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NECESSITY IN XENOTRANSPLANTATION

Islamic Perspectives Revisited

Kee Lam Wong¹ and Waleed Fekry Faris²

Abstract

*Organ failures cause significant problems and sufferings which affect the livelihood, quality of life and decrease in life expectancy to the person. The caregivers, family and community also carry the disease burden and costs of the organ failures. Allotransplantation (AT) offers probable cures to organ failure but is limited by the supply of human organs. Organ shortages have resulted in numerous biomedical ethical problems and illegal activities. Xenotransplantation (XT) and specifically Porcine Xenotransplantation (PXT) has high expectations from researchers and clinicians to be the alternative to AT. From the Islamic perspectives, multiple deliberations and fatwas are issued that vary from total prohibition to conditional permissibility and full permissibility. Often, *ḍarūrah* or dire necessity is invoked to make XT or PXT permissible. The relevant biomedical issues and whether pre-conditions for *ḍarūrah* have been satisfied are discussed.*

Keywords: necessity, *ḍarūrah*, dire necessity, xenotransplantation, porcine xenotransplantation.

1. Introduction

Organ replacement therapies for failed organs, e.g., dialysis for kidney failure, have been invented for decades and have steadily improved since. However, no machines or biomedical system can replace the full physiological functions of different vital organs.³

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³ J. J. G. Martínez & K. Bendjelid, "Artificial Liver Support Systems: What is New

The cost of supportive therapies, damaged quality of life and burden on physical and psychological health of the patients and caregivers are considerable.^{4 5} Thus, Organ Transplantation (OT) with human organs (AT) is needed for these organ failures. At its first inception, the application of AT was restricted. With technological improvements, increasing advances in the understanding of the immunology of rejection and modification of post-transplant immunosuppression, more and more patients are eligible to receive OT and have improved quality of life and survival post-transplant. AT becomes a standard and commonplace therapy for patients with various acute and chronic organ failures. However, patients with different organ failures increase substantially but not the source of donor organs. Inevitably, the demand for OT far exceeds the supply of organs creating long backlogs and waiting lists for AT globally.

The growing shortages of donor organs create problems in many domains, from procurement and allocation to bioethical controversies, non-ethical and illegal activities. Policy makers, clinicians and researchers are actively searching for methods to procure adequate supplies of donor organs to satisfy the demand for OT. However, growing different organs from human stem cells or cellular layers *ex vivo* or *in vitro* to replace fully the functions of all these organs are not foreseeable in the foreseeable future.⁶

Organ XT has the potential to mitigate donor supply shortages and solve the problems that have arisen from these shortages for Muslims and non-Muslims alike. For example, in transplant tourism, AT operation in the organ ‘traded’ regions may only have sub-optimal facilities causing higher mortality, rejection, infection and other

over the Last Decade?” *Annals of Intensive Care* 8, no. 109 (2018): 1–14.

⁴ J. V. Bonventre, F. P. Hurst, M. West, I. Wu, P. Roy-Chaudhury & M. Sheldon, “A Technology Roadmap for Innovative Approaches to Kidney Replacement Therapies a Catalyst for Change,” *Clinical Journal of the American Society of Nephrology* 14, no. 10 (2019): 1539–1547.

⁵ D. J. Hurst, L. A. Padilla, D. K. Cooper & W. Paris, “Scientific and Psychosocial Ethical Considerations for Initial Clinical Trials of Kidney Xenotransplantation,” *Xenotransplantation*, 29, no. 1 (2022): 1–5.

⁶ J. V. Bonventre et al., “A Technology Roadmap for Innovative Approaches to Kidney Replacement Therapies...”

post-transplant complications in the recipients.⁷ XT, especially Porcine Xenotransplantation (PXT), is actively pursued as the alternative to human sourced organs because of its advantages over other xenografts (XGs) (*vide infra*).

From the Islamic perspectives, OT had been performed in pre-Islamic period and early Islamic period. These include auto-transplantation, AT, and XT.⁸ Necessity holds the key to avert prohibition in Islam and is relied upon for various bioethical issues in OT. The acceptance of PXT from the Islamic perspectives through the application of necessity is probably an oversimplification and premature.^{9 10 11} As of now, the authors opined that PXT has not satisfied the pre-conditions required for *ḍarūrah* or dire necessity. This paper reviews the PXT's present status and discusses the biomedical ethics and applicability of *ḍarūrah* in OT, XT and PXT.

2. Review of Necessity in Islamic Perspectives

Necessity is explicitly mentioned in the Qur'an, long before the Necessity in Common Law.¹² However, the Qur'an, hadiths and sunnah have not laid down the preconditions for necessity and *ḍarūrah* in one single place. Throughout the years, there are numerous deliberations or decisions from Islamic jurists and authorities. Using the same set of Qur'an verses, hadiths and sunnah, these deliberations from jurists were vastly different.¹³ Amidst these

⁷ D. Atighetchi, *Islamic Bioethics: Problems and Perspectives* (Dordrecht, the Netherlands: Springer, 2007).

⁸ J. Ali, "Islamic Perspectives on Organ Transplantation: A Continuous Debate," *Religions*, 12, no. 8 (2021): 7–22.

⁹ M. Z. Butt, *Organ Donation and Transplantation in Islam: An Opinion*, 2019.

¹⁰ M. F. M. Zailani, M. N. Hamdan & A. N. M. Yusof, "Human–Pig chimeric organ in organ transplantation from Islamic bioethics perspectives," *Asian Bioethics Review* (2022): 1–8.

¹¹ D. Rodger, D. J. Hurst & D. K. C. Cooper, "Xenotransplantation: A historical–ethical account of viewpoints," *Xenotransplantation*, 30 (2023): 1–7.

¹² As described in J. Candlish, "'Necessity' in criminal and medical jurisprudence: A comparison of common law and Islamic law concepts," *IJUM Law Journal* 152 (2007): 215–229.

¹³ S. Hamdy, "Rethinking Islamic legal ethics in Egypt's organ transplant debate," In J. E. Brockopp & T. Eich, eds., *Muslim Medical Ethics: from Theory to Practice* (Columbia, South Carolina: The University of Southern Carolina Press, 2008), 78–93.

inconsistencies and controversies, the applications, preconditions, and limitations for necessity and *darūrah* are gradually established. These principles are becoming consistent and certain. Nevertheless, some degree of flexibility is allowed to cater for specific situations or changing circumstances.¹⁴

2.1 The Notion of Necessity

Shari'ah is the way of life for Muslims. What are permissible (*halāl*) and prohibited (*ḥaram*) are prescribed by the Qur'an, hadith and sunnah. Al-Qur'an proclaims explicit and implicit obligations and prohibitions. Being forgiving and merciful, Allah provides relieves and the pre-conditions for relieves where the performance of such obligations will result in harm, hardship, or injury. Necessity is often used as the relief in biomedical issues.

From Islamic perspectives, Necessity is divided into three categories:

- a) Need: a loose term meaning defining what one wants. A person will not suffer immediately if the need is not satisfied.
- b) Simple necessity: a higher level of need with more urgency to acquire or satisfy. As such, one's life and other *maqāsid shari'ah* are not threatened. The consequences of not satisfying simple necessity are only hardship and inconveniences.
- c) *darūrah*: necessity with sufficient intensity to avert prohibition.¹⁵

2.2 Reliefs using *darūrah* (Dire Necessity)

Maqāsid al-sharī'ah is the foundation of invoking *darūrah* in most situations. It was initially established for the purpose of protection of the five hierarchical higher objectives: *al-dīn* (faith), *al-naḥs* (life), *al-'ird* (dignity or progeny), *al-'aql* (intellect or mind) and *al-mal* (property or wealth).¹⁶ ¹⁷ Honor or dignity has been added by some

¹⁴ M. Z. Al-Mutairi, "Necessity in Islamic Law," (PhD Thesis, The University of Edinburgh, 1997).

¹⁵ M. Z. Al-Mutairi, "Necessity in Islamic Law," 68–69.

¹⁶ N. U. Haq, "The importance of the higher objectives of Islam (*maqasid*

authors.¹⁸ In general, the safety of human health and security of life are often placed above all (*sharī'ah*) obligations.¹⁹ Many of these situations invoking *darūrah* are well described and quoted in deliberations and decisions: unlawful food and hunger (starvation),^{20 21 22} worship and sickness or injuries,²³ faith and compulsion (duress),²⁴ seeking of treatment for sickness or injury where treatment is effective etc. (Table 1), dignity of body and public interests,²⁵ compliance with statutory laws,²⁶ permissible homicide and ummatic dangers.²⁷

al-sharī'ah in medicine,” in *FIMA Yearbook 2020*, ed. M.M. Nordin (Amman: Jordan Society for Islamic Medical Sciences, 2022), 1-8.

¹⁷ A. Padela, “Maqāṣidī Models for an “Islamic” medical ethics,” *American Journal of Islam and Society* 39, no. 1-2 (2022): 72-114.

¹⁸ M. Albar, “Organ transplantation: A Sunni Islamic perspective,” *Saudi Journal of Kidney Diseases and Transplantation* 23, issue 4 (2012): 50.

¹⁹ M. J. Samdani, “Doctrine of necessity (In Islamic Jurisprudence),” *Global Journal of Human Social Science: Arts & Humanities - Psychology* 19, no. 12 (2019): 53-58.

²⁰ The Qur'an, 2:173.

إِنَّمَا حَرَّمَ عَلَيْكُمُ الْمَيْتَةَ وَالْدَّمَ وَالْحَمَّ الْخَنِزِيرِ وَمَا أُهْلَ بِهِ لِغَيْرِ اللَّهِ فَمَنْ اضْطُرَّ غَيْرَ بَاغٍ وَلَا عَادٍ فَلَا إِثْمَ عَلَيْهِ إِنَّ اللَّهَ غَفُورٌ رَحِيمٌ ١٧٣

“He has only forbidden you ‘to eat’ carrion, blood, swine, and what is slaughtered in the name of any other than Allah. But if someone is compelled by necessity—neither driven by desire nor exceeding immediate need—they will not be sinful. Surely Allah is All-Forgiving, Most Merciful”.

²¹ A. I. Padela, S. W. Furber, M. A. Kholwadia & E. Moosa, (2014), “Dire necessity and transformation: Entry-points for modern science in Islamic bioethical assessment of porcine products in vaccines,” *Bioethics* 28, no. 2 (2014): 59-66.

²² Y. H. M. Safian, “Necessity (*darura*) in Islamic Law: A Study with Special Reference to the Harm Reduction Programme in Malaysia,” (PhD Thesis, University of Exeter, 2010), 31-42.

²³ M. Z. Al-Mutairi, “Necessity in Islamic Law,” 115-117.

²⁴ *Ibid*, 81-91.

²⁵ A. Sachedina, *Islamic Biomedical Ethics: Principles and Application* (Oxford University Press, 2009), 175-180.

²⁶ M. Ghaly, “Religio-ethical discussions on organ donation among Muslims in Europe: An example of transnational Islamic bioethics,” *Medicine, Health Care and Philosophy* 15, no. 2 (2012): 207-220.

²⁷ M. A. Albar & H. Chamsi-Pasha, *Contemporary Bioethics Islamic Perspective* (Switzerland: Springer International Publishing, 2015), 69.

Table 1 Seeking Treatment or Remedy for Diseases^{28 29}

Category	Requirements
Mandatory	<ol style="list-style-type: none"> 1 Effective treatment is available. 2 Treatment is saving life or vitality. 3 Public interest or public health, <i>maṣlahāh</i>, is involved.
Encouraged and preferred	<ol style="list-style-type: none"> 1 Treatment is likely to be successful and harm is unlikely. 2 Disease will affect activities and duties of self, family, and community. 3 Mode is <i>halāl</i> or <i>ḥaram</i> but permissible through <i>darūrah</i>
Optional (Facultative)	<ol style="list-style-type: none"> 1 Benefits from treatment are not proven or uncertain. 2 Illnesses or side effects from mode of therapy are uncertain. 3 Autonomy is allowed in deciding acceptance or refusal of treatment. 4 Informed consent is to be available except in emergency.
Abstinence preferred	<ol style="list-style-type: none"> 1 Treatment is unlikely to be beneficial. 2 Harm from treatment is likely to be more than benefits.
Prohibited	<ol style="list-style-type: none"> 1 Treatment involves amulet (other than Qur'an), sorcery, divination, talisman or encroaches on creeds etc. 2 Treatment involves the use of prohibited material: wine or intoxicant,

²⁸ Adapted and modified from M. A. Albar & H. Chamsi-Pasha, *Contemporary Bioethics Islamic Perspective*, 55–56.

²⁹ Adapted and modified from M. Z. Butt, *Organ Donation and Transplantation in Islam*, 22 -24.

pork, blood, or products from killing of unlawful animals.
ḍarūrah may be applied to reverse the prohibition.

Since one of the pre-conditions for *ḍarūrah* is the absence of a permissible (lawful) alternative, the application of *ḍarūrah* in biomedical ethics is expected to vary with time, place and change in technology for specific issues or location. Given the absence of a system of precedence in Islamic Legal System, generalization and universal applicability could be difficult. Thus, each issue needs to be judged according to Islamic Law by the local authority to decide on whether *ḍarūrah* can be invoked.

2.3 Pre-conditions and Proportionality in *ḍarūrah*

Darūrah is applicable to a person and episode specific. The deliberations may be applied or extrapolated to other persons through analogy (*qiyās*). Pre-conditions are not set clearly in Qur'an, hadiths and sunnah and have evolved over time. The search for these pre-conditions through the decided scenarios helps to improve consistency in deliberations or expectations from Muslims facing similar situations. This can also minimize the over-use or unjustified use of *ḍarūrah*.

2.3.1 The Harm

A severe harm or a threat of severe harm that affects one or more of *maqāṣid al-sharī'ah* must be present. Compliance with *Sharī'ah* rules, laws or obligations will result in the harm or the person will suffer from the harm or consequences of the harm. Thus, trivial or non-serious harms are excluded. The harm or consequence(s) of the harm is (are) real, immediate, and certain, and believed by the person that the harm(s) is (are) immediate and certain.

The scope of harm covers injuries and extends to significant or unreasonable hardship involving the *maqāṣid al-sharī'ah* necessities. The scope has evolved to include protection of society, economic

systema and political administration.³⁰ As of date, most deliberations concentrate on physical or quantifiable harms. Psychological or mental harms and benefits are often neglected or relatively under-evaluated.

2.3.2 The Prohibited Act

A prohibited act can or likely can prevent, mitigate, lessen, or remove the harm. The prohibited act:

- a) may be an unlawful act or an act that delays or neglects an obligation (e.g., salat or fasting) and is to the harm going to be inflicted to the person.
- b) is actionable or executable with no better and lawful alternative available at the time or immediate future.
- c) must be stopped if a permissible or lawful alternative becomes available.
- d) is only allowed to the point of relieving the harm or being sufficient for ordinary life activities e.g., eating just enough to prevent starving to death.

Prohibited acts can be classified into three categories: a) the prohibited act is permitted, and sin is not committed; b) the prohibited act is allowed but the sin is removed; c) the prohibited act remains prohibited and sin is committed. *Darūrah* is only applicable for the first two classes of prohibited acts.³¹ Where more than one prohibited act can be chosen, the prohibited act with the lesser or least harm needs to be chosen.

2.3.3 The Person

Jurists permit subjectivity, the tolerance of the harm by the person and variations at specific situations. However, the person must have adequate analysis and perception of the harm, degree of certainty and unavailability of lawful alternatives. The personal perception of the threat is sufficient. Muslim jurists classify certainty into four levels (100%, 75%, 50% and < 25%). The threat must be perceived to have

³⁰ Y. H. M. Safian, "Necessity (darura) in Islamic Law," 55.

³¹ Ibid 83–85.

a certainty of more than 75%.³² Subjective analysis needs to take into consideration the personal characteristics, including age, sex, previous life experiences, physical conditions etc., that can have been or may be caused by the harm.

The often-neglected concern is the tolerance or acceptability of the types of harms or risks from the execution of the prohibited act by the person (patient). This can vary among different persons (patients). This is very important in biomedical issues like OT, XT and PXT. Risks from the procedure and post-transplant immunosuppression are definite and certain. Like all other medical treatments, the ultimate decision whether to undergo the transplant is the acceptance by the patient, after these risks are duly informed.

2.3.4 Limitations

Darūrah is bound by its limitations that include infringement on other people's rights, causing grievous bodily harm, committing sinful and prohibited acts (murder or rape)³³ or contradicting any rulings on needs from Qur'an, hadiths and sunnah.³⁴

In OT, it means the human donor cannot be killed or has foreseeable serious complications from donation or after donation. For XT, the donor animals must be treated well with good livelihood, health, normal or accepted fertility. All procedures, manipulations, slaughtering, procurement of organs, burial or cremation must be respectful to the animals with least suffering. In addition, certain organs, e.g., those carrying genetic information like testis and ovary, are not allowed to be transplanted (*vide infra*).³⁵

³² Ibid 116.

³³ Wahbah Zuhaili, quoted in Y. H. M. Safian, *Necessity (darura) in Islamic Law*, 87-88.

³⁴ N. M. Isa, "Darurah (Necessity) and its application in Islamic ethical assessment of medical applications: A review on Malaysian fatwa," *Science and Engineering Ethics* 22, no. 5 (2016): 1319–1332.

³⁵ A. I. Padela & R. Duivenbode, "The ethics of organ donation: Donation after circulatory determination of death, and xenotransplantation from an Islamic perspective," *Xenotransplantation* 25, no. 3 (2018): 1–12.

3 Necessity in biomedical ethics context

Biotechnology has changed the landscape of medical care tremendously. Islamic biomedical ethics is to control the outcome of biotechnological applications and their effects on societal functions and values to make sure these applications do not contradict humanity or moral standards, as seen from Islamic perspectives. It has been suggested that Muslims should keep open to novel treatments that are developed to relieve permanent incapacity and sufferings for the affected person and those that are costly to the family and healthcare system. In addition, jurists acting on their own can be difficult because these decisions and deliberations on such biotechnologies require substantial and in-depth understanding and ramifications of the biotechnology itself. Appropriate jurists-specialists interface would facilitate such decisions and deliberations.³⁶

According to the Principalists of ‘Western’ biomedical ethics, there are four domains: autonomy, beneficence, non-maleficence and justice. In these four domains, necessity in the literal sense is entrenched. For biomedical issues considered by Islamic jurists, the deliberations or decisions often involve necessity. These may be simple necessity or *darūrah* and may involve one or more of these domains, especially for OT and PXT.

3.1 Biomedical Ethics

3.1.1 Autonomy

Saving and preservation of life is a necessity for Muslims and non-Muslims. However, the decision to undertake such actions in Western biomedical ethics is personal. This includes euthanasia in some jurisdictions.

In Islam, the basic concept on the person as a being is different. Man is created by Allah and acts as the vicegerent for Allah. He is only

³⁶ A. I. Padela, “Jurists, physicians, and other experts in dialogue: A multidisciplinary visions for Islamic bioethical deliberations,” in *Medicine and Shariah: A Dialogue in Islamic Bioethica*, ed. A. I. Padela (University of Notre Dame Press, 2021), 227–234.

the custodian of the body and soul that are entrusted in him by Allah. He is bound by the *Shari'ah* and other laws derivable from the Qur'an. In other words, he does not have full freedom in making decisions with regards to his body and its contents (organs). He is allowed to make rational decisions and be responsible for his own well-being, to his family and ultimately to Allah. Thus, he has the obligation and duty to preserve good health, prevent any preventable diseases, seek, and receive treatment for any sickness or ill-health, not to injure or hurt himself. However, *ḍarūrah* can be invoked to bypass any possible prohibitions on autonomy.

Within the bounds of autonomy, Muslims are given the right to make and be responsible to decisions on his/her matters. This would include consent for treatment³⁷ and possibly, consent to undergo experimental treatment. Healthcare service providers are also bound by informed consents in providing treatments and conducting clinical researches.³⁸

3.1.2 Beneficence

Doing good (deeds), beneficence, is accepted universally and crosses cultures and civilizations. Beneficence covers wide ranges of activities that involve intentions, attempts, promotions of good or for good causes to oneself or others. Non-Islamic (Western) biomedical ethics conforms with these.

There are quite a lot of references in Qur'an and *sunnah* with respect to beneficence. Islamic biomedical ethics on beneficence is built upon these to provide 'ease, comfort, and benefit to others', i.e., the best possible (affordable) healthcare to the patients.³⁹ The Qur'an (41:46) says:

مَنْ عَمِلْ صَالِحًا فَلِنَفْسِهِ وَمَنْ أَسَاءَ فَعَلَيْهَا وَمَا رَبُّكَ بِظَلَمٍ لِّلْعَبِيدِ ٤٦

“Whoever does good, it is to their own benefit. And

³⁷ M. A. Albar & H. Chamsi-Pasha, *Contemporary Bioethics Islamic Perspective*, 111.

³⁸ M. Ebrahimi & K. Yusoff, “Islamic identity, ethical principles and human values,” *European Journal of Multidisciplinary Studies* 2, no. 6 (2017): 329-333.

³⁹ M. I. Khan, “The agreement and divergence between Islamic medical ethics and contemporary biomedical ethics,” in *FIMA Yearbook 2020* ed. M. M. Nordin (Amman: Jordan Society for Islamic Medical Sciences), 57–71.

whoever does evil, it is to their own loss. Your Lord is never unjust to 'His' creation.

3.1.3 Non-maleficence

Treatments or interventions need to be given if benefits exceed the risks that a person or a patient can accept. Islam does not permit harm. Islamic axioms place 'avoiding harm' above 'doing good'. In other words, for all ethical decisions, the lesser harm takes precedent over benefit. After this consideration, the option with the best benefit will be chosen.^{40 41} The Qur'an (6:160) says:

مَنْ جَاءَ بِالْحَسَنَةِ فَلَهُ عَشْرُ أَمْثَالِهَا وَمَنْ جَاءَ بِالسَّيِّئَةِ فَلَا يُجْزَى إِلَّا مِثْلَهَا وَهُمْ لَا يُظْلَمُونَ ١٦٠

Whoever comes with a good deed will be rewarded tenfold. But whoever comes with a bad deed will be punished for only one. None will be wronged.

3.1.4 Justice

Islam embraces justice comprehensively in all dimensions.⁴² The Qur'an has verses that stress on justice. The Qur'an (57:25) says:

لَقَدْ أَرْسَلْنَا رُسُلَنَا بِالْبَيِّنَاتِ وَأَنْزَلْنَا مَعَهُمُ الْكِتَابَ وَالْمِيزَانَ لِيَقُومَ النَّاسُ بِالْقِسْطِ وَأَنْزَلْنَا الْحَدِيدَ فِيهِ بَأْسٌ شَدِيدٌ وَمَنْفَعٌ لِلنَّاسِ وَلِيَعْلَمَ اللَّهُ مَنْ يَتَصَرَّفُ وَرُسُلُهُ بِالْغَيْبِ إِنَّ اللَّهَ قَوِيٌّ عَزِيزٌ ٢٥

Indeed, We sent Our messengers with clear proofs, and with them We sent down the Scripture and the balance 'of justice' so that people may administer justice. And We sent down iron with its great might, benefits for humanity, and means for Allah to prove who 'is willing to' stand up for Him and His messengers without seeing

⁴⁰ Ibid, 67.

⁴¹ H. Chamsi-Pasha & M. A. Albar, "Western and Islamic bioethics: How close is the gap? *Avicenna Journal of Medicine* 3, no.1 (2013): 8-14.

⁴² M. I. Khan, "The agreement and divergence between Islamic medical ethics and contemporary biomedical ethics," 68-69.

Him. Surely Allah is All-Powerful, Almighty.”⁴³

Applying these principles in Islamic biomedical ethics means all patients should be treated justly with no preferences or discriminations according to ethnicity, colour, sex, etc. The exclusion criteria in AT may be construed as injustice as patients with comparable organ failure are not given equal opportunity of getting AT because of organ shortages.

3.2 Application of necessity and *ḍarūrah* in biomedical ethics

Well-being is perceived as vital. Sicknesses affect the well-being and relief from sickness is generally accepted as desirable. Refusing treatment for any treatable disease is often unimaginable. Though some jurists hold contrary opinions, necessity is often applied in seeking and receiving treatment, undergoing research and advice on new biotechnological advances (Table 1). The harms and benefits to the person also extend to the harms and benefits to the community and the public at large (*maṣlahāh*).

To satisfy what are required for *ḍarūrah* at the personal level, the person must suffer from a medical condition(s) that could:

- a) affect his/her life at this moment (immediate) or near future with high certainty or probability.
- b) cause his/her life in danger or shorten his life expectancy.
- c) inflict physical, social, or psychological suffering, pain, or agony.
- d) have negative impact on his/her quality of life (well-being) if the harm is allowed to continue.
- e) improve or have benefited from a prohibited medical treatment.

The prohibited treatment is:

- a) effective or likely to be effective to preserve or save life; relieve suffering, pain, or agony; improve his/her quality of life.
- b) the best option after a thorough harm-benefit, what-if and proportionality analysis.
- b) the only option with no other available (Islamic) lawful treatment.
- c) accessible, affordable, and executable.

⁴³ Other verses include 60:8, 16:90, 5:8, and 38:26.

- d) provided by a trusted experienced and Allah-fearing medical practitioner.⁴⁴

The execution of the prohibited treatment:

- a) will not inflict harm on other people or conflict with other hierarchical necessities in *maqāṣid al-shari'ah* (faith, life, intellect, progeny, wealth).
- b) must be target based with the minimal effective amount for the shortest possible period.⁴⁵ Overtreatment means unnecessary treatment and should be avoided.
- c) will be stopped once the harm or the anticipated harm has been resolved or a lawful treatment is available.

Examples of prohibited treatments that are permissible include porcine gelatin in capsules, porcine insulin, trypsin in influenza vaccine etc. Treatments with porcine derived products are not permissible because another lawful alternative becomes available, e.g., Menimune meningococcal vaccine (porcine), Clexane and Fraxiparine.⁴⁶

4 Application of *darūrah* in OT

In OT, the recipient has organ failure. Acute organ failure can cause suffering with probable and immediate death. Chronic organ failure can result in suffering, decreased quality of life, and shortened survival despite supportive therapy. Given the availability of respective technology and support, the organ failures are reversible after AT with accepted risks to the recipient and minimal risks to living organ donors.

The principles of biomedical ethics reshuffle to the order of autonomy, justice, non-maleficence and beneficence where justice in deciding allocation and procurement of organs occupies a higher position in the hierarchy. However, the Qur'an and hadiths are silent on OT. Despite using almost identical quotes and references to the

⁴⁴ Y. H. M. Safian, "Necessity (darura) in Islamic Law," 132.

⁴⁵ N. M. Isa, "Darurah (Necessity) and its application in Islamic ethical assessment of medical applications," 1323.

⁴⁶ Ibid, 1329.

Qur'an, hadiths and sunnah, three groups of deliberations in slightly varied forms are held by Muslim jurists and authorities for *darūrah* and OT:^{47 48 49}

- a) not permissible because OT involves the body that is sanctify, both for living or deceased.
- b) permissible with conditions.
- c) always permissible.

The classical hadith, narrated by Aisha, Ummul Mu'minin, is used by jurists to prohibit any form of mutilation of the human body (Sunan Abi Dawud 3207)⁵⁰:

حَدَّثَنَا الْقَعْبِيُّ، حَدَّثَنَا عَبْدُ الْعَزِيزِ بْنُ مُحَمَّدٍ، عَنْ سَعْدٍ، - يَغْنِي ابْنُ سَعِيدٍ - عَنْ
عُمَرَ بِنْتِ عَبْدِ الرَّحْمَنِ، عَنْ عَائِشَةَ، أَنَّ رَسُولَ اللَّهِ صَلَّى اللَّهُ عَلَيْهِ وَسَلَّمَ قَالَ " كَسْرُ عَظْمِ
الْمَيِّتِ كَكَسْرِهِ حَيًّا "

The Messenger of Allah ﷺ said: Breaking a dead man's bone is like breaking it when he is alive.

Geographical variation in permissibility of OT does exist. Among the Sunnis, Arab Muslims scholars permit OT. From the Indo-Pakistan subcontinent, Muslim scholars take spirituality as priority above living and disallow OT.⁵¹ On the other hand, *Shī'ites* jurists and scholars in the Middle East hold OT permissible.⁵²

Butt remarked 'that jurists who cited human dignity as a reason to prohibit the use of body parts did so based on the norms of their times. Today, however, organ transplantation (OT) is viewed in a totally different light, and, rather than a violation of human dignity, it

⁴⁷ A. Ali, T. Ahmed, A. Ayub, S. Dano, M. Khalid, N. El-Dassouki, A. Orchanian-Cheff, S. Alibhai & I. Mucsi, "Organ donation and transplant: The Islamic perspective," *Clinical Transplantation* 34, no. 4 (2020): 1–12.

⁴⁸ J. A. Ali, "Islamic perspectives on organ transplantation: A continuous debate," *Religions* 12, no. 8 (2021): 7–22.

⁴⁹ A. Sharif, "Organ donation and Islam: challenges and opportunities," *Transplantation* 94, no. 5 (2012): 442–446.

⁵⁰ <http://www.sunnah.com>

⁵¹ J. A. Ali, "Islamic perspectives on organ transplantation" 8-9.

⁵² M. S. Siraj, "How a compensated kidney donation program facilitates the sale of human organs in a regulated market: The implications of Islam on organ donation and sale," *Philosophy, Ethics, and Humanities in Medicine* 17, no. 10 (2022): 1–18.

is seen as the ultimate gift',⁵³

The rule on inviolability and prohibition of mutilation of the body is not absolute. With due respect to the body observed, post-mortem is permissible and accepted by Muslims on the ground of the laws of land and public interest.⁵⁴ Consequential rules on sanctified body are the balance between harms and interests of human beings. At times of conflicts, the lesser of harms or sacrifice of lesser of the interests is chosen for the greater one.⁵⁵

Since there are significant suffering and threat to the life of the recipient, *darūrah* can be invoked in OT according to most jurists who permit OT. The donor, living or deceased, must be well respected and dignified. The reasoning can be simple and straightforward. Allah will not only look after the benefit of one single individual but will take care of all human beings giving them the desired benefits and enjoyment in this world and hereafter.⁵⁶ Thus, Allah presides over all individuals on their body, how to use the body to his own interests and to all others around him. Man, being the vicegerent of Allah, should act in the interest of Allah in himself and all other beings accordingly to benefit himself and all others. This is an obligation and well above ordinary altruism. Therefore, organ donation by Muslims should be permissible for the benefits of the recipient or the community at large but not for benefits purely to themselves or personal gains.^{57 58}

There are some differences when the pre-conditions in *darūrah* are applied in OT. The decision for OT is determined by clinical evidence. The degree of organ failure, severity and urgency for OT relies almost entirely on medical opinion that is mostly objective. Subjectivity is only minor or additive. As a pre-requisite, a known success rate (benefits) for that OT must be established.⁵⁹

⁵³ M. Z. Butt, *Organ Donation and Transplantation in Islam*, 40.

⁵⁴ *vide supra*, Section 2.2.

⁵⁵ *vide supra*, Section 2.3.

⁵⁶ A. Sachedina, *Islamic Biomedical Ethics*, 44, 82, 86.

⁵⁷ D. Atighetchi, *Islamic Bioethics: Problems and Perspectives* (Dordrecht, the Netherlands: Springer, 2007), Chapter 7, 161–197.

⁵⁸ M. S. Siraj, "How a Compensated Kidney Donation Program Facilitates the Sale of Human Organs....," 7–8.

⁵⁹ N. M. Isa, "Darurah (Necessity) and Its Application in Islamic Ethical Assessment of Medical Applications," 1325.

On immediacy, there are two groups. One is immediate in acute organ failures e.g., liver and heart failure. The other group, which is far more common, is chronic organ failure e.g., kidneys. Any waiting period to invoke *ḍarūrah* is a clinical decision rather than a judicial requirement.

From the Islamic perspectives, lawful organ is a must. The donation of organs must be out of altruism, voluntary or with consent. The health or life of living donor must not be significantly jeopardized. Compliance with the laws of land, e.g., opt out for organ donation, can invoke *ḍarūrah* for public benefits (interests). Human organs are not tradable commodities. Organs obtained from illegal practices, e.g., organ trades are prohibited. Moreover, different Islamic jurisdictions still have different rulings on organ donation after death, Muslim to non-Muslim donation or financial compensation for organ donation etc.

On limitations, not all organs are permitted in OT. Some jurists classify human parts into three types: those that are unique, those that are in pairs and those of which there are four of a kind. Those organs that are unique, vital for bodily functions or with aesthetic importance are not allowed to be procured for live donation.⁶⁰ Organs that carry genetic information that inflicts on progeny, e.g., ovary and testis, are explicitly prohibited.⁶¹

For the donor, the rights of donors must be observed. Killing another person for his organ is prohibited. The donor must not have any serious foreseeable harm after donation. In XT, the donor animals must be well treated and have least suffering from the procuring of the organ(s).

5 *Darūrah* in the context of XT and PXT

XT is transplant of xenografts (XG) across species. These include different tissues, cells, or organs. PXT is XT using porcine xenografts (PXG). The ultimate goal for XT or PXT is to achieve successful transplantation of XG or PXG into human body that is comparable to AT.

⁶⁰ A. Sachedina, *Islamic Biomedical Ethics*, 187–188.

⁶¹ A. I. Padela & R. Duivenbode, “The ethics of organ donation...,” Table 2, 5.

5.1 XT and AT: Islamic perspectives

AT is the transplant of human tissue or organs from one person to another. Data from human organ AT can be used as benchmarks to assess the benefits and harms of XT and PXT. In contrast to AT, XT has five groups of medical obstacles:

- a) anatomical and structural incompatibility.
- b) severe immunological rejection.
- c) physiological incompatibility.
- d) cross species infections (xenozoonosis).
- e) cancer risk from animal retrovirus and other carcinogenic viruses, and/or immunosuppression.

Each of these has significant impacts on the harms and benefits to the recipient. XGs using pig's bones, goat's amnion tissue etc. had been used successfully.^{62 63} However, after years of trials, there is still no successful full organ XT on human recipient for organ failure.

From the Islamic perspectives, the over-riding and additional requirement for XT is a permissible XG that is pure and clean. There are debates on the source of XGs from different animals and the requirement of lawful slaughtering. According to Omar and Muda, there are three groups of opinions:

- a) Tissues and organs from lawful animals that are slaughtered lawfully are clean and permissible to be used in XT.
- b) Lawful animals that are not slaughtered lawfully is carrion. For the latter, opinion is divided: i) tissues or organs without blood or fluid and hard objects are clean (bone, tooth, horn, nail, tusk); ii) all carrions are unclean; iii) tissues or organs with blood flow are unclean and require invoking *darūrah* to be permissible.
- c) Tissues and organs from prohibited animals, except pigs and dogs, are similar to carrion. For pigs, all parts are unclean and require *darūrah* to be permissible. For dogs, opinion is divided: i) all parts unclean and require *darūrah* to be permissible; ii) only mouth and

⁶² M. Albar, "Organ transplantation: A Sunni Islamic perspective," 817–822.

⁶³ N. Omar & Z. Muda, "The application of the rule of Istihsan bi Al-Maslahah (Juristic Preference by Interest): A practical approach on some medical treatment," *International Journal of Academic Research in Business and Social Sciences* 7, no. 5 (2017): 365–376.

saliva are unclean; hard objects are permissible but inner parts are unclean and require *darūrah* to be permissible; iii) all parts are clean and permissible.⁶⁴

XT has its own advantages over AT. Since XG supply can be potentially unlimited, XT can solve the problems associated with human Organ Shortages e.g., risks to living organ donor, unjust procurement and allocations of organs, low cadaveric donation rate, exclusion of patients, transplant tourism, black markets for organ trading, organ trafficking, duress, illegal extraction, exploitation of poor countries, one-kidney villages etc. Multi-organ OTs, repeat OTs, OT for unusual organs and non-attempted organs could be possible.

For Muslims, XT provides additional advantages. Controversies to define and determine death for organ donation, Muslim to non-Muslim organ donations and receiving organs, and financial initiatives or compensation for organ donation can be avoided. For jurists who oppose all forms of OT using human organs and who question or disagree with the definition of and decision on brain death and ‘donation after circulatory determination of death’ for OT,^{65 66} XT provides the much-needed alternative replacing the need of procuring organs from human, alive or deceased.

5.2 PXT and Non-Human Primate-XT (NHP-XT)

NHP are used as donors and recipients in XT research. NHP as a donor has the distinct advantage of closer physiological similarity with human. Monkeys have much higher hazards in biosafety because of their genetic proximity to human. Baboons and chimpanzees are often used in NHP-XTs. In addition, NHP are used as recipients in PXT before clinical PXT in human.

These NHPs have an intrinsic problem with anatomical compatibility. For example, baboon heart or liver are small. Thus, recipients must be of small size and NHP-XGs are inappropriate for usual human adult. Secondly, NHPs has a much smaller potential as

⁶⁴ Ibid.

⁶⁵ A. I. Padela & R. Duivenbode, ‘The Ethics of Organ Donation...’, 6 – 7.

⁶⁶ A. Sharif, ‘Organ Donation and Islam...’ *Transplantation*, 442–446.

supply of donor organs because they have small litter sizes, long reproduction cycles, difficulty in breeding and genetic manipulation (GM) etc. In addition, some of them are endangered species and not allowed to be used.

Pigs are different. Those disadvantages of NHPs as source of donor organs are largely overcome. Pigs have anatomical and structural similarity to human organs e.g., liver, kidneys, and heart; and the potential of unlimited supply because of short reproduction cycle, large litter size, familiar domestication and breeding etc. Some porcine cells or organs have physiological compatibility to human and such products have been used therapeutically for a long time e.g., porcine insulin. In addition, genetically modifications for pigs are possible and available to reduce post-transplant medical obstacles.^{67 68 69}

It is almost impossible to have repeated NHP-XT because of limited supply of NHP organ from the same or similar animal. For PXT, the supply of donor organs from the same litter or similar genetic constitution is highly possible. For example, in porcine islet transplantation, the attrition rate for the implanted porcine islets is high. This can be compensated by repeated islet PXT.

NHP as recipients in PXT helps in pre-clinical research. However, the immune system and response of NHPs to PXG can be substantially different from human. Some pre-formed antibodies e.g., to porcine xenoantigens, may be present in NHP but not in human. These results of NHP-PXT cannot be extrapolated to human.

5.3 *Darūrah* in the context of PXT

Use of XG, e.g., animal's bones, had been reported in contemporary Islamic literatures.⁷⁰ Apparently, *darūrah* had not been discussed or

⁶⁷ J. Denner, "Porcine endogenous retroviruses and xenotransplantation," *Viruses* 13, no. 11 (2021): 1–17.

⁶⁸ A. N. Carrier, A. Verma, M. Mohiuddin, M. Pascual, Y. D. Muller, A. Longchamp, C. Bhati, L. H. Buhler, D. G. Maluf & R. P. H. Meier, "Xenotransplantation: A New Era," *Frontiers in Immunology* 13 (2022): 1–11.

⁶⁹ D. Rodger, D. J. Hurst & D. K. C. Cooper, "Xenotransplantation: A historical–ethical account of viewpoints," *Xenotransplantation* 30 (2023): 1–7.

⁷⁰ M. A. Albar & H. Chamsi-Pasha, Contemporary Bioethics Islamic Perspective, 210.

invoked. There are three groups of PXGs:

- a) transformed or derived porcine products.
- b) acellular tissues.
- c) cells and organs.

For acellular or decellularized PXG, they do not have robust cellular antigens to trigger rejection. In contrast to organ PXG, rejections occur in Cells and Organs PXT. Cell PXT has less severe rejection, simpler macro- and micro-environments for engraftment and better post-PXT functioning. Major Organ PXTs are much more complicated. In addition to more severe rejection, many products with different physiological functions are produced by these solid organs e.g., kidney and liver. They could have complicated homeostatic mechanisms that are mediated differently by these porcine organs, e.g., porcine renin and erythropoietin. In addition, each Organ PXT can have its own unique problems following transplant, e.g., left ventricular hypertrophy or failure after porcine heart PXT or overgrowth of kidney PXG after kidney PXT.

Adherence to general biomedical ethics is similar in most researches in PXT. Religious perspectives apparently are not set as a priority for research and applications of PXT in the reported studies (*vide infra*).

As of today, PXT offers the best anatomical and structural compatibility. There are significant advances in attempts to overcome the major obstacles: lessened rejections from genetically modified pigs and new intensive immunosuppression, better physiological adaptation, and controllable cross species infections. The most feared porcine retrovirus has not been shown to be a problem following Islet PXT (*vide infra*).⁷¹

Contemporary Muslim jurists and scholars are divided on PXT.⁷² For those jurists who reject PXT, the human body is pure and needs to remain pure to meet Allah's expectation. PXG is impure. Any impurities or uncleaned tissues or organs, that are implanted or transplanted, are not acceptable. Numerous jurists and scholars, who allow PXT, rely on *ḍarūrah*. Two pre-conditions are laid down for human PXT:

⁷¹ J. Denner, "Porcine endogenous retroviruses and xenotransplantation," 8 – 9.

⁷² D. Atighetchi, *Islamic Bioethics: Problems and Perspectives*, 181 – 183.

- a) if the PXT is done for an emergency where no alternative medicine or other (lawful) organ is available;
- b) the harm from the transplant must be less than the harm from not performing the PXT (the principle of proportionality)^{73 74 75 76 77}

This recommendation is apparently made in view of the interests of the individual and misses out on public interests, which are as important. The major advantage of PXT is unlimited supply of (animal) donor organs at low costs. Given the enormous number of Muslim and non-Muslim patients requiring OT, PXT can benefit many patients at affordable costs (in the future). Eventually, this may stop all black markets for sale of human organs, organ trafficking, transplant tourism and other crimes or immoralities related to human Organ Shortages.

5.3.1 Basic requirements allowing PXT: Islamic perspectives.

The interests of the recipient with organ failure and the donor animal must be respected and attended to. Criteria need to be established to allow PXT:

- a) The recipient must suffer from one or more organ failures that affect his health and life.
- b) The respective organ from donor animal is available.
- c) The animal should be reared properly and slaughtered lawfully, if necessary.⁷⁸ Burial or cremation of the donor pig should be respected.
- d) To ensure the shortest warm ischemic time for better engraftment,

⁷³ M. Z. Butt, *Organ Donation and Transplantation in Islam*, 33.

⁷⁴ A. I. Padela & R. Duivenbode, "The ethics of organ donation....," 7 – 8.

⁷⁵ H. A. Qotadah & M. Syarifah, "Pig kidney xenotransplantation as an alternative solution of Hifdz Al Nafs," *International Journal of Islamic Khazanah* 12, no. 2 (2022): 94–102.

⁷⁶ M. F. M. Zailani, M. N. Hamdan & A. N. Yusof, "Human–Pig chimeric organ in organ transplantation from Islamic bioethics perspectives," *Asian Bioethics Review* (2022): 1–8.

⁷⁷ D. Rodger, D. J. Hurst & D. K. C. Cooper, "Xenotransplantation: A Historical–ethical Account....," 2.

⁷⁸ W. Paris, R. J. H. Seidler, K. FitzGerald, A. I. Padela, E. Cozzi & D. K. C. Cooper, "Jewish, Christian and Muslim Theological Perspectives about Xenotransplantation," *Xenotransplantation* 25, no. 3 (2018): 5.

the procurement may take place when the animal is still alive. This procurement of the organ from the donor animal should minimize the suffering of the animal and uphold the animals' rights and welfare.

- e) PXT must produce benefits to the recipient through a functional organ relieving his suffering and saving his life.
- f) The PXT is the only method available to the recipient.
- g) The PXT has a reasonable chance of success.
- h) Public interests will not be harmed e.g., porcine associated infection will not be disseminated and may be benefited with less disease burdens and less public health expenses.
- i) The harms and benefits of the PXT must be compared to the natural state and history of progression of the organ failure, supportive therapy, and AT in the recipient.⁷⁹ This issue is recipient-group specific and appropriate benchmarks from comparable recipients with organ failure should be used.

5.3.2 Permissible porcine therapeutic products

Consumption of pork is explicitly prohibited in Islam. However, porcine, or porcine derived medical products are used with conditional approval. There are three groups of jurists' opinion:

- a) all porcine related biomedical products are *haram* and not permitted to be transplanted into human body. These products undoubtedly will include porcine organs.
- b) transformed PXG is permitted because of either structural change or change of purpose other than ingestion as food.
- c) PXG is permitted after *darūrah* is invoked and pre-conditions for *darūrah* are satisfied. These permissible products are either derived from pigs or porcine acellular products and tissues. The typical example is porcine heart valves that are used for respective valvular replacements.⁸⁰ *Darūrah* is invoked and the porcine heart valve can only be used if the patient's condition is testified by a

⁷⁹ Adapted and modified from M. Z. al-Mutairi, "Necessity in Islamic Law," (PhD Thesis, The University of Edinburgh, 1997), 130.

⁸⁰ O. Ali, F. Aljanadi & H. Rabbi, "The use of porcine bioprosthetic valves: An Islamic perspective and a bioethical discussion," *Journal of the British Islamic Medical Association* 11, no. 4 (2022): 1–9.

specialist doctor and an alternative lawful heart valve is not available.

Transformed porcine products are permissible if the transformation successfully changes the physical properties (appearance, smell, and taste etc.), chemical or biochemical properties (molecular structure, genetic makeup etc.), unique (phenotypic) characteristics or the mode of use other than ingestion. Sufficient dilution or use of minute quantities may make these prohibited materials permissible.^{81 82} The often-quoted permitted examples include vinegar derived from wine and tanned hide from unlawful animals. This principle of transformation (*istihalah*) is extended to permit the use of gelatin in vaccines and capsules, and trypsin in vaccines.^{83 84} An Australian study of Jewish, Muslim, and Hindu perspectives on use of porcine or bovine surgical products emphasised the need for surgeons to know and communicate with patients of different religious backgrounds with regards to use of these products. However, most often than not, the information on these products is inadequate.⁸⁵ From Islamic perspectives, porcine surgical products can be used where *darūrah* is invoked or with sufficient transformation, like gelatin. To safeguard the interests of Muslim patients and medical practitioners, it will be advisable to consider *halāl* certification of surgical products or appliances that are derived from lawful animals lawfully slaughtered.

This principle of transformation probably is not applicable to

⁸¹ S. A. Ismail & A. Setiawan, "Shari'ah concept of medicine and seeking remedy," In M. M. Nordin, ed., *FIMA Yearbook 2020*, 31–35.

⁸² A. S. Rosman, A. Khan, N. A. Fadzillah, A. B. S. Darawi, A. Hehsan, A. M. Hassan, M. A. Ghazali, Ikhsan & Z. Haron, "Fatwa debate on porcine derivatives in vaccine from the concept of physical and chemical transformation (Istihalah) in Islamic jurisprudence and science," *Journal of Critical Reviews* 7, no. 7 (2020): 1037–1045.

⁸³ A. I. Padela, S. W. Furber, M. A. Kholwadia & E. Moosa, "Dire Necessity and Transformation...", 59–66.

⁸⁴ H. Musa & M. M. Nordin, "The permissibility of judicially prohibited and impure substances in medicines from the perspective of contemporary Fiqh Councils," in *FIMA Yearbook 2020*, ed. M. M. Nordin, 36–39.

⁸⁵ C. Easterbrook & G. Maddern, "Porcine and bovine surgical products: Jewish, Muslim, and Hindu perspectives," *Arch Surg* 143, no. 4 (2008): 366–370.

Cell or Organ PXT because the physical properties, e.g., appearance and the genetic constitution remains substantially porcine even after all GMs⁸⁶ or in humanized chimera.⁸⁷

5.3.3 Porcine acellular or decellularized tissues PXT

Porcine acellular or decellularized tissues or products do not stimulate the recipient's immune system significantly. Thus, rejection is not an obstacle. Since porcine cells are not involved, endogenous and genome associated viral infection will not occur. Other infections in the XG can be excluded or cleared by appropriate technologies.

From Islamic perspectives, the three groups of opinion are the same.⁸⁸ These PXGs will be permissible if a) a change of usage for PXG to PXT and not consumption is accepted, or b) *darūrah* is invoked.

5.3.4 Porcine Cells and Organs

Organ PXT has distinct advantages over AT. Donor animals can be pre-conditioned such that their organs can be better prepared and safer from rejection and infection for transplantation: a) a longer period is available for detection of pathogens; b) latent infections can be excluded with appropriate detection methods; c) anti-viral drugs can be developed and used in porcine donor and human recipient; d) the donor animal may be vaccinated to protect the donor cells or organs if required.^{89 90}

⁸⁶ W. Paris, R. J. H. Seidler, K. FitzGerald, A. I. Padela, E. Cozzi & D. K. C. Cooper, "Jewish, Christian and Muslim Theological Perspectives about Xenotransplantation," 1–8.

⁸⁷ J. V. Bonventre, F. P. Hurst, M. West, I. Wu, P. Roy-Chaudhury & M. Sheldon, "A technology roadmap for innovative approaches to kidney replacement therapies, a catalyst for change," *Clinical Journal of the American Society of Nephrology* 14, no. 10 (2019): 1539–1547.

⁸⁸ *vide supra*, section 5.3.2.

⁸⁹ J. Denner, "Xenotransplantation — A special case of One Health," *One Health* 3 (2017): 17–22.

⁹⁰ J. Denner, "Porcine endogenous retroviruses and xenotransplantation," *Viruses* 13, no. 11 (2021): 9-11.

5.3.4.1 Roadmap in Cell and Organ PXT

Modern day biomedical ethics is much more stringent. Contemporary PXT⁹¹ without good theoretical and basic research data cannot be performed in most, if not all, countries. The historical NHP to human XT, like Baby Fae,⁹² probably will not be performed again. The whole XT research direction is on developing the appropriate protocol to achieve and improve clinical Organ PXT to human recipients.

PXT on NHP or pre-clinical PXT is considered to be the pivotal step toward Organ PXT in human.⁹³ Undoubtedly, this is going to provide better understanding of and possible solution to various PXT obstacles. With the NHP-PXT models, safety of trial drugs or regimen could detect serious complications before applying to human recipients, e.g., anti-CD154 associated thrombosis and unsuitability of calcineurin inhibitors for islet PXT.⁹⁴ The micro-encapsulation and portal of islets PXT can also be tested.⁹⁵ However, certain targeted biologics towards the xenoantigens in NHP-XT may not be appropriate to human. Given the differences of the immune system and physiological systems between NHP and human, the final tests still need to be performed on human recipients. Five steps are involved in this Roadmap:

- a) preparation of the porcine donor:
 - i) reduce as much as possible the xenoantigens that trigger rejections. These include knock-out genes, transgenesis, tolerance induction and humanized chimera.
 - ii) reduce endogenous and exogenous infection, e.g., porcine

⁹¹ Quoted in M. Albar, "Organ transplantation: A Sunni Islamic perspective," 818.

⁹² Quoted in F. Dayan & B. Ali, "The application of necessity to xenotransplantation: constitutional & Islamic bioethical perspective," *Llkogretim Online* 19, no. 2 (2020): 1246–1253.

⁹³ T. S. Min, H. J. Han & S. H. Park, "Porcine xenotransplantation to primate," *Asian-Aust J Anim Sci* 23, no. 11 (2010): 1535–1542.

⁹⁴ S. H. Hong, H. J. Kim, S. J. Kang & Chung_Gyu Park, "Novel immunomodulatory approaches for porcine Islet Xenotransplantation," *Current Diabetes Reports* 21, no. 3 (2021): 1–8.

⁹⁵ T. S. Min, H. J. Han & S. H. Park, "Porcine xenotransplantation to primate," *Asian-Aust J Anim Sci* 23, no.11 (2010): 1538.

- endogenous retrovirus (PERV), porcine cytomegalovirus (PCMV), porcine Hepatitis E (PHE).
- iii) ensure the welfare and livelihood of the porcine donors are observed.
 - b) preparation of the recipient: innovative and appropriate immunosuppression regimens using drugs and targeted therapy.
 - c) selection of human recipients in experimental studies: to study and accumulate data on PXT kinetics and dynamics, especially for physiological compatibility.
 - d) enrolment of first stage clinical trials: choose the right group of patients with organ failure receiving the respective Organ PXT.
 - e) human Organ PXT clinical trials: full scale application of human Organ PXT.

5.3.4.2 Recent achievements in Cells and Organ PXT

The understanding of rejections in XT has increased tremendously. More and more powerful immunosuppressive drugs or biologics (targeted therapy) are increasingly available to suppress rejection. However, over-zealous immunosuppression may not be the best way forward because such regimen is likely to be costly and damaging to the recipient in the long term. Maximize the rejection prevention by GM and immunomodulation of the donor with the least immunosuppression for the recipient is the best approach.

Genetical engineering is a powerful tool in PXT and is the centrepiece towards success in human Organ PXT. This can be applied in multiple points of the rejection cascade and post PXT obstacles. GMs of the porcine genome can decrease or abrogate rejection, enhance physiological compatibility, decrease post-XT syndromes, and eliminate endogenous retrovirus genomes.⁹⁶ The humanized transgenic porcine chimera is another alternative, but this gets the genetic composition of the donor animal closer and closer to the human genome. The ethical concern eventually would be how to define these animals (pigs) to be animals (pigs) or human. This issue is less problematic in porcine chimeras generated by blastocyst

⁹⁶ M. Shahab, N. U. Din & N. Shahab, “Genetically engineered porcine organs for human xenotransplantation,” *Cureus* 14, no. 9 (2022): 1–4.

complementation from GM pigs because the donor is porcine and the organ is human. Finally, GMs must not be excessive as to affect the rights of the donor animals.⁹⁷ The more the GMs, the more the donor animal is distant from its natural state. This may affect the livelihood, fertility and well-being of the donor animal that need to be protected.

5.3.4.2.1 Minimize rejection and prolong PXG survival

The cascade of rejection of PXG is complex, involving interplays of natural anti-porcine xenoantigen antibodies, complement, thrombosis, inflammation, and different cell types. Achievements have been substantial in these two critical areas:

- a) Modification of donor pigs: these include induction of tolerance,⁹⁸ humanized chimera,⁹⁹ GMs to produce pigs with multiple knockout genes and transgenesis for expression of protective protein for complement and coagulation,¹⁰⁰¹⁰¹ and immunomodulation of donor, e.g., implantation of subcapsular autologous porcine thymus in kidney PXG.¹⁰² There is also the possibility of customized pigs to tailor to individual patient with organ failure especially to those who require repeated PXT (blastocyst complementation).

From the Islamic perspective, human-animal (porcine)

⁹⁷ Hadiths quoted in M. A. Albar & H. Chamsi-Pasha, *Contemporary Bioethics*....., 56.

⁹⁸ P. A. Vagefi, J. A. Shah & D. H. Sachs, "Progress towards inducing tolerance of pig-to-primate xenografts," *International Journal of Surgery* 23 (2015): 291–295.

⁹⁹ J. V. Bonventre et al., "A technology roadmap for innovative approaches.....," 1546.

¹⁰⁰ D. K. C. Cooper, H. Hara, H. Iwase, T. Yamamoto, Z. Y. Wang, A. Jagdale, M. H. Bikhet, H. Q. Nguyen, J. B. Foote, W. D. Paris, D. Ayares, V. Kumar, D. J. Anderson, J. E. Locke & D. E. Eckhoff, "Pig kidney xenotransplantation: progress toward clinical trials," *Clinical Transplantation* (2021): 35(e14139).

¹⁰¹ D. Niu, X. Ma, T. Yuan, Y. Niu, Y. Xu, Z. Sun, Y. Ping, W. Li, J. Zhang, T. Wang & G. M. Church, "Porcine genome engineering for xenotransplantation," *Advanced Drug Delivery Reviews* 168 (2021): 229–245.

¹⁰² R. A. Montgomery, J. M. Stern, B. E. Lonze, V. S. Tatapudi, M. Mangiola, M. Wu, E. Weldon, N. Lawson, C. Deterville, R. A. Dieter, B. Sullivan, G. Boulton, B. Parent, G. Piper, P. Sommer, S. Cawthon, E. Duggan, D. Ayares, A. Dandro, and Z. A. Stewart, "Results of two cases of pig-to-human kidney xenotransplantation," *New England Journal of Medicine* 386, no. 20 (2021): 1891.

chimera has the most controversy.¹⁰³ Inserting part of the human genome into the animal (pig) to produce a chimera or humanized protein may infringe the purpose of divine creation of and dignity of man. Moreover, chimeric PXT is likely to be more permissible if the required human organ can be grown in a chimeric pig (blastocyst complementation) or the donor organ can be devoid of porcine cells as much as possible. For all chimeric PXTs, *darūrah* still needs to be invoked.

b) Reduction or suppression of rejection by recipient:

Immunosuppressive therapy to counter rejection is a double-edged sword. Without immunosuppressive therapy, the organ graft will be rejected and fail. However, substantial morbidity and mortality are associated with post-transplant immunosuppression. It had been reported that forty percent of patients with kidney AT died with a functional kidney graft. Most of the deaths were related to immunosuppression.¹⁰⁴

New combination of immunosuppressive drugs, biologics and other adjunctive therapy dampens the immune response, increases graft survival, and maintains graft functions. A better preparation of the donor organ (PXG) that decrease the intensity of rejection will help to lessen the need of intensive immunosuppression and thus, reduce the consequent morbidity and mortality.

Most of the data on immunosuppressive regimens are from pre-clinical studies that involve NHP-PXT systems. Recent data on heart and kidney PXT had been reported.¹⁰⁵ ¹⁰⁶ More data may be emerging soon.

¹⁰³ M. F. M. Zailani, M. N. Hamdan & A. N. M. Yusof, "Human–Pig chimeric organ in organ transplantation...", 2-4.

¹⁰⁴ B. I. Shaw & A. D. Kirk, "Kidney xenotransplantation steps toward clinical application," *Clinical Journal of the American Society of Nephrology* 14, no. 4 (2019): 620–622.

¹⁰⁵ R. A. Montgomery et al., "Results of two cases of pig-to-human kidney xenotransplantation," 1889–1898.

¹⁰⁶ A. N. Carrier, A. Verma, M. Mohiuddin, M. Pascual, Y. D. Muller, A. Longchamp, C. Bhati, L. H. Buhler, D. G. Maluf & R. P. H. Meier, "Xenotransplantation: A New Era," *Frontiers in Immunology* 13 (2022): 1–11.

5.3.4.2.2 Physiological compatibility

Most Islamic jurists' deliberations and decisions on PXT miss out on the importance of physiological compatibility. Porcine proteins from organ PXG have their own species-specific physiological properties and auto-regulatory (homeostatic) mechanism. In AT, there are no such problems because the human proteins are similar and have similar physiological functions. In XT, the physiological consequences may be different and may be much more pronounced with Organ PXT. When the Cell or Organ PXG is transplanted to the recipient, these porcine proteins may act differently. These differences result in different PXT specific syndrome in the NHP and human recipients. For example, in kidney PXT, there may be overgrowth of PXG, hypovolemic syndrome and anemia caused by inadequate erythropoiesis from porcine erythropoietin. Other syndromes include the maladaptive ventricular hypertrophy following heart PXT.^{107 108 109}

Genetic modification can be performed on the donor pig to decrease growth hormone receptor that is alleged to be the cause of over-growth of PXG¹¹⁰ or to produce humanized protein with the desired physiological function.¹¹¹ With more research on human recipients, the 'real' physiological changes and the consequences would be studied. Remedies could be developed accordingly. These will pave the way for full clinical Organ PXT for human recipients with organ failure.

¹⁰⁷ Ibid.

¹⁰⁸ D. K. C. Cooper et. al., "Pig kidney xenotransplantation: progress toward clinical trials." 4-5.

¹⁰⁹ V. S. Tatapudi & A. D. Griesemer, "Physiologic considerations of pig-to-human kidney xenotransplantation," *Current Opinion in Nephrology and Hypertension* 32, no. 2 (2023): 193–198.

¹¹⁰ Ibid.

¹¹¹ B. Cho, E. J. Lee, S. M. Ahn, G. Kim, S. H. Lee, D. Y. Ji & J. T. Kang, "Production of genetically modified pigs expressing human insulin and C-peptide as a source of Islets for Xenotransplantation," *Transgenic Research* 28, no. 5–6 (201): 553-555.

5.3.4.2.3 Cross species infections

The prevention of potential pathogens of the donor animals starts from the parent animals that are raised in isolated and biosecured environments. Clean embryo transfer, Cesarean section, colostrum deprivation, early weaning and infection screening are effective means to eliminate potential pathogens, e.g., PCMV and PHE, in the donor.^{112 113}

Among porcine zoonotic infections, PERV is a major concern. PERV is integrated into the porcine genome as multiple copies of the provirus that are constantly present in the porcine genome irrespective of tissue types.¹¹⁴ PERV-A and PERV-B can infect human cells whereas PERV-C does not infect human cells. Substantial number of PERV provirus can be knockout in porcine cells in culture and pigs through genetic editing. This has the potential of clearing most if not all the PERV provirus in the porcine genome. Other measures that could decrease the potential harms from PERV include selection of low expression PERV-A and PERV-B pigs, use of anti-viral drugs, vaccination, and RNA interference. Choice of PERV-C free pigs can decrease the transmission of PERV infection including PERV-A/C combination.^{115 116} In addition, transgenesis for knockout genes does not influence the pattern of PERV trans-infection in the skin of the transgenic pigs.¹¹⁷

¹¹² J. Denner, “Porcine endogenous retroviruses and xenotransplantation,” *Viruses* 13, no. 11 (2021): 1.

¹¹³ S. Halecker, S. Hansen, L. Krabben, F. Ebner, B. Kaufer & J. Denner, “How, where and when to screen for porcine cytomegalovirus (PCMV) in donor pigs for xenotransplantation,” *Sci Rep* 12, no. 21545 (2022): 1–10.

¹¹⁴ U. Mazurek, M. C. Kimsa, B. Strzalka-Mrozik, M. W. Kimsa, J. Adamska, D. Lipinski, J. Zeyland, M. Szalata, R. Slomski, J. Jura, Z. Smorag, R. Nowak & J. Gola, “Quantitative analysis of porcine endogenous retroviruses in different organs of transgenic pigs generated for xenotransplantation,” *Current Microbiology* 67, no. 4 (2013): 505–514.

¹¹⁵ *Ibid.*, 507–509.

¹¹⁶ J. Denner, “Porcine endogenous retroviruses and xenotransplantation,” 9–11.

¹¹⁷ M. Kimsa-Dudek, B. Strzalka-Mrozik, M. W. Kimsa, I. Blecharz, J. Gola, B. Skowronek, A. Janiszewski, D. Lipinski, J. Zeyland, M. Szalata, R. Slomski & U. Mazurek, “Screening pigs for xenotransplantation: Expression of porcine endogenous retroviruses in transgenic pig skin,” *Transgenic Research* 24, no. 3 (2015): 529–536.

Data from islet cells and heart PXT to NHP, PXT to human and *ex vivo* perfusion in human using porcine organ or cellular bioreactor showed absence of transmission of PERV or clinically significant PERV from donor to recipient.¹¹⁸ In other words, PERV has not caused any infection risk to the PXT recipients and the community. However, it would still be advisable to minimize this risk as much as possible until more safety data are available.

5.3.4.2.4 Cell and Organ PXT attempted in human

Islet PXT had been performed with wild type and genetically modified porcine islets for patients with Type I diabetes mellitus (islet cell failure) with varying success.¹¹⁹ Human C peptide may have protective function against various complications in diabetes mellitus. Porcine C peptide from islets PXT does not have full physiological function of human C peptide in human. Transgenic pigs expressing human proinsulin with human C peptide are produced and may provide more benefits to the recipient in future Islet PXT.¹²⁰

Using organs sourced from genetically modified pigs, one heart PXT on a patient with heart failure and three kidney PXTs on three decedent patients were performed and reported.¹²¹ Three different immunosuppression protocols were used. The patient with heart PXT died of multi-organ failure two months after PXT. Two kidney PXG was pre-implanted with porcine thymus (thymokidney) after *ex vivo* perfusion with Static Preservation Fluid.¹²² No hyper-acute rejection occurred. The thymokidney functioned well 54 hours post PXT per protocol. The third patient with kidney PXT had thrombotic microangiopathy post-PXT while on a ‘standard immunosuppression’ plus rituximab regimen. The thrombotic

¹¹⁸ J. Denner, “Porcine endogenous retroviruses and xenotransplantation,” 8.-9

¹¹⁹ M. Shahab, N. U. Din & N. Shahab, “Genetically engineered porcine organs for human xenotransplantation,” *Cureus* 14, no. 9 (2022): 2-3.

¹²⁰ B. Cho, E. J. Lee, S. M. Ahn, G. Kim, S. H. Lee, D. Y. Ji & J. T. Kang, “Production of genetically modified pigs. . . .” 556.

¹²¹ A. N. Carrier et. al., “Xenotransplantation: A new era,” 6-7.

¹²² R. A. Montgomery et al., “Results of two cases of pig-to-human kidney xenotransplantation,” 1892.

microangiopathy may be part and parcel of an antibody-mediated rejection. Two of these three decedent patients with kidney PXT had their own functioning kidney before PXT. It was unclear how the kidney PXT was working by itself. The efficiency of the kidney PXT to clear creatinine or other toxic products can be better ascertained if the kidney PXT is performed on a recipient with no functioning kidneys.

5.4 *Darūrah* and achievements in PXT

There are substantial advances in treatment and prevention of rejection, understanding and management of physiological compatibility and no evidence of porcine derived zoonosis developing in PXT recipients or in the community.

The major determinants for invoking *darūrah* are the certainty of success, benefits, and reduced harm in the PXT recipient. The benefits to the recipient should include survival advantage for immediate, short, medium, and long term; improved physical and psychological quality of life; less burden to patients and carers. Benefits to the community at large would include medical, general utilitarian, social and political interests. Very few people realize that Muslims could have a much higher stake in PXT especially for those who object human donors for OT, alive or deceased.

The benefit-harm analysis involves the problems that can occur in the four phases following PXT and their comparison with allograft (Table 2). Using porcine organs that have anatomical compatibility to human, the technological aspect of transplantation is easily satisfied. Better procurement and *ex vivo* perfusion of the organ PXG improve the immediate post PXT functions. The *ex vivo* perfusion by customized fluid may eliminate most of the ‘impure’ blood and tissue fluid from the PXG as well.

Table 2 Problems following PXT¹²³

Survival Phases following PXT	Problems
Immediate	Structural and technical complications Hyper-rejection

¹²³ Modified from A. N. Carrier et al., “Xenotransplantation: A new era,” 1–11.

Short-term	Rejection Acute infection from immunosuppression Physiological incompatibility
Medium-term	Rejection Dysfunction PXG Post-PXG syndromes Opportunistic infection Cross species infection
Long-term	Chronic rejection Dysfunction PXG Post-PXG syndromes Opportunistic infections Cross species infections

Exception for Islets PXT, the present data are still limited to the early phase of PXT. Data on short-term, medium-term and long-term survival are limited or not available. Therefore, these determinants for invoking *darūrah* are not available. Without these data on definite or established benefits and harms, PXT should not be permissible.

On the issue of public interests with respect to costs and accessibility in developing world, these are not solved by PXT at this stage. The genetically modified pigs and their care are costly. Follow up treatments with complicated immunosuppressive regimens are expensive and require support from experts who may not be available in the developing countries. Two issues in the future may help:

- a) After clinical PXT is proven to be successful, the optimal GMs combination can be determined. Mass production of such pigs can bring down the cost of these organ PXGs.
- b) If blastocyst complementation using human stem cells is successful, the chimeric organ remains human and customized to the recipient. Post-transplant immunosuppression with the respective expertise may not be required.

5.5 Proposed Roadmap for PXT in human

Since the benefits and harms from Organ PXT are not sufficient to satisfy the preconditions of *darūrah*., any permission for Organ PXT

relying on *darūrah* is premature. New data need to be constantly collected, analysed, and discussed among medical experts and jurists before making any deliberations and advice on Organ PXT.

The following roadmaps according to different categories of porcine origin is proposed:

- a) Porcine derived or transformed products: need *halāl* certification and continuing search of lawful alternative.
- b) Acellular PXT: need *halāl* certification and continuing search of lawful alternative.
- c) Cell PXT: continue with search for physiological compatibility for each cell type, e.g., islets, stem cells, neurons, skin.
- d) Organ PXT with anatomical and physiological compatibility: continue with attempts in NHP and human, e.g., kidney, liver, heart.
- e) Other non-attempted organs or multiple organs: wait until data and reviews on other PXT are available, e.g., lung, small bowel, whole pancreas, adrenals.

5.5.1 Experimental Research in PXT

A small study of 163 patients with kidney failure and 40 healthcare providers showed that pig-to-human XT could be accepted if the results of PXT was comparable to AT. The great majority of patients would accept PXT if they had no religious concern. Data were not collected on the religious background of the respondents in this survey¹²⁴ As of now, Organ PXT to human body for organ failure are limited. This major determinant for acceptance of PXT will not be available for quite some time.¹²⁵

Islamic biomedical ethics do not prohibit medical research. Quality researches by researchers are allowed.¹²⁶ The XTs in the Islamic contemporary period probably would not satisfy the present-day biomedical ethics. The Muslim researcher must have the

¹²⁴ A. I. Padilla, D. Hurst, R. Lopez, V. Kumar, D. K. C. Cooper & W. Paris, "Attitudes to clinical pig kidney xenotransplantation among medical providers and patients," *Kidney360* 1, no. 7 (2020): 657–662.

¹²⁵ *vide supra*, Section 5.4.

¹²⁶ J. Rajab & M. Irfan, "Contemporary international principles of medical ethics," In M. M. Nordin, ed., *FIMA Yearbook 2020*, 22–30.

intention of doing the research for the benefits of the mankind for the sake of Allah, ensure the rights of human and animals are protected, maintain objectivity and safety, avoid, and prevent harm as much as reasonable, trustworthy in collection and publication of data.

For the medical researchers and healthcare providers, the first step is to achieve non-maleficence: making sure the PXT survives the first stage of engraftment without causing immediate harms to the recipient. The PXT then needs to go through the subsequent phases with consequential benefits in immediate, short, medium, and long term to the recipient, family, ummah and public at large.

On the participation of recipients with organ failure in PXT, man is given freedom of choices by Allah in all daily events. Sacrificing oneself or interests of oneself are highly honoured in Islam. The Qur'an (2:195) says:

وَأَنْفِقُوا فِي سَبِيلِ اللَّهِ وَلَا تُلْقُوا بِأَيْدِيكُمْ إِلَى التَّهْلُكَةِ وَأَحْسِنُوا إِنَّ اللَّهَ يُحِبُّ
الْمُحْسِنِينَ ١٩٥

“Spend in the cause of Allah and do not let your own hands throw you into destruction ‘by withholding’. And do good, for Allah certainly loves the good doers.”

And in the verse 59:9 it says:

وَالَّذِينَ تَبَوَّءُوا الدَّارَ وَالْإِيمَانَ مِنْ قَبْلِهِمْ يُحِبُّونَ مَنْ هَاجَرَ إِلَيْهِمْ وَلَا يَجِدُونَ فِي
صُدُورِهِمْ حَاجَةً مِمَّا أُوتُوا وَيُؤْتُونَ عَلَى أَنْفُسِهِمْ وَلَوْ كَانَ بِهِمْ خَصَاصَةٌ وَمَنْ يُوقِ شَحْ
نَفْسِهِ فَأُولَئِكَ هُمُ الْمُفْلِحُونَ ٩

“As for those who had settled in the city and ‘embraced’ the faith before ‘the arrival of’ the emigrants, they love whoever immigrates to them, never having a desire in their hearts for whatever ‘of the gains’ is given to the emigrants. They give ‘the emigrants’ preference over themselves even though they may be in need. And whoever is saved from the selfishness of their own souls, it is they who are ‘truly’ successful.

Muslims with organ failure may invoke *darūrah* and participate in Organ PXT for public interests and future benefits of patients with

respective organ failures. This obviously is out of benevolence, altruism, and personal sacrifice.

The four domains of the Principalists' biomedical ethics are not hierarchical. For Muslims to participate in PXT, a re-arranged hierarchical order may be more appropriate:

- a) Autonomy: the patients, family members or custodians are given the freedom of choice and are fully informed about the expected outcomes from the PXT.
- b) Justice: participation is non-discriminatory, and all his/her interests and rights are fully protected and respected before, during and after the participation.
- c) Non-maleficence: harms must be put under intensive scrutiny and be removed, if necessary, e.g., in failed kidney PXT, the kidney PXG could be removed, and dialysis reinstated.¹²⁷ This does not include decedent persons.
- d) Beneficence: decedent PXT recipient will not have any benefits. As of now, the potential benefits for surviving PXT recipients could be minimal and short-lived.¹²⁸

5.5.2 Clinical trials in Cell and Organ PXT

NHP-PXT cannot replace studies in human PXT especially some post-XT syndromes found in NHP-PXT are not detected in human PXT, e.g., proteinuria and hypoalbuminemia after kidney PXT to NHP. The first stage will be to test out the clinical efficacy and safety using GM pigs, new immunomodulation and immunosuppressive regimens.

A stringent patient selection process for PXT is essential to achieve the best possible results. Given the uncertainty on risk and benefits of PXT, participation of the PXT recipient is entirely a personal decision.¹²⁹ PXT needs to be the best available and possible alternative to the patients with organ failure at the time. This means those eligible for AT, who would have been already enrolled for AT, will be excluded. In addition, those recipients with extremely high

¹²⁷ A. N. Carrier et al., "Xenotransplantation: A new era," 5-6.

¹²⁸ Ibid, 7-8.

¹²⁹ D. J. Hurst, L. A. Padilla, D. K. C. Cooper & W. Paris, "Scientific and psychosocial ethical considerations for initial clinical trials of kidney xenotransplantation," *Xenotransplantation* 29, no. 1 (2022): 1-5.

risks need to be excluded as well because their underlying risks could have negative impacts on their lives and survival after PXT. The latter is very important to avoid negative perception for the whole PXT program by patients with organ failure and the community at large.¹³⁰

The second issue is appropriate benchmarking. Data from AT are inappropriate. AT has been established for a long time with known safety and efficacy profiles. PXT needs to go through the same learning curve of AT in the past. It is not envisaged that PXT can achieve the same degree of safety and efficacy within a considerable period of clinical application.

In addition, the recipients selected in the first stage of PXT clinical trial should be those excluded from routine AT because of age, co-morbidities etc. Therefore, the results of PXT should be compared to patients with organ failure who are refused AT and receive supportive therapy only,^{131 132} or where human organ is not available. The latter data may be a range or an average because the results could vary from centres to centres. The researchers and recipients may have to decide how much excess risk of PXT above these benchmarks can be accepted. At this stage, it is unrealistic to expect kidney PXT for kidney failure can achieve the proposed 90% survival for 1-year post-transplantation as in chronic dialysis.

Most authors suggest that experimental PXT should begin with kidney PXT because replacement therapy (dialysis) is easily available. If severe rejection or side effects from immunosuppression occur, the PXG can be removed, and immunosuppression can be stopped. The PXT recipient can revert to dialysis. Moreover, replacement therapy for liver and heart failure are less effective. It should be more urgent to get an alternative OT. This pressing need may put liver and heart PXT to a higher order for research in clinical PXT.

¹³⁰ R. Chaban, D. K. C. Cooper & R. N. Pierson, "Pig heart and lung xenotransplantation: Present status," *Journal of Heart and Lung Transplantation* 41, no. 8 (2022) 1020.

¹³¹ A. N. Carrier et. al., "Xenotransplantation: A New Era," 5-6.

¹³² D. K. C. Cooper et al., "Pig Kidney Xenotransplantation: Progress Toward Clinical Trials," 7-8.

6 Conclusion

From the Islamic perspectives, porcine products have been permitted to be used in medical treatments through the application of *istihalah* and *ḍarūrah*. Cell and Organ PXT have the potential to solve problems with human Organ Shortages and biomedical controversies that could be worse in the Muslim world. However, Cell and Organ PXT are still experimental. Comprehensive data on clinical benefits and harms are lacking. *Darūrah* cannot be invoked at this stage because this important precondition in *ḍarūrah* is not satisfied.

Continuing preclinical and clinical research should be continued. For Muslim patients with organ failure who participate in experimental research, *ḍarūrah* can be invoked for public interests and future benefits to patients with organ failure. *Darūrah* can also facilitate the participation of Muslim researchers in PXT.

Finally, information and deliberations on XT and PXT must be communicated appropriately and timely to Muslims, ummah and community at large such that they could be correctly informed about the development, achievements and expectations for XT and PXT.^{133 134} These can be mediated by the respective Muslim association, Iman and healthcare practitioners in a concerted manner.

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¹³³ Ahmed, M., Kubilis, P., & Padela, A. "American Muslim Physician Attitudes Toward Organ Donation," *Journal of Religion and Health* 57, no. 5 (2018): 1717–1730.

¹³⁴ A. I. Padela & Ebrahim Moosa, "Muslim doctors and Islamic bioethics: Insights from a National Survey of Muslim Physicians in the United States," in *Medicine and Shariah*, ed. A. I. Padela (University of Notre Dame Press, 2021), 193–225.

TRANSLITERATION TABLE

CONSONANTS

Ar=Arabic, Pr=Persian, OT=Ottoman Turkish, Ur=Urdu

Ar	Pr	OT	UR	Ar	Pr	OT	UR	Ar	Pr	OT	UR	
ء	ب	پ	پ	ز	ز	ز	ز	گ	—	g	g	g
ب	ب	ب	ب	ژ	—	—	ř	ل	l	l	l	l
پ	پ	پ	پ	ژ	—	zh	j	م	m	m	m	m
ت	ت	ت	ت	س	s	s	s	ن	n	n	n	n
ث	—	—	ṭ	ش	sh	sh	ş	ه	h	h	h ¹	h ¹
ث	th	th	th	ص	ş	ş	ş	و	w	v/u	v	v/u
ج	j	j	c	ض	ḍ	ḍ	ḍ	ی	y	y	y	y
چ	—	ch	çh	ط	ṭ	ṭ	ṭ	ة	-ah	—	—	-a ²
ح	ḥ	ḥ	ḥ	ظ	ẓ	ẓ	ẓ	ال	al ³	—	—	—
خ	kh	kh	kh	ع	‘	‘	‘	—	—	—	—	—
د	d	d	d	غ	gh	gh	ğh	—	—	—	—	—
ڈ	—	—	d	ف	f	f	f	—	—	—	—	—
ذ	dh	dh	dh	ق	q	q	q	—	—	—	—	—
ر	r	r	r	ك	k	k/g	k/ñ	—	—	—	—	—

¹ – when not final

² – at in construct state

³ – (article) al - or l-

VOWELS

	Arabic and Persian	Urdu	Ottoman Turkish
Long	ا	ā	ā
	آ	Ā	—
	و	ū	ū
	ي	ī	ī
Doubled	ي	iy (final form i)	iy (final form i)
	و	uww (final form ū) uvv (for Persian)	uvv
Diphthongs	و	au or aw	ev
	ی	ai or ay	ey
Short	ا	a	a or e
	ا	u	u or ū
	ا	i	o or ö
	ا	i	i

URDU ASPIRATED SOUNDS

For aspirated sounds not used in Arabic, Persian, and Turkish add h after the letter and underline both the letters e.g. جھ jh گھ gh

For Ottoman Turkish, modern Turkish orthography may be used.

AL-SHAJARAH

Vol. 28, No. 1, 2023

Contents

ARTICLES

DENYING AND DEFLECTING THE RACISM OF EMPIRE: THE TROPE OF
THE 'MALEVOLENT NATIVE' IN THE WRITINGS OF THE COLONIAL
FUNCTIONARY AND AUTHOR HUGH CLIFFORD 1
Farish A Noor

NORMS OF RISE AND FALL OF CIVILIZATIONS IN THE QUR'AN 27
BENEFICIAL KNOWLEDGE AND JUSTICE AS A MODEL
Arshad Islam and Ruqaiya Taha Al-Alwani

NINETEENTH-CENTURY *KITĀB JAWI* SUFI WORKS IN PATTANI, THAILAND 51
MAINSTREAMING ETHICAL SUFISM OF AL-GHAZALI
Jajat Burhanudin

TRANS-NATIONALISM AND CIVILISATIONAL IDENTITY 73
RUMI ON LAND, LANGUAGE AND LOVE
Amir H. Zekrgoo

CENTRAL ASIAN WAQF STUDIES DURING COLONIAL, SOVIET,
AND INDEPENDENCE PERIODS: A LITERATURE REVIEW 97
Osman Bakar, Sultonov Uktambek, and Ganiyev Avazbek

BRIDGING TRADITION AND MODERNITY IN THAI ISLAM 119
THE POLITICAL AND RELIGIOUS ROLES OF SURIN PITSUWAN (ABDUL HALIM)
Imtiyaz Yusuf and Pham Thuy Quynh

MANUSCRIPT STUDIES

KITĀB AL-MAWĀHIB AL-'ALIYYAH FĪ AL-JAM'Ī BAYN AL-HIKAM 143
AL-QUR'ĀNIYYAH WA AL-ḤADĪTHIYYAH (BOOK OF HIGH TALENTS IN THE
INTEGRATION OF QUR'ANIC AND HADITH WISDOM): A MANUSCRIPT STUDY
Mohamed Aslam Akbar

REVIEW ESSAY

MEMENTO MORI: EXISTENTIAL AND RELIGIOUS PERSPECTIVES ON DEATH 163
Arief Subhan

THE GENESIS OF ISLAMIC SCIENCE: 175
THE CONTRIBUTION OF CLASSICAL INDIAN SCIENCE REVISITED
Osman Bakar

BOOK REVIEWS 187

WoS-Indexed under Arts & Humanities Citation Index, Current Contents/Arts and Humanities and Scopus

ISSN 1394-6870



9 771394 687009

ARTICLES

- SUNAN KUDUS' STRATEGIC APPROACH TO CULTURAL ADAPTATION IN THE SELF-OTHER PERSPECTIVE 209
Sartini

- ISLAM IN MODERN MALAY LITERATURE 237
EXAMINING THE ROLE AND POSITION OF "STORY" IN PERSURATAN BARU
Mohd. Zariat Abdul Rani and Muhd. Zulkifli Ismail

- AFGHAN AND PAKISTANI TALIBAN 259
A COMPARATIVE STUDY OF THEIR POLITICAL IDEOLOGY AND RELIGIOUS AFFILIATIONS
Muhammad Kalim Ullah Khan and Osman Bakar

- THE CONSCIOUSNESS OF TURKIYE IN MALAYSIA 281
OTTOMAN HISTORY IN MALAYSIAN SECONDARY HISTORY TEXTBOOKS (1989-2022)
Tayfun Akgun and Ahmad Murad Merican

- TEMPORAL AND GEOGRAPHICAL FORCES IN SHAPING IBN KHALDUN'S THEORY 315
RELEVANCE AND APPLICATION IN MODERN SOCIETAL DYNAMICS
Zhilwan Tahir and Abdul Wahed Jalal Nori

- ABUL KALAM AZAD'S IDEA OF RELIGIOUS PLURALISM FOR AN INCLUSIVE INDIAN NATIONALISM 343
A CIVILISATIONAL REVISIT
Md Yousuf Ali and Osman Bakar

- NECESSITY IN XENOTRANSPLANTATION 367
ISLAMIC PERSPECTIVES REVISITED
Kee Lam Wong and Waleed Fekry Faris

REVIEW ESSAY

- SOME REFLECTIONS ON THE ISLAMIZATION OF KNOWLEDGE 407
Arfah Abdul Majid & Khairudin Aljunied

- BOOK REVIEWS** 425

