

The Malaysian Medical Association's Position Paper on Organ Donation and Transplant

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Organ donation and transplant has become one of the most significant advances in medicine, and it has been shown to save lives and enhance the quality of life for many people. *Organ donation* refers to the removal of an organ from a person (donor) who legally consents to the act, either while the donor is alive or after death (Tamuli et al., 2019). Meanwhile, *organ transplantation* refers to a medical procedure where a section of or a complete organ that has been donated is transferred and implanted to a new position in the same person or in a separate individual (Calne, 2023). Common organs involved in donation and transplantation include the kidney, heart, liver, pancreas, intestines, lungs, bones, bone marrow, skin, and cornea. Organs used for transplantation can generally be categorized into deceased (cadaveric) and living. Cadaveric donations can be further categorized into donation after brain death (DBD) and donation after circulatory death (DCD), while living donations can be further divided into related and unrelated donations. In addition, there are also human tissues that can be donated and transplanted such as stem cells, bone, sperm, etc.

In Malaysia, the first organ donation and transplant procedure performed was a living donor kidney transplant in 1975 (Cowie et al., 2023). Since then, organ donation and transplant has continued to grow and develop and has included milestones such as the first heart transplant in 1997, and more recently the first living kidney transplant for a person living with HIV (PLHIV) in 2022 (Hassandarvish, 2019; Zainudin and Saw, 2023).

Despite having made much progress, organ donation and transplantation remains a controversial subject matter ethically and legally as this practice needs to safeguard public interest and garner public trust on the one hand, while needing to maintain safe and equitable transplantation practices and programmes on the other. Hence, detailed and stringent ethical guidelines and laws are required. Legislations related to organ donation systems also vary across different countries- some implement an opt-out system, while others, including Malaysia, adopt an opt-in system for organ donation. Both cadaveric and living organ donations also bring with them specific ethical issues worth examining individually.

The National Organ, Tissue and Cell Transplantation Policy published in 2007 is the main guidance for transplantation in Malaysia. In regards of the practice of cadaveric organ donation, the Human Tissues Act 1974 currently regulates this. The primary purpose of this law is to enable the removal of cadaveric tissues for medicinal, educational, and scientific purposes.

However, there are currently no legislations in place to regulate the practice of living organ donations and this practice is currently guided by another guideline published by the Ministry of Health (MoH) titled

“Unrelated Living Organ Donation- Policy and Procedure”. The MoH has also published other related guidelines including those for stem cells/cord blood donation and transplantation. In addition, the Malaysian Medical Council (MMC) has also published an ethical guideline on “Organ Donation” and “Brain Death”, and other relevant bodies that have produced guidelines and consensus statements include the National Transplant Resource Centre, the Malaysian Society of Transplantation and the Malaysian Society of Intensive Care (see list of Guidelines and Policies at the end of this article).

In relation to organ trade and trafficking, the Anti-Trafficking in Persons and Anti-Smuggling of Migrants (Amendment) Act 2022 is relevant, as is the fact that Malaysia is a signatory of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism to combat organ trafficking, transplant tourism and transplant commercialism and to encourage adoption of effective and ethical transplantation practices around the world.

Developments in the field of transplantation medicine mean that our current laws and guidelines, especially the Human Tissue Act 1974 have become antiquated and are unable to resolve the new ethical and legal issues that have arisen. It is unfortunate that this legislation has remained unchanged, despite the call to do so in the first position paper by Dr Rajamohan Annamalai on this topic that was adopted by the MMA in 2001.

As a result, there needs to be urgent action taken to update our current laws, or to enact new laws, related to organ donation and transplantation. These should also be consistent with international standards set by the World Health Organization (WHO) and the World Medical Association (WMA). We reiterate here the urgent need especially to review and update the Human Tissue Act 1974. There is also a need to ensure that our national ethical, clinical, and professional guidelines related to this practice are up to date with current practices and research in the area.

In the process, the following issues related to organ donation and transplantation should be addressed and included:

1. Cadaveric Organ Donation

Organ demand greatly outweighs organ supply in Malaysia leading to an organ shortage crisis. In view of this, there is a need to re-examine if the current opt-in system should be maintained, if it can be optimized, or if it would be feasible to shift to other alternative systems (such as an opt-out system which has been introduced in our neighboring countries). In doing so, the local social, medical, and cultural norms should be considered.

There is also a need to clearly define a hierarchy of the deceased person’s next-of-kin to avoid any confusion, delays, and uncertainties during the organ procurement process. This is especially important in identifying the correct person to consent to the procedure.

Ethical grey areas related to the dead donor rule have emerged with proposals for new practices such as including the possibility of allowing organ donation under anaesthesia for organ donors who have life support withdrawn to prevent wastage, and the use of normothermic regional perfusion in heart transplants. Such ethical quandaries need to be thoroughly studied and considered when revising local legislation related to organ donation and transplant.

2. Living Organ Donation

Legislation, be it by way of updating current available legislation, or by enacting new laws, must also address living organ donation in Malaysia as a substantial percentage of organ donation and transplant are performed via such situations. Currently, this practice is only being guided by a MoH guideline (titled “Unrelated Living Organ Donation- Policy and Procedure”).

The rights of potential donors need to be addressed, as should issues pertaining to the selection criteria for donors, the requirements and process in obtaining donor’s informed and voluntary consent as well as the requirement for professional care of donors and follow-ups.

In general, living donors should be fully informed of the risks, advantages, and repercussions of donation. They should be recognized as competent under the law and capable of considering the facts given to them. Additionally, they should be behaving freely, without undue influence or coercion. Furthermore, efforts should be taken to guarantee that the decision to give is free of coercion, and financial incentives. These can be done by mandating all living organ transplants to be reviewed by a Hospital Clinical Ethics Committee.

3. Definition of Human Tissue

A clear definition of a human tissue is required as this can influence practices that are allowed in the country. Whether this should include provisions related to stem cell tissues, and reproductive cells (such as ovum and sperm), and how they related to donation for therapeutic and research purposes need to be considered.

4. Determination of Death

Clarity on the standards and procedures for determining both brain death and cardiopulmonary death is required, as well as a clear legal threshold for when death has happened to ensure adherence to the dead donor rule is required. Additionally, to avoid any potential conflicts of interest, doctors who determine that a potential donor has died should not take part in the actual removal of the donor's cells, tissues, or organs or in the subsequent transplant procedures. They also should not be involved in the care of the intended recipients of the donated cells, tissues, or organs.

5. Quality, Safety and Efficacy of Procedures

Only suitably qualified medical doctors who have undergone specialized training, academic research, and clinical experience in authorized institutions should be allowed to perform organ procurement and transplantation procedures in order to guarantee the quality, safety, and effectiveness of such procedures, and to preserve trust in the medical profession.

6. Prohibitions on Commercialisation of Human Organ and Tissues

In principle, donating organs, tissues, and cells must always be done voluntarily and without receiving any financial gain. Therefore, the selling of cells, tissues, or organs for transplantation as well as the buying or proposing to buy them by live individuals or the heirs of the deceased must be prohibited. The restriction on paying for cells, tissues, and organs should extend to all persons, including transplant recipients who seek to avoid domestic rules by traveling to locations where commercialization bans are not enforced.

7. Confidentiality

Confidentiality must be maintained at all times. This includes the protection of personal anonymity and privacy of both donors and recipients.

8. Organ Donation and Transplantation in Minors

As a general rule, the removal of cells, tissues or organs of minors for transplantation should be prohibited. However, very narrow exceptions may be ethically justifiable and legally permitted such as in the case of familial donation of regenerative cells when a therapeutically comparable adult donor is not available. In such circumstances, provisions need to outline specific measures to protect minors such as the review and approval by an independent body, the role of consent from the parent(s) or legal guardian, the role of minor's objection and assent as well as the role of professional counseling to potential donors to assess and address any pressure in the decision to donate.

9. Xenotransplantation

Xenotransplantation refers to any procedure that involves the transplantation, implantation, or infusion into a human recipient of live cells, tissues, or organs from a non-human animal source (Shcickanz, 2012). Animal to human transplantations, including those involving chimeras raise additional issues, especially that of transmitting virus and pathogens. There will also have additional religious concerns over the use of specific animal products in the Malaysian context and these need to be adequately addressed. Consultation and dialogue from various religious authorities in addition to the medical and scientific community is required. While cases of solid organ xenotransplantation have not yet been recorded in Malaysia, biological products, drugs or medical devices that have are sourced from non-living cells, tissues or organs of animals (e.g. bioprosthetic heart valves) which are not considered as xenotransplantation products by the FDA have been in use locally (Krishnasamy, 2007).

10. Coordinating Transplant, Systems and Registry

Organ allocation should be governed by established clinical criteria and ethical conventions, rather than by financial or other concerns. Allocation rules should be equitable, externally justified, and transparent, as specified by adequately constituted bodies.

In addition, to maintain the sustainability of the practice, capacity building and additional manpower is required within the specialty. Recognition and protected time should be given to people involved in the practice such as transplant coordinators and tissue and organ procurement (TOP) team members.

Conclusion

The fast growth of transplantation medicine necessitates regular and thorough re-evaluation of the laws and rules governing organ transplantation and donor procedures. These issues are complex and pose ethical and legal quagmires. A whole of government and whole of society effort is required to adequately address these issues, including the involvement and collaboration from diverse religious leaders, as well as the medical and scientific sectors. It is our position that the laws and guidelines related to organ donation and transplant in Malaysia (including those listed in the appendix) need to be reviewed and updated urgently.

References

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Appendix

Below are a list of laws, guidelines, policies and resources that are related to organ donation and transplant in Malaysia:

Laws

- Human Tissue Act 1974.
- Anti-Trafficking in Persons and Anti-Smuggling of Migrants (Amendment) Act 2022.

Guidelines

- Organ Transplantation. 2006. Malaysian Medical Council.
- Brain Death. 2006. Malaysian Medical Council.
- Guidelines on Importation and Exportation of Human Tissues and/or any Body Part. 2006. Disease Control Division, Ministry of Health Malaysia.
- National Guidelines for Haematopoietic Stem Cell Therapy (2nd Edition). 2022. Ministry of Health Malaysia.

Policies

- National Organ, Tissue and Cell Transplantation Policy. 2007. Ministry of Health Malaysia.
- Unrelated Living Organ Donation- Policy and Procedure. 2011. Ministry of Health Malaysia.
- The National Standards for Cord Blood Banking and Transplantation. 2019. Ministry of Health Malaysia.
- National Standards for Stem Cell Transplantation. 2009. Ministry of Health Malaysia.

Resources

- National Transplant Resource Centre (<https://www.dermaorgan.gov.my>)