically dependant on the family one of whom needs an organ, may see it as their obligation to donate. Similarly spouses who are dependent on their life partner may find it difficult to refuse requests for organs.

Institutions practising live donor transplantation usually develop mechanisms to allow a potential donor who is under pressure to withdraw without unduly upsetting family relationships. In facilitating the potential donor to make a free and informed decision on organ donation, the institution should provide him/her with adequate information on all aspects of donor surgery including short and long term risks.

Many institutions provide "donor advocates" who are physicians independent of the team looking after the recipients or the transplant team. These donor advocates help the potential donors with their decision making by providing independent and objective advice. Potential donors

should have access to other members of the team, such as nurses and social workers, whom they may find easier to relate to. Finally, the potential donor should be assured that at any time he changes his mind about donating an organ, his wishes will be respected. Persons, who are mentally incompetent to decide should not be allowed to donate.

Recent issues on abuse of autonomy have risen where unrelated donors have specified which type of patients should receive their organ. This is not acceptable.

Principle of non-maleficence

In the surgery of organ retrieval for transplantation, actual physical harm is being inflicted on the donor who is otherwise healthy and well. Donors run the risk of mortality and both physical and psychological morbidity. The act of live donor organ donation thus is a balance between risks and benefit. One may argue that the donor does not accrue any direct benefit by his act. However, it has been shown that live related donors may benefit from the act of donation through improvement in self esteem and a sense of satisfaction that they have done something for their loved ones.

The risks to the donor are normally minimal and all potential donors should be made aware of this fact. In donor nephrectomy, the mortality rate has been reported to be around 0.03% in some studies. Hence the medical work-up of the potential donor should be as thorough and comprehensive as possible and where any doubt exists that the potential donor may undergo more than the minimum risk, the surgery should not be carried out.

The surgical team should also be well trained and have all the necessary technical support.

Principle of beneficence

The principle of beneficence dictates us to do good for others especially when there is no risk involved for the benefactor. In the context of live organ donation, the goal of beneficence may override that of non-maleficence if the probability of benefit greatly outweighs the risks.

Principle of justice

This is more relevant to the allocation of organs (see below) as it calls for a fair, equitable and appropriate treatment in the light of what is due to the patient based on his failing health and not influenced by other factors, like usefulness to society, social standing and so on.

Commercialisation of transplantation - a moral and ethical issue

In the 1980s survival of transplanted kidneys improved considerably with the introduction of newer forms of drugs to suppress the body's immune system. At the same time it is well known that kidney transplant patients enjoy a better quality of life compared to dialysis patients. The demand for kidney transplant increased but the supply from cadaveric sources remained low. This led to the phenomenon of selling of organs by the poor. This became rife in some of the third world and developing countries and rich patients from other part of the world went to countries like India, Pakistan or the Philippines, to purchase organs for transplant.

The sale of organs became a lucrative trade for some except that the poor donor was often paid a paltry sum for his kidney or eye while the unscrupulous doctors and middle men profited. The rampant commercialisation and exploitation of the poor shocked the international transplantation community and the International Society of Transplantation and many national societies condemned the practice.

The trafficking in organs has confounded medical ethics. Questions of law, morality, justice and economics emerge. Although the governments in these countries have passed laws to ban such commercial donation of organs for transplantation, the practice has not totally ceased and in fact has slipped into an illicit trade. A number of ethical issues can be identified in this rampant commercialisation of transplantation.

The person who lives in abject poverty, or who has to support his starving family, has very few options. The doctor who operates purely for monetary gains will obviously lower his standards of donor selection with concomitant harm to the donor in terms of morbidity and even fatality. The rampant commercialisation has led to criminal activities where persons are kidnapped and organs removed and in some countries prisoners are forced to donate their organs as well as organs removed from executed prisoners. Some potential recipients choose not have organs from prisoners.

There are attempts to regulate this sordid commercialisation with proposals such as rewarded gifting and other measures. However these measures remain open to potential abuse. Other proposals have treated organs as commodities with one suggesting that there should be a futures market in organs. The American Medical Association has, after some heated debate, recently considered it not totally unfavourable to pay for cadaveric organ donation. There are also proposals, not yet universally accepted, that live donors should be financially rewarded.

3. ETHICAL ISSUES IN CADAVERIC ORGAN DONATION

The major source of donor organs in the Western countries is the cadaver. Even in organ transplantation where live donor is possible and available, such as kidney transplantation, the main or preferred source of organs is still the cadaver. There are a number of ethical issues relating to cadaveric organ donation.

Consent for organ donation following death is usually given in two ways. In the "opting in" system presently practised in this country a person states his intention to donate his organs when he is alive and this is recorded in a document. Upon his death and in circumstances where organ retrieval is possible, the doctors who note his wishes can then proceed to harvest the organs. Doctors will also have to take note of the views of the immediate relatives of the deceased. As with the case of a live donor, consent should be freely given without any form of pressure or inducement.

In another system of giving consent, "the presumed consent" or "the opting out system"are considered. In "presumed consent", a person is deemed to have consented if he had not clearly stated that he did not wish to donate his organs. Such a system is practised in many countries including Singapore and a number of European countries and has led to improvements in organ donation rates. In the "opting out system" one assumes that the citizens of the country have access to all the information required to make an "informed" decision and have the freedom to make a decision not to donate his organs without fear of being "blacklisted". Administrative mechanisms must be in place to help the individual decide.

Respect for the dead is a fundamental part of our religion and culture. In organ transplantation removal of organs from the dead is carried out with due care and concern like in any other surgery, without mutilation or disfigurement of the body.

As the practice of transplantation develops further more and more organs can be transplanted and this can lead to multiple organ retrieval, which will leave the cadaver with few organs remaining. It is important for doctors to maintain respect for the dead and exercise discretion on the proper limits of organ retrieval.

In cadaver organ transplantation, the definition of death is crucial as organs are best removed when the heart is still beating but the patient is dead. Such a situation is called brain death. It is important that pronouncement of death is done using rigid criteria and persons performing tests to determine brain death are independent of the transplant team as well as the team looking after the recipient. Although arguments still continue on the definition of death, most doctors accept the notion that brain death is the final criterion of death.

4. ETHICAL ISSUES IN ORGAN ALLOCATION

The numbers of organs have never been sufficient to meet the demands and the waiting time for patients to receive organs continue to grow. In heart and liver failure, transplantation is life saving. A system of allocation of a very scarce resource, that of organs, has to be instituted. This has become a subject of much discussion and debate among not only the medical community but also the public at large. The ethical principles utilised in allocating organs include utilitarian, justice and autonomy.

The **utilitarian** principle emphasise that an action is considered right if it results in more good than an alternate action. In organ allocation this principle may make use of medical indicators which predict better outcome as justification for giving an organ to a particular recipient. Such medical indicators include tissue typing characteristics. It precludes consideration such as the social worth of the patient.

MMC Guideline on Brain Death, 2006

The principle of **justice** attempts to ensure equitable access of patients to an organ sharing system. It allows consideration of other factors than just utilitarian ones. Thus a patient who is waiting for an organ for a long time should also be considered as a potential recipient even though another patient may have a better tissue match.

The principle of **autonomy** may be applied when a patient refuses to receive an organ allocated to him, in which case it can be given to the next suitable waiting candidate. Although there are doctors who emphasise utilitarianism as the main criterion for allocation of organs, in general in any given situation all factors are considered together and a consensus achieved.

5. CONFIDENTIALITY

The entire process of live un-related or cadaveric organ retrieval from the donor and the transplantation into the recipient should be carried out in strict confidence at all levels of healthcare workers and doctors involved. The persons involved should not be revealed to each other or their relatives, as subsequent outcome, whether favourable or unfavourable, may have serious repercussions when the parties involved become mutually identified.

6. PROTOCOL FOR ORGAN TRANSPLANTATION

The annexure to this Guideline sets out the protocol to be adopted in the administrative procedures in organ transplantation. It includes objective evaluation of the living related donor. Unrelated living donors are usually not accepted, except under special circumstances, and only after strict evaluation by the Unrelated Transplant Approval Committee (UTAC).

7. CONCLUSION

Ethical issues have been associated with organ transplantation from the beginning and will continue to be a major consideration in this field. Doctors practising in this field must be aware of all the issues and ensure that they do not transgress any ethical principles. The continued commercialisation of transplantation and the shortage of organs pose major challenges to ethics and the way organ transplantation will develop in future. Further developments in the transplantation field particularly the availability of new organs or tissue through genetic engineering or cloning for xeno-transplantation will pose new issues in medical ethics.

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ANNEXURE

GUIDELINE FOR ORGAN TRANSPLANTATION FROM LIVING DONORS

1. AIM

The aim of this guideline is to lay out the procedures for organ donation by living donors.

2. OBJECTIVE

The objectives of this guidelines are :

a. to ensure that the potential donor of an organ or part of an organ has undergone evaluation and understands the risks involved.

b. to ensure that the institution performing the transplantation follows the procedures according to ethical principles and practices as accepted at present .

3. TERMINOLOGY

3.1 Related living donors are those with genetic relationship with the recipient and are :

i. parents or children
ii. grandmother/grandfather
iii. siblings of the same mother and same father
iv. siblings with either same mother different father or same father but different mother
v. uncle or aunt
vi. first cousins

3.2 Living donors who are emotionally related are :

i. those with long standing friendship with recipient
ii. wife/husband of the recipient

3.3 Unrelated living donors are those who do not fall into the above categories.

4. BACKGROUND

Organ transplantation is a treatment of no choice for patients with end-stage disease, except for renal failure.

Organ donation is either from recently deceased persons (cadaveric) or living persons. Cadaveric organ donation in this country is 1:3 compared to living donors. Because of this shortage, the availability of organs for transplantation from living donors has become more important.

At present, some 80% of kidney transplantations are from living donors. Almost all liver transplantations are from living donors and many of them are unrelated donors.

Because of the risks involved when donors are living, and to prevent exploitations of such donors, in countries like USA and Britain, special committees function to evaluate potential unrelated donors.

5. ISSUE

5.1 Safety of Living Donors

The donation of organs by living donors engenders various risks to their health. These risks are short term during the process of retrieval of the organ and the surgery involved, and long term due to loss of one of the organs or part of an organ. A study in the USA has shown that the risk of death in a living person who donates a kidney is between 0.003 – 0.06%. The risk in an adult living liver donor is 1 in 750 when the recipient is a child and 1 in 100 when the transplantation is from adult to adult.

5.2 Commercial Abuse of Organ and Tissue

Because organs and tissue for donation are in short supply in situations where the demand is high, abuse of such donation may be abused. Amongst these are sale and purchase of organs. In many countries the poor are known to donate kidneys to those who can afford to pay to solve their health problems. For the poor, this is easy income without considering the risks involved.

6. GENERAL GUIDELINES FOR ORGAN DONATION BY LIVING DONORS

6.1 An individual willing to donate organ must be :

a. An adult legally able to give consent
b. Aware of all risks that can occur
c. Physically and mentally fit
d. Fully aware of the decision he/she is making
e. Able to fully evaluate and understand all information given to him/her
f. Not have received any coercion or any advice or opinions from sources other then the institution which is planning the transplantation.

6.2 The process of evaluation of a living related donor is laid down in the Guideline on Organ Transplantation, MOH.[1] in *Appendix I* – Renal Replacement Therapy Guidelines of the Ministry of Health, section 111 Renal Transplantation, subsection on Living Related Donor workup and *Appendix II* – Workup of the live donor

1. Refer Guideline on Organ Transplantation, Ministry of Health

6.3 Living unrelated donors must have access to all available information before signing the consent form. Enough time must be given for such consent. The doctor involved must ensure that the freedom to give consent is not hampered. The potential donor and the recipient or the recipient's family should not be known each other to avoid any financial transaction.

Information which the potential donor must understand include:

a. The choice of treatment for the patient including the treatment without organ transplantation.
b. The types of tests which need to be carried out, and the risks and complications of such tests
c. The short term and long term risks, including the risk of death
d. The success rate of the transplantation in general and the success rate of the institution performing the transplantation, and
e. The need for follow-up treatment.

6.4 The donor must be free to obtain opinion and information from any specialist regarding the advantages and disadvantages of transplantation involving lining donors, particularly on disabilities and possible death.

6.5 Potential donor must know that he may withdraw his consent at any time without giving any reason and no action will be taken against him.

6.6 No financial transactions are permitted except payment for expenses incurred by the donor, payable by a third party.

6.7 The donor must be given the guarantee that all possible steps will be taken to minimize the risk to him.

7. ORGAN DONATION BY LIVING RELATED DONOR

The donation of organ by a living related donor must follow the general guidelines for living donors. It is the responsibility of the institution performing the transplant to ensure that all guidelines are followed.

8. ORGAN DONATION BY LIVING UNRELATED DONOR

Organ donation from unrelated donors is primarily not accepted unless in special circumstances. Such special circumstance may prevail when there is no suitable related living donor or a cadaveric donor for liver transplant. In such situations, application should be made for approval from the Unrelated Transplant Approval Committee (UTAC)

UTAC is established to evaluate the application for organ donation by living donor without genetic relationship and without any emotional relationship with the recipient. The guideline to be followed by UTAC is clearly defined.

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