



**GUIDELINE OF
THE MALAYSIAN MEDICAL COUNCIL**

**ORGAN, TISSUE, CELL
TRANSPLANTATION AND CELL
THERAPIES
VERSION 2/2025**

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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 created 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 living donors, particularly in liver transplantation, have also emerged in the context of non-maleficence of living donors who run the risk of mortality and physical and psychological morbidity.

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

Organs obtained from non-human donors (xenotransplantation), and human cloning for organ procurement remain contentious issues.

PREAMBLE

Over the last few decades, the scope of transplantation has developed rapidly. Additionally, the development of multiple cell-based therapies has necessitated an update of the previous Guideline of the Malaysian Medical Council 006/2006 on Organ Transplantation.

Organ transplantation is an effective form of treatment for end-stage heart, liver and kidney failure. Cellular therapies have developed beyond haemopoietic stem cells to include Chimeric Antigen Receptor T-cells (CAR T-Cells), Natural Killer (NK) Cells, Dendritic cells and Mesenchymal cells. While organ and stem cell transplantation save lives, tissue transplantation such as bones, cartilage, tendons, cornea and heart valves can improve quality of life.

Among the ethical issues in transplantation are those related to indications, procurement and allocation. This guideline adheres to the general ethical principles of beneficence, non-maleficence, respect for autonomy, equity and justice. In addition, we should also ensure confidentiality and transparency. Ethical issues of consent, the shortage of organs available for transplantation and commercialization of transplants are addressed by this Guideline. This updated Guideline covers the above ethical issues with additional topics for underage donors and advanced cell therapies.

1 DEFINITIONS

“Organ” means a perfusable human organ for use in transplantation, whole or in parts, and whose specific function is intended to return after revascularization and reperfusion. Includes adjunct vessels that are retrieved with the organ for use in organ transplantation.

“Tissues” mean a functional group of human cells for use in transplantation.

“Cells” mean the fundamental biological unit of a human organism that is for use in transplantation.

“Donor” means a living or deceased person from whom cells, tissues or organs are retrieved.

“Transplant” means to implant cells, tissues or organs into a recipient.

2 PROVISIONS

2.1 GENERAL PRINCIPLES

The transplantation of deceased tissues in Malaysia is governed by the Human Tissues Act 1974. The Act enables the removal of tissues from cadavers for therapeutic, medical education and research purposes under two conditions: -

- a. at the expressed request of the donor, which may be given at any time either in writing or orally stated during the deceased's last illness in the presence of two witnesses;
- b. in the absence of objection from the deceased and with consent of the next of kin.

These provisions of the Malaysian Human Tissue Act aim to safeguard the rights and interests of donors, recipients, and the public, while promoting ethical conduct and ensuring the safe and appropriate use of human tissues and organs in transplantation and medical research.

Organ, tissue and cell transplantation raises numerous ethical issues that must be carefully considered to ensure the well-being and dignity of the individuals involved. Important ethical considerations related to this includes:

- i. **Informed Consent**
Patients donating tissue and those receiving transplants must provide informed consent. This means they understand the procedure, its risks, benefits, and alternatives, and consent voluntarily without coercion.
- ii. **Maintaining Privacy and Confidentiality**
Donor and recipient identities should be kept confidential to protect their privacy. Medical information should only be disclosed with appropriate consent or as required by law.
- iii. **Respect for Autonomy**
Donors should have the autonomy to make decisions about their bodies and tissues. They should be able to specify how their tissues are used and for what purposes, within legal and ethical boundaries.
- iv. **Respect for Dignity**
Donors and recipients should be treated with dignity and respect throughout the transplantation process, recognising their inherent worth as human beings.
- v. **Practice Cultural Sensitivity and Cultural Humility**
Recognise and respect cultural beliefs and practices related to organ and tissue donation, transplantation, and death.
- vi. **Balancing benefits and risks**

The aim of transplantation procedures is to benefit the recipient. At the same time, harm should not be intentionally or unnecessarily inflicted upon donors or recipients.

vii. **Avoidance of Commercialisation**

Human tissue should not be commodified or traded for profit. Donors should not be financially incentivised to donate, and recipients should not have to pay exorbitant fees for transplantation services.

viii. **Safety and Quality Assurance**

Transplantation procedures must adhere to strict safety and quality standards to minimise the risk of transmission of infections or other complications.

ix. **Fair Allocation of Resources**

Given the scarcity of donor tissues and organs, fair and transparent allocation processes should be in place to ensure resources are distributed efficiently and ethically.

x. **Equitable Access**

Access to transplantation services should be fair and equitable, regardless of factors such as socioeconomic status, race, ethnicity, or gender.

xi. **Ongoing Monitoring and Evaluation**

Transplantation programmes should be subject to ongoing monitoring and evaluation to assess their ethical, clinical, and societal implications and to identify areas for improvement.

Ethical guidelines for research involving human tissues must be followed, including obtaining informed consent,

ensuring research benefits outweigh risks, and protecting participants' rights and welfare.

2.2 ETHICAL PRINCIPLES

While some ethical issues related to organ and tissue transplantation are similar in both deceased and living organ transplants, there are also distinct ethical issues that are related to each practice that will be discussed in this guideline. Nevertheless, all these ethical issues can be considered from the perspective of the four Principles of Biomedical Ethics first proposed by Beauchamp and Childress in 1979:

2.2.1 Respect for Autonomy

Autonomy in health refers to the patient's capacity to think, decide, and act on the basis of such thought, and make decisions freely and independently. Respecting a patient's autonomy involves acknowledging the value and decision-making rights of patients and enabling them to act autonomously, including when their choices differ from the healthcare professional's recommendations. It requires healthcare professionals to help patients come to their own decisions after they have been given thorough information and is closely linked to the practice of informed consent.

2.2.2 Beneficence

Beneficence refers to a moral obligation to act for the benefit of others. Morality requires not only that healthcare professionals treat patients autonomously and refrain from harming them, but also that they should contribute to their patient's welfare. Hence, a healthcare professionals' primary obligation is to act for the patient's medical benefit.

2.2.3 Non-maleficence

Non-maleficence means avoiding harm and is linked to the Latin maxim of '*primum non nocere*'. This principle imposes an obligation on the healthcare professional not to inflict harm. The

potential good and harms and their probabilities need to be weighed up at the same time to decide what overall is in the patient's best interest.

2.2.4 Justice

The principle of justice attempts to delineate fairness. It can be divided into the categories of criminal justice and distributive justice, among others. Criminal justice is related to the legal provisions that are enacted, while distributive justice oftentimes pertain to the distribution of limited resources.

2.3 APPLICATION OF ETHICAL PRINCIPLES IN ORGAN, TISSUE & CELL TRANSPLANTATION

2.3.1 Living Donors

Living donors can come from family members when they are known as "living 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.

2.3.2 Respect for Autonomy

Since the beginning of organ transplantation, clinicians have: -

- i. Emphasized 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 should ensure that living donors make the decision to donate voluntarily without any duress so that the principle of autonomy is respected.
- ii. One justification for living organ donation is that it is an exercise of individual autonomy and in practice, donors have made the decision on their own free will.

- iii. Institutions practicing living donor transplantation must 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 them with adequate information on all aspects of donor surgery including short- and long-term risks.
- iv. Institutions should 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.
- v. 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. The potential donors should be assured that at any time they change their mind about donating an organ, their wishes will be respected.
- vi. Persons, who are mentally incompetent to decide should not be allowed to donate.
- vii. Allowing unrelated donors to specify who should receive their organ is not acceptable.

2.3.3 Principle of Non-Maleficence

- i. 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 living donor

organ donation thus is a balance between risks and benefit.

- ii. One may argue that the donor does not accrue any direct benefit by his act. However, it has been shown that living 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.
- iii. The risks to the donor are normally minimal and all potential donors should be made aware of this fact. 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 experience more than the minimum risk, the surgery should not be performed.
- iv. The surgical team should be well-trained and have all the necessary technical support.

2.3.4 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 situations where donation may be lifesaving, the goal of beneficence may override that of non-maleficence.

2.3.5 Principle of Justice

This is more relevant to the allocation of organs.

2.3.6 Transparency

Transparency emphasises openness and clarity in decision-making processes, ensuring that stakeholders understand the criteria and procedures used in organ allocation. Transparent allocation systems help build trust among patients, donors, healthcare providers, and the public, fostering confidence in the fairness and integrity of the organ allocation process.

2.3.7 Commercialisation of transplantation

In line with the Istanbul Declaration, the procurement or donation of organs, tissues and cells for financial gain is prohibited.

2.4 ETHICAL ISSUES IN DECEASED ORGAN DONATION

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

Consent for organ donation following death is usually given in two ways. In the “opting in” system presently practiced in this country, a person states their intention to donate their organs when they are still alive, and this is recorded in a document. Upon their death and in circumstances where organ retrieval is possible, the doctors who note their wishes can then proceed to procure the organs. Doctors will also have to take note of the views of the immediate relatives of the deceased. Consent should be freely given without any form of pressure or inducement.

Respect for the deceased 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 deceased with few organs remaining. It is important for doctors to maintain respect and exercise discretion on the proper limits of organ retrieval.

In deceased 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 or death by neurological criteria. 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.

2.5 ETHICAL ISSUES IN RECIPIENTS

All recipients should give their informed consent after having received counselling from a Registered Medical Practitioner who has been credentialed and privileged to undertake the intended transplant procedure.

2.6 CONFIDENTIALITY

The identity of the recipients should not be revealed to the family of the deceased organ donor and unrelated stem cell donors.

2.7 ETHICAL PRINCIPLES FOR ALLOCATION

The necessity of an organ allocation system is paramount in addressing the complex ethical and practical dilemmas surrounding the distribution of scarce medical resources. Organ transplantation stands as a beacon of hope for countless individuals grappling with life-threatening conditions, offering the promise of extended life and improved quality of life. However, the demand for organs far surpasses the available supply, creating a pressing need for a fair and transparent system to allocate these precious resources.

In Malaysia, like in many parts of the world, the demand for organs far outweighs their availability. This scarcity underscores the critical importance of establishing an equitable organ allocation system rooted in ethical principles. Without such a system in place, the distribution of organs could be subject to bias, discrimination, and undue influence, jeopardising both the integrity of the transplant process and the trust of the public. The ethical principles utilised in allocating organs include utilitarianism, justice, autonomy and transparency.

2.8 UTILITARIANISM

Utilitarianism is a moral theory that advocates for actions that maximise overall happiness or utility for the greatest number of people. In the context of organ allocation, utilitarian principles prioritise allocating organs to recipients who will derive the greatest benefit from them, such as those with

the highest probability of survival and improved quality of life post-transplant.

2.9 JUSTICE

Justice in organ allocation pertains to the fair and equitable distribution of organs among potential recipients. This principle emphasizes the need to ensure that allocation decisions are not influenced by factors such as socioeconomic status, race, or celebrity status, but rather based on medical need and urgency.

2.10 AUTONOMY

In organ allocation, autonomy involves respecting the preferences and values of potential recipients regarding transplantation, including their right to refuse the organ offered without compromising their eligibility to receive the next available organ.

2.11 SPECIFIC ETHICAL ISSUES

Ethics Committees

- a. Each transplant centre should have a hospital ethics committee.
There should be a transplant ethics committee at national level.
- b. This Transplant Ethics Committee shall be established to advise any ethical issues relating to:
 - i. Ethical principles to guide the balance of criteria relating to utility and equity for entry onto transplant waiting lists and allocation protocols for determining transplant recipients.
 - ii. Ethical principles to guide criteria for access to transplantation by international patients.
 - iii. Ethical principles to guide consideration of an appeals mechanism relating to clinical decisions about entry onto transplant waiting lists.
 - iv. Ethical principles to guide criteria for re-transplantation.
 - v. Ethical issues on directed deceased donation.
 - vi. Ethical issues regarding impaired capacity on decision making.

- vii. Ethical issues regarding donors who are minors.

2.12 CELL & TISSUE BANKING

Banking of cells & tissues for transplantation must adhere to strict safety and quality standards to minimize the risks of transmission of infection or other complications. Cell & tissue banks must adhere to the relevant safety and quality standards.

2.13 DISPOSAL OF UNUSED ORGANS/TISSUES

- i. Unused Organs and Tissues: The next-of-kin shall be informed by the Procurement Team if the organs and/or tissues are not used and the next-of-kin shall be consulted on the method of disposal.
- ii. It is mandatory to obtain consent from the next-of-kin if the organs and/or tissues are to be used for purposes other than transplantation.
- iii. Any incidence of unused organ and/or tissue shall be investigated and reported to the respective governing bodies and respective governing bodies.
- iv. Any unused organ and/or tissue which are not claimed by the next-of-kin shall be disposed with dignity in accordance with the guidelines on disposal of human materials.

2.14 MINORS

Based on the Child Act 2001, a minor (child) is defined as an individual who has not yet attained the age of legal majority which is eighteen years.

2.14.1 Donors who are Minors

a. Organ Donation

Living organ donation by minors is not allowed.

b. Tissue and Cell Donation

Living donorship from minor donors is ethically appropriate when the following conditions are met:

- i. No HLA-matched adults are available to donate. Siblings are often sought because donors unrelated to recipients can be hard to find.
- ii. A strong personal relationship exists between donor and

recipient.

- iii. Risks to the donor are minimal compared with benefits to both donor and recipient.
- iv. There is consent from both parents and if appropriate, donor assent.

c. Donor Advocate

Prior to transplant, it is recommended to engage donor advocates who are not on the transplant team treating the recipient to represent the minor donors. The advocate will help the donor to understand the risks and benefits of stem cell donation, try to resolve potential medical and psychological problems and obtain assent from the child without any pressure. A medical ethicist may also be involved to provide an unbiased assessment.

d. Assent for minor donors over 8 years of age

Determining whether assent is voluntary can be difficult, however, raising a question of whether it is ethically permissible to move forward with bone marrow harvest despite a child's fears. One remedy could be to appoint an independent adult advocate to meet alone with the prospective living donor child to investigate his or her concerns and then speak on his or her behalf.

2.15 ORGAN DONATION AND TRANSPLANTATION AMONG NON-CITIZENS

All related or unrelated living organ donation and transplantation involving non-citizens; either as living donors or recipients shall adhere to the necessary processes as stated in the unrelated living organ donation policy and procedures.

2.16 XENOTRANSPLANTATION

Xenotransplantation presents a complex ethical consideration that intersect with scientific, medical, and societal concerns. Current ethical views on xenotransplantation emphasise the importance of balancing potential benefits with risks and ethical considerations, including concerns about safety, informed consent, animal welfare, and the potential for zoonotic

infections.

One perspective in the ethical discourse surrounding xenotransplantation emphasises the need for rigorous oversight and regulation to ensure the safety of both xenotransplant recipients and the general public. This view emphasizes the precautionary principle and calls for transparent decision-making processes that prioritise safety and minimise risks associated with xenotransplantation procedures.

Another perspective underscores the ethical imperative to prioritise human health and well-being while also recognizing the potential benefits of xenotransplantation in addressing the critical shortage of donor organs for transplantation. Proponents argue that with appropriate research, monitoring, and regulation, xenotransplantation could offer life-saving treatments for patients with end-stage organ failure and other medical conditions.

Overall, contemporary ethical views on xenotransplantation highlight the need for multidisciplinary approaches that integrate scientific expertise, ethical analysis, and public engagement to navigate the complex challenges and opportunities presented by this emerging field of medicine.

2.17 NOVEL CELL THERAPIES

Hematopoietic stem cells (HSC) or other types of cells such as mesenchymal stem cells (MSC) as well as somatic cells such as T lymphocytes, Natural killer (NK) cells, dendritic cells etc. can be modified through many technologies include somatic cell technologies, cell immortalization technologies, ex-vivo gene modification of cells using viral vector technologies, genome editing technologies, cell plasticity technologies, 3D technologies and any combination of the above methods. The products have potential to be utilized for gene therapy in thalassemia or haemophilia, targeted therapy for cancer treatment or immune modulation in autoimmune or infectious disorders, repair or regenerative therapies. (refer to the National Guidelines on Stem Cell and Cell-Based Research and Therapy).

Cell and tissue therapy for non-homologous use are classified under Class II. A Class II product is “highly processed”, used for other than normal function, is combined with non-tissue components, or is used for metabolic purposes”. It is regulated as a biologic product by the National Pharmaceutical Regulatory Agency and Medical Device Authority, Ministry of Health Malaysia.

3 CONCLUSION

These guidelines serve as a framework for navigating the complex ethical terrain of human tissue transplantation, promoting ethical conduct and safeguarding the interests of donors, recipients, and society as a whole.

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5 NOTE

5.1 The following are the members of the drafting committee for this guideline:

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5.2 This guideline was first published on 14th November 2006.

5.3 This updated guideline was approved by the Ethics Committee on 26th November 2024 and adopted by the Malaysian Medical Council on 18th February 2025.

5.4 This document will be due for review in 5 years, or earlier as necessary.