Vol. 3, No. 1, pp. 238-244 | 2025
CFORSJ Procedia

A LEGAL ANALYSIS OF XENOTRANSPLANTATION IN MALAYSIA

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ABSTRACT

Xenotransplantation is the transplantation of living cells, tissues, or organs from animals to humans which has emerged as a potential solution to the persistent organ shortage in Malaysia. As demand for human organs continues to exceed supply, xenotransplantation offers a promising alternative to alleviate the critical gap and reduce mortality among patients awaiting transplantation. This study adopts a library research method**,** examining statutory materials, scholarly literature, and policy documents to assess the existing Malaysian legal framework relevant to xenotransplantation. The analysis highlights that although Malaysia has enacted laws such as the Animal Welfare Act 2015, which regulates ethical treatment of animals, and the Biosafety Act 2007, which governs genetically modified organisms, these laws only provide fragmented and indirect regulation. They do not comprehensively address the complex ethical, biosafety, medical, religious, and liability issues uniquely associated with xenotransplantation. The findings reveal a significant regulatory gap, particularly in areas such as source animal requirements, genetic modification controls, infection risk management, consent standards, clinical trial governance, and post-transplant monitoring. In view of these shortcomings, this study proposes the establishment of a dedicated Xenotransplantation Act to provide a holistic and specialised legal framework. Such legislation would ensure patient safety, uphold ethical standards, support scientific advancement, and align Malaysia with international best practices as xenotransplantation moves closer to clinical application.

Keywords: *Xenotransplantation, Organ Shortage, Laws*

Introduction

Organ transplantation has always been referred to as a miracle in the modern medical world. In each transplant procedure, organs from human donors will be transplanted to another human recipient as treatment for end stage organ failures. This medical procedure is very promising and gives hope to patients though in reality, human organs are hard to obtain. This scenario which is also known as 'organ shortage' is becoming increasingly critical due to limited supply of human organs, while on the other hand, demand remains very high. Therefore, one of the suitable solutions considered is to obtain the necessary organ supply from alternative sources, such as animals. The transfer of organs from animals to humans for medical purposes is known as xenotransplantation. This process includes the transfer and use of living cells, tissues, or organs from animals to humans especially when the demand is extremely high compared to the available supply.

The History of Xenotransplantation

The concept of xenotransplantation has been around for over the past 300 years. As early as the 17th to 20th centuries, there were cases where patients received blood transfusions from various types of animals to treat certain pathological diseases. Animal skin like frog skin, was also often used for patient care (Cooper et al.2015). Keith Reemtsma is reported to have transplanted chimpanzee kidneys into 13 different patients at Tulane University, where one patient gradually recovered and survived for nine months after the kidney transplant. Even at that time, animals were chosen as a source of organs because they were available and abundant. However, most recipients of animal organs experienced failure, ending in the death of these patients due to incompatibility between the human recipient's organs and the donor animal's organs (Boulet et al.2022). While in 1964 there was another significant development when Hardy transplanted a chimpanzee heart into a human, but the patient survived for only two hours. Then, in 1992, Starzl transplanted the liver of a baboon into a patient. The operation was successful, and the patient managed to survive for 70 days after the transplant (Starzl et al.1993). Growth began using pig organs to be transplanted into humans as a replacement for the required organs in 1993 (Cooper et al.2015).

The Need for Xenotransplantation

Organ transplantation can help patients with end-stage organ failure enjoy a better quality of life, extend their life expectancy, and reduce long-term medical costs However, with the existence of organ transplantation from one human to another, this indirectly provides an opportunity for a better and more secure life for these patients. Nevertheless, obtaining the required organ is not an easy task. Not only must the organ be compatible with the recipient in terms of size and type, but there are also several other biological factors that must be considered.

Another big hurdle is to get the supply of these needed organs. Shortage of organs is a major problem faced by Malaysia since mid-1980's. It is also become a global issue that has reached to a critical stage (Esker et al.2015). The demand for these organs is soaring high compared to the supply which is scarce. Most of the patients must wait for a long time to get their needed organs. Data in Malaysia by the Ministry of Health in 2023 reported 9941 patients are still queuing in the waiting list for organs, whereas only 79 organ and tissue transplantations managed to be carried out (2023). This shows the gap between supply and demand for organs. However, awareness of organ donation is increasing as in 2025, 15,253 new organ donor registrants came forward, and 68 actual cadaveric donor cases were successfully performed (Ministry of Health Malaysia, 2025).

Another frequently arising issue is that individuals who had previously pledged to become potential organ donors often withdraw and do not fulfil their pledge when the time comes. It is even more disheartening when the donor's own family members prevent the organ donation from proceeding, especially when the potential donor is no longer able to decide due to being in a coma or suffering from brain death. Brain death occurs when there is no blood and oxygen flow to the brain, causing the entire brain, including the brainstem (the part of the brain that controls life functions such as breathing and heartbeat), to permanently and irreversibly stop functioning. This condition often involves patients experiencing injuries such as bleeding or swelling in the head, stroke, respiratory arrest, brain cancer, or brain infection (Encephalitis) (Ministry of Health Malaysia, 2025). There are also cases involving

organ donors who were unable to fulfil their noble intention of donating organs such as the heart, lungs, and liver due to their death occurring at home, and only certain organs like the cornea of the eye could still be donated (Palansamy.2022). However, an interesting recent discovery, which may be able to extend the shelf life of the harvested organ, is when a group of researchers in Zurich, Switzerland known as Liver4Life has successfully created a device that can be used as a storage or transit place for organs before the organ can be transplanted to a suitable organ recipient. The research team claims that their design can cause donor lungs that have been removed from the donor to be stored in this special storage place for up to several days, before the organ is transplanted to a suitable organ recipient. The first case of an organ recipient who used this storage box, successfully stored the donor's lung for three days before being transplanted to the organ recipient, and now the organ recipient has successfully lived depending on the lung for a year (Piec.2022). Previous practices saw the organs being stored in very cold places, which could sometimes damage the organs. The creation of this device also allows emergency surgeries that are usually performed to transplant organs to be replaced with elective surgeries, which are more peaceful, orderly and effective.

Animals as Organ Sources

It is commonly known that xenotransplantation is a process where an organ source is obtained from a species that is not the same as the species to which the organ is transplanted (cross species). Studies have also shown that animals such as pigs have high potential to be a solution to the problem of shortage of human organs and much-needed cells (Mou et al.2015). The main factor that must be considered in carrying out the xenotransplantation procedure is of course related to the safety of the user or patient himself, who must agree to undergo the process of receiving organs from animals. This refers to the need to obtain written and voluntary consent from the patient, after first being given an explanation by the doctor about the purpose, method, risks, benefits and effects of undergoing the xenotransplantation procedure. Not only that, but all the benefits and risks of the procedure must also be managed well and carefully to avoid any problems arising later.

In addition, the welfare of animals used for xenotransplantation purposes must also be taken into account, since in order to obtain good quality organs, these animals need to be raised in good and clean conditions to allow all organs, tissues and cells produced to not be contaminated with any germs. Pigs are said to be the most suitable animal for the xenotransplantation procedure because this animal is a very easy species to raise and it can reproduce very quickly and easily. Pigs are also said to have many similarities from an anatomical point of view, allowing them to supply as many organs, tissues and cells as needed at a rapid and diverse rate (Boulet.2022). A pig's organs are said to have many similarities to humans, including its heart, kidneys, lungs, liver, skin and pancreas (Cooper.2012). For example, genetically modified pig kidneys have been taken and used as replacements for human kidneys. The two patients were brain-dead and were connected to ventilators to ensure that oxygen supply remained in the body of both patients throughout the research. The purpose of the research was to see whether the pig kidney organs could function in the human body and to measure the rate of xenograft rejection. The results of the study found that both patients were able to produce urine well, even more, when compared to the amount produced by the patients when using their original kidneys. Interestingly, the pig kidneys were also reported to function well without any signs of (Montgomery et al .2022).

In a separate case, a 62-year-old male patient who needed kidney dialysis received a kidney from a genetically modified pig. The results of the pig kidney transplant to the patient showed that the kidney was functioning properly and the patient no longer needed dialysis. Unfortunately, the patient died, but not from failure of his new kidney, but from a heart problem he was suffering (Kawai et al .2025). It is predicted that one day, by using pigs as a source of organs, tissues and cells, the problem of illegal organ sales, the dependence of some countries on criminals who are about to be executed and living organ donors, can be reduced as a source of obtaining the needed organs (Ekser et al. 2015).

The United States of America is also experiencing a shortage of organs to help patients in need of organ transplants. The number of patients in need of organ donations is increasing even though the supply of organs needed is also very difficult to find. It is reported that more than 100,000 patients are still on the waiting list for organs even though only a third of these patients will succeed in getting the organs they need (Organ Procurement and Transplantation Network..2018). Xenotransplantation is said to have the

potential to meet the organ supply needed by thousands of patients who are waiting, due to the large number of organs that can be obtained from animals, especially from pigs. Indirectly, it is expected that more patient lives will be saved with this solution. However, taking organs from pigs is also risky. This procedure may invite the risk of infection with porcine endogenous retrovirus (PERV) which is said to exist in the genome of pigs themselves (Hryhorowicz et al. 2017). Pigs are considered ideal donors due to their physiological similarities to humans. However, the risk of zoonotic pathogen transmission poses a substantial barrier to their use (Lin.2024). The progress in genetic engineering of pigs opens new avenues for clinical applications of xenotransplantation.

Future research should focus on optimizing the genetic modifications to further reduce immunological barriers and enhance the longevity and functionality of xenografts in human recipients. Moreover, the development of more sophisticated screening and monitoring techniques for potential zoonotic pathogens, including single-stranded DNA viruses, is essential to ensure the safety of xenotransplantation procedures (Lin.2024). In the United States, the Food and Drug Administration (FDA) will regulate all activities related to xenotransplantation under the Public Health Service Act and the Food, Drug and Cosmetic Act. The FDA is responsible for ensuring that the animal sources and organs used meet the established standards, namely pathogen-free and quarantined (The Centre for Biologics Evaluation and Research.2016). This is very important to ensure the safety of animal organs for patient use and to ensure that no zoonotic infections occur in humans. Because of this risk, any patient who agrees to undergo this xenotransplant procedure must have agreed to have their health monitored throughout their lives, including through blood sampling and being restricted from donating blood or tissue to other patients. However, the xenotransplant procedure in the United States is still in the research stage and this method has not yet been widely offered to patients in general as a solution to the problem of organ shortage. To ensure the welfare of the animal source of these organs, for example pigs will be raised in special places to ensure the absence of pathogens that can cause the animal to become a source of germs or other diseases. Data regarding the source of organs from specific animals, organ recipient patients, facilities and clinical data must be stored for up to 50 years for easy reference if needed. Donor animal specimen samples and records of recipient patients from the animal must be maintained to facilitate regulation and the process of tracing back patient data in the event of any infection or infectious disease after the xenotransplant procedure is carried out. At that time, early detection and control to curb the transmission of the disease are necessary to prevent further spread.

Xenotransplantation and the Laws in Malaysia

Malaysia does not yet have a specific Act that regulates the practice of xenotransplantation. Although this solution is still new and has not been practiced in Malaysia, there are certain sections in several separate Acts, which may be suitable to be used as a guide when needed in the future.

i) Human Tissues Act 1974 (Act 130)

This Act is the only Act that deals exclusively with the management and use of human tissue in organ donation activities. This Act was gazetted on 14 March 1974 and came into force on 1 January 1975. There are five main sections in this Act which are applicable throughout Malaysia. However, the shortcomings of this Act are that it is very brief and only specifies organ donation from cadavers or deceased persons as the source of the required organs.

Section 1 of this Act clearly states the title, application and commencement of this Act. Section 2(1) of the Act further describes the transplantation of human parts permitted by the Act whether for therapeutic, educational or medical research purposes, however this section only mentions the transplantation of human body parts only and does not specify any procurement of organs from other sources, whether from animal or plant sources. Indirectly, this Act does not cover the activities of taking or donating the required organ source from non-humans.

Sections 3, 4 and 5 among others, concern the transplantation of human body parts which must be carried out by registered medical practitioners and if there is any human body that is not claimed by the heirs, then the hospital will be given the right to manage the body. Therefore, it can be concluded that the Human Tissue Act 1974 is entirely about the use and donation of human organs only and does not cover any issues related to the procurement of organs from other sources.

The National Organ, Tissue and Cell Transplantation Policy 2007 is also found to regulate the donation of human organs obtained from living donors. For example, in paragraph 6.1 of this policy, it is stated that the best organs and tissues are those obtained from cadaveric donors, but if found suitable and reasonable, then they can be considered for collection from living donors. Priority is still given to the collection of organs from cadaveric donors when compared to living donors. This policy only mentions the source of organ collection, whether from cadaveric donors or from living people. There is no provision that mentions the collection of organ sources from non-humans.

Another policy that has been introduced is the Policy and Procedures for Unrelated Living Organ Donation 2011. This policy was introduced to regulate organ donation activities among living donors. Again, there is no provision in this policy that mentions or allows other than humans as the required source of organs.

Also in 2006, the Malaysian Medical Council issued a guideline on organ donation, known as the Malaysian Medical Council Guidelines on Organ Donation (2006). This Guideline focuses solely on organ donation activities which are sourced from human beings. However interestingly, the Guideline does also mention about organ donations from non-humans and human cloning issues, which it describes as interesting, but too hot and controversial in nature. Other than that, there are no further statements regarding xenotransplantation being mentioned in the Guidelines.

ii) Biosafety Act 2007 (Act 678)

The National Biosafety Board was established to regulate the release, import, export and controlled use of living modified organisms, and the release of products of such organisms, with the aim of protecting human, plant and animal health, the environment and biodiversity. The Biosafety Act 2007, which regulates genetically modified organisms (GMOs) and ensures safety in the implementation of this biotechnology process, may be extended to cover xenotransplantation procedures as well, when it involves the use of organ resources obtained from genetically modified animals. Although this Act does not directly mention the word xenotransplantation, however, some provisions under this Act can be applied to xenotransplantation research involving the use of genetically modified animals.

This Act also stipulates that any other written law relating to import and export, human health, plant and animal health, the environment and biodiversity shall be read together. However, in the event of any inconsistency between the provisions of this Act and any other law, section 2(2) states that the former shall prevail.

The xenotransplantation procedure involves the introduction of genetically modified animal organs into the human body, and this can cause various risks. Therefore, a safety assessment must be carried out beforehand, to assess the potential risks to human health, including the possibility of transmission of diseases originating from animals (zoonotic infections) and immune rejection. Section 12(1) of the Act does not allow anyone to carry out any release, or importation of living modified organisms, without first obtaining approval from the National Biosafety Board. An assessment of the risks and adverse effects that may impact humans, plants, animals and the environment must be carried out beforehand before any release of genetically modified organisms (GMOs) into the environment or use on humans. This is very important to ensure everyone's safety and to ensure that preventive measures can be taken immediately to reduce the level of risk (section 36(1). This is very important to ensure everyone's safety and to ensure that preventive measures can be taken immediately to reduce the level of risk. Not only that, but Section 6 allows for the establishment of a Genetic Modification Advisory Committee to provide scientific and technical advice if necessary.

Section 14 further stipulates that any research involving GMOs must obtain special approval from the Biological Safety Board. Therefore, the use of genetically modified animals such as pigs, for the purpose of xenotransplantation is also included in the requirement to obtain this special approval. Based on section 16, any researcher must inform the Biological Safety Board if GMOs are to be released for research. Therefore, in the context of xenotransplantation, if genetically modified animals are to be used for organ transplantation studies, researchers must notify the Biosafety Board regarding the experiment. Assessment of any risks and implementation of risk management strategies to mitigate any adverse effects on public health and safety are a priority. Researchers must first conduct a comprehensive risk

assessment to ensure that the use of genetically modified animals in xenotransplantation will not pose a significant risk to human health, including the possibility of disease transmission from animals to humans (zoonotic diseases as clearly spelt out in section 18. If genetically modified animals (such as pigs) are to be imported into Malaysia for the purpose of xenotransplantation research, a permit must be obtained under section 20 of the Act. It is important to note that any import of GMOs for research purposes must comply with the regulations set out in this Act and obtain appropriate approval from the Biological Safety Board.

Section 22 provides for liability and compensation in the event of adverse effects resulting from the use of GMOs. In the context of xenotransplantation procedures, any unintended negative effects (such as zoonotic infections or risks to human health) may give rise to liability issues. Therefore, researchers and relevant institutions must comply with the requirements under this section, including ensuring that adequate insurance coverage or compensation mechanisms are in place. Xenotransplantation research, particularly involving genetically modified animals, may involve proprietary techniques and organisms that are classified. Section 23 concerns confidentiality, detailing how information about such organisms must be treated confidentially to protect the intellectual property of the researcher or organization involved.

Holistically, although the Biosafety Act 2007 (Act 678) does not specifically mention xenotransplantation procedures, various sections under this Act are directly related to research activities and the use of genetically modified organisms, particularly animals used for this xenotransplantation process. Therefore, it can be concluded that with the existence of the Biosafety Act 2007, there are already legal provisions detailing important requirements such as safety assessment, research approval, risk management, notification, liability, and confidentiality, which can regulate xenotransplantation to be carried out safely, ethically, and in accordance with national biosafety standards. Therefore, any xenotransplantation research in Malaysia must comply with the requirements under this Act to protect public health, animal welfare, and environmental integrity.

iii) Animal Welfare Act 2015 (Act 772)

Another Act that must also be considered is the Animal Welfare Act 2015. This Act aims to promote the welfare and responsibility of animal owners, as well as to protect animals from any abuse and neglect. This Act regulates the ethics of animal use. Therefore, animals used for xenotransplantation must also be ensured of their welfare, well-cared for and not abused as stipulated in this Act. Section 24 of the Act puts the responsibility of animal owners to provide adequate care and meet the needs of their animals, such as a suitable environment, food, and medical treatment. Even animals used for research, testing or teaching purposes must also be ensured of their physical, natural and health needs as prescribed under section 26. Any effort to breed animals for the use in any research and testing activities must obtain approval from the Animal Welfare Board which is responsible for managing and supervising animal welfare. Therefore, in the context of xenotransplantation procedures, the welfare of animals bred for organ harvesting must also be taken into account, especially to ensure that the procedure carried out is in accordance with the law and does not violate any existing legal provisions.

CONCLUSION

Xenotransplantation is not a new issue. Although it has been introduced for a long time and various experiments and attempts to make it successful have been carried out, it has not been officially established in Malaysian society. Xenotransplantation may seem like a complex and high-risk procedure, especially when it involves the lives of human organ recipients, as well as the lives of animals from which organs are taken. However, its benefits have the potential to be a solution to the problem of organ shortage and promisingly save the lives of thousands of patients. At the same time, numerous challenges and unresolved questions must be addressed before it can be considered a viable primary source for obtaining the necessary organ supply. Each procedure carried out must be ensured that the benefits outweigh any probable risks that might occur. In other words, the benefits must outweigh the harms if this xenotransplantation to be resorted to. The legal implications also need to be clear so that problems related to rights and liabilities do not arise later. Therefore, it is suggested that strict permission and monitoring, whether at the national level, university or from any research institution, is necessary to allow more research to be conducted to ensure the development of a

xenotransplantation process that is safe, effective and compliant with civil and Islamic laws. The establishment of a dedicated Act to regulate xenotransplantation procedures is strongly recommended to ensure that all related activities are conducted in full compliance with legal requirements. Furthermore, in the Malaysian context, the formulation of national-level Syariah rulings is imperative, given Islam's status as the country's principal religion.

References

Animal Welfare Act 2015 (Act 772) (Malaysia).

Biosafety Act 2007 (Act 678) (Malaysia).

Boulet, J., Cunningham, J. W., & Mehra, M. R. (2022). Cardiac xenotransplantation: Challenges, evolution, and advances. *JACC: Basic to Translational Science.*

Cooper, D. K. C., Ekser, B., Burlak, C., Ezzelarab, M., Hara, H., Paris, L., Tector, A. J., Phelps, C., Azimzadeh, A. M., Ayares, D., Robson, S. C., & Pierson, R. N. III. (2012). Clinical lung xenotransplantation: What donor genetic modifications may be necessary? *Xenotransplantation*, *19*, 144–158.

Cooper, D. K. C., Ekser, B., & Tector, A. J. (2015). A brief history of clinical xenotransplantation. *International Journal of Surgery, 23*(B), 205–210.

Ekser, B., Cooper, D. K. C., & Tector, A. J. (2015). The need for xenotransplantation as a source of organs and cells for clinical transplantation. *International Journal of Surgery, 23*, 199–204.

Human Tissues Act 1974 (Act 130) (Malaysia).

Kawai, T., Williams, W. W., Elias, N., Fishman, J. A., Crisalli, K., Longchamp, A., Rosales, I. A., & Riella, L. V. (2025). Xenotransplantation of a porcine kidney for end-stage kidney disease. *New England Journal of Medicine, 392*(7), 1933–1940.

Lin, X. F. (2024). Pathogen-free pigs for safer xenotransplantation: Advances and challenges in genetic engineering. *International Journal of Molecular Zoology, 14*(4), 244–254.

Malaysia Medical Council. (2006). *Guidelines 006/2006*.

Ministry of Health Malaysia. (2007). *National Organ, Tissue and Cell Transplantation Policy*.

Ministry of Health Malaysia. (2011). *Policy and Procedures for Unrelated Living Organ Donation*.

Ministry of Health Malaysia. (n.d.). *National Transplant Centre*. https://dermaorgan.gov.my/pendermaan-organ

Montgomery, R. A., Stern, J. M., Lonze, B. E., Tatapudi, V. S., Mangiola, M., Wu, M., Weldon, E., & Stewart, Z. A. (2022). Results of two cases of pig-to-human kidney xenotransplantation. *New England Journal of Medicine, 386*, 1889–1898. https://doi.org/10.1056/NEJMoa2120238

Mou, L., Chen, F., Dai, Y., Cai, Z., & Cooper, D. K. C. (2015). Potential alternative approaches to xenotransplantation. *International Journal of Surgery, 23*, 322–326.

Organ Procurement and Transplantation Network. (2018). *National data*. https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/

Peic, C. (2022, June 8). World's first: Doctors successfully transplant human liver in a machine. *Medical News Today*.

Public Health Service. (2022, June 23). *Guideline on infectious disease issues in xenotransplantation*.

Starzl, T. E., Fung, J., & Tzaki, A. (1993). Baboon-to-human liver transplantation. *The Lancet, 341*, 65–71.

U.S. Food & Drug Administration. (n.d.). *Xenotransplantation*. https://www.fda.gov/vaccines-blood-biologics/xenotransplantation

U.S. Food and Drug Administration, Center for Biologics Evaluation and Research. (2016, December 13). *Source animal, product, preclinical, and clinical issues concerning the use of xenotransplantation products in humans*.

Yiswaree, P. (2022, June 10). National Transplant Centre: Almost all organ donation pledges' wishes cannot be fulfilled. *Malay Mail*.