

# **BREATHING NEW LIFE INTO DRY BONES: THE EVOLVING PARADIGMS IN THE REGULATION OF HUMAN TISSUE TRANSFER IN KENYA**

*Augustus Mutemi Mbila*<sup>102\*</sup>

## **Abstract**

The story is told of Daedalus who grafted bird feathers to his arms with a view to escaping from his island prison in Crete and fly to Mainland Greece. Although fictitious, recent developments in human organ, tissue and cell transfer have demonstrated that the story of Daedalus was way ahead of schedule and a vision for things to come. There has been attempts at xenotransplantation, a practice that has raised several ethical and legal concerns. Human tissue banking, property rights of donors, and organ trafficking are other issues that need to be addressed. Human organ, tissue and cell transfer saves lives that would otherwise have been lost. Like the Biblical Ezekiel that the Lord instructed to breath new life into dry bones in a valley, organ, tissue, and cell transplant breathes new life to bodes that would have died, in the absence of comparable alternatives or possibilities of repair. On the other hand, organ, tissue, and cell transfer is subject to failure, which might expose the patient to more danger that they initially faced, and the donor to a problem they never had. These issues need to be addressed by law. Anchored on these emerging paradigms, this paper explores the mysteries and the realities of human organ, tissue, and cell transfer and the extent to which the law has addressed them. It then recommends legislative repeal to address the issues raised.

**Keywords: Transplantation; Property Rights; Organ Trafficking; Tissue Banking; Xenotransplantation; Regulation**

---

<sup>102\*</sup> LL.B. (Hons) (University of Nairobi), LL.M. (Regional Integration and East African Community Law) - (University of Dar es Salaam and University of Bayreuth in Germany), Ph.D. (Candidate), Lecturer and Consultant in Law. The author can be reached on [augumtemi@gmail.com](mailto:augumtemi@gmail.com) for comments on this paper.

## 1.0 Introduction

Transplantation of human organs, tissues or cells saves many lives that would otherwise have been lost. It also restores essential functions that have no comparable alternatives or possibilities of repair. This is comparable to what Biblical Prophet Ezekiel prophesied in the Book of Ezekiel 37:1-14 where the Lord ordered him to breath new life into dry bones in a valley.<sup>103</sup> Transfer of human tissue, organs and cells can save lives and restore critical human functions. For example, transplantation of human heart valve enables the human heart to pump blood through the body again. Transplantation of haematopoietic stem cells can cure congenital or acquired diseases like leukaemia. Likewise, a corneal graft can restore sight in corneal blindness.<sup>104</sup>

Statistics have shown that numbers on human organ, tissue and cell transplant continue to increase. Data from the Global Observatory on Donation and Transplantation shows that for the year 2021, there were 92,532 kidney, 34,694 liver, 8,409 heart, 6,470 lung, 2,025 pancreas, and 172 small bowel transplants globally.<sup>105</sup> In total, there were 38,156 deceased donors, comprising 29,611 Donation after Brain stem Death (DBD) donors and 8,545 Donation after Circulatory Death (DCD) donors. In 2020, there had been 81,003 kidney, 32,615 liver, 8,103 heart, 5,142 lung, 1970 pancreas, and 158 small bowel transplants globally. Total transplants increased by 11.3% in 2021 compared to the 2020 numbers.

Despite the increase in human organ, tissue and cell transplant in recent years, several countries are yet to enact laws to govern the evolving paradigms in this area. Questions have been raised regarding property ownership in transplanted organs, tissue and cells, the problem of organ donation due to poverty, and organ harvesting and trafficking, among other emerging issues. In its fortieth (40<sup>th</sup>) assembly in 1987,<sup>106</sup> the World Health Assembly requested the Director General to explore the possibility of developing appropriate guiding principles for human organ transplants, in collaboration with other organs and bodies. These WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation (The Principles) were developed and endorsed during the WHO 63<sup>rd</sup> Assembly in May 2010, through Resolution WHA63.22.<sup>107</sup> The Principles recognise the fact that there has been increased transplantation of human organs from deceased, as well as living, donors

---

103 Ezekiel 37:1-14, available at <https://www.biblegateway.com/passage/?search=Ezekiel%2037%3A1-14&version=NIV>. Accessed on April 2, 2023.

104 WHO, "Transplantation". Available at [https://www.who.int/health-topics/transplantation#tab=tab\\_1](https://www.who.int/health-topics/transplantation#tab=tab_1). Accessed on April 2, 2023.

105 GODT, "2021 Global Report", Available at <https://www.transplant-observatory.org/2021-global-report-5/>. Accessed on April 2, 2023

106 Fortieth World Health Assembly, Geneva May 4-15, 1987, Available at <https://www.afro.who.int/sites/default/files/2017-06/WHA40-13.pdf>. Accessed on April 2, 2023

107 See WHO, "WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation". Available at <https://apps.who.int/iris/bitstream/handle/10665/341814/WHO-HTP-EHT-CPR-2010.01-eng.pdf?sequence=1>. Accessed on April 2, 2023.

to sick and dying patients since the Second World War and that this practice has extended, and greatly enhanced the quality of, hundreds of thousands of lives.

The push and pull factors for increased transplantation were identified as advancement in medical technology, commercial trafficking in organs, growing ease in international travel and communication and the need for an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes.<sup>108</sup> There are 11 Principles and this paper will analyse them and the extent to which Kenya has implemented them. Against this background, this paper will examine the evolving paradigms in organ, tissue and cell transplantation and the extent to which Kenyan Law regulates these paradigms.

## **2.0 Tissue Banking**

In practice, any human tissue can be harvested and banked for research or clinical use. Placenta,<sup>109</sup> cord blood, penile skin, sperm, nipple areola complex,<sup>110</sup> ovarian and testicular tissue,<sup>111</sup> and blood vessels have been subjected to autologous banking recently. Human tissue banking raises a number of ethical concerns pertaining to such values as privacy, autonomy, bodily integrity, and dignity. In addition to the ethical concerns, tissue banking also raises such legal and non-legal concerns as commercialisation of the tissue by donors and those taking care of it, regulatory safeguards, informed consent and confidentiality. Commercialising banked human tissue further triggers psychological, social, religious and cultural questions with regard to the treatment of the human body. Hospitals and commercial biobanks have in the recent past been criticised for commercialising the human body.<sup>112</sup> Hence, the need for relevant legislation and regulatory frameworks on tissue banking has been raised.<sup>113</sup> None of the 11 WHO Guiding Principles provides for the means of handling banked human tissue. Instead, the Principles provide for general commercialisation of human tissue. Guiding Principle 5 cells, tissue and organs should only be donated freely, without any monetary payment or other reward for value and that purchasing of such tissue, cells and organs should be banned. Yet, the same principle states that the donor can be reimbursed the costs they incurred while recovering, processing, preserving and supplying the cells, tissues or organs for transplantation.

---

<sup>108</sup> Ibid, *Preamble*.

<sup>109</sup> Bárcena A, Muench MO, Kapidzic M, Gormley M, Goldfien GA, Fisher SJ. 'Human placenta and chorion: Potential additional sources of hematopoietic stem cells for transplantation.' *Transfusion*. 2011;51(Suppl 4):94S–105S.

<sup>110</sup> Ahmed AK, Hahn DE, Hage JJ, Bleiker EM, Woerdeman LA. 'Temporary banking of the nipple-areola complex in 97 skin-sparing mastectomies.' *PlastReconstrSurg*. 2011;127:531–9.

<sup>111</sup> Kar ME, Carrillo AJ, Jennell JL, Yalcinkaya TM. 'Robotic-assisted laparoscopic ovarian tissue transplantation.' *FertilSteril*. 2011;95:1120.e5–8.

<sup>112</sup> Nelkin D, Andrews L. 'Homo economicus: the commercialization of body tissue in the age of biotechnology.' *Hastings Cent Rep* 1998; 28:30–39.

<sup>113</sup> Bauer K, Taub S, Parsi K. 'Ethical issues in tissue banking for research: a brief review of existing organizational policies'. *Theor Med Bioeth* 2004; 25:113–142.

Guiding principle 7 states that physicians and other health professionals should not engage in transplantation if the cells, tissue or organs have been procured through exploitation, coercion or purchase. Per Guiding Principle 9, the allocation of cells, tissue and organs should follow clinical criteria and ethical norms and not financial or other considerations. Most legislations have not set this clinical or ethical criteria in place. The Kenyan Human Tissue Act<sup>114</sup> only covers the removal of tissue from bodies of deceased persons.<sup>115</sup> The Act has no provision on tissue banking. Similarly, the Public Health Act<sup>116</sup> has no provision on how to handle banked human tissue. It also contains no provisions on cell, tissue, or organ transfer. Part XI of the Health Act<sup>117</sup> is titled “Human Organs, Human Blood, Blood Products, Other Tissues and Gametes.” This Part contains no provisions on cell, tissue or organ banking. The closest the Act comes is asking the Parliament to pass a Law that establishes the Kenya National Blood Transfusion Service with the mandate of developing a comprehensive and coordinated national blood service based on voluntary non-remunerated blood donations so as to guarantee availability of adequate and safe blood.<sup>118</sup> To achieve this objective, the Kenya National Blood Transfusion Service Bill, 2020 was gazetted on March 23, 2020. Part IV of the Bill is about Management of Blood Services. Under Clause 29, the Service shall operate a National Blood Transfusion Reference Laboratory. If passed, therefore, the handling of banked human blood will be adequately regulated. This is not the case with other human cells, tissue and organs.

Over time, several issues have been raised with regard to tissue banking for clinical use and research. For example, scandals have been exposed regarding the non- consensual retention of organs from post-mortem examinations and privacy issues arising from such activities.<sup>119</sup> Further, studies have opined that where cells, tissues and organs were banked for a particular study and the study has been completed, consent should be sought from the donor or next of kin for subsequent research, unless the consent was omnibus. These issues require proper regulation.

### **3.0 Property Rights of the Cells, Tissues and Organs**

The question of property rights in donated cells, tissues and organs is a complex one, both ethically and legally. It is widely acknowledged that no person can own another person as that would be slavery and a violation of article 4 of the Universal Declaration of Human

---

<sup>114</sup> No. 34 of 1966.

<sup>115</sup> The Long Title states that it is “...An Act of Parliament to make provision with respect to the use of parts of bodies of deceased persons for therapeutic purposes and purposes of medical education and research; and for matters connected therewith and incidental thereto...”

<sup>116</sup> Cap 242, Laws of Kenya.

<sup>117</sup> No 21 of 2017.

<sup>118</sup> *Ibid*, section 85.

<sup>119</sup> See Walker B, “Inquiry into Matters Arising from the Post-mortem and Anatomical Practices of the Institute of Forensic Medicine” (New South Wales Government, 2001); and Mason K et al, “Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey” (2001) 64 (5) MLR 710.

Rights.<sup>120</sup> Even more complex is the question of a person owning their own body.<sup>121</sup> John Locke opined that “...every man has property has a property in his own person...”<sup>122</sup> Yet, Stephen Munzer has opined that “...persons do not own their bodies but [...] they do have limited property rights in them...”<sup>123</sup>

Regarding the ownership of a deceased human body, the longstanding jurisprudence has been that a corpse cannot be legally owned as possesses no property rights. In *The Haynes’ Case*, a 17<sup>th</sup> Century Court of Appeal (Lent Assize in Leicester) held that there can be no property in a corpse by stating that the property remained “...in the owners, that is, in him who had property therein, when the dead body was wrapped therewith; for the dead body is not capable of it...a dead body being but a lump of earth hath no capacity...”<sup>124</sup> This remained the position until 1908 when the High Court of Australia heard *Doodeward vs Spence*,<sup>125</sup> where Doodeward had acquired the mummified corpse of a two-headed child, which he then sought to exhibit on tour. It was seized by police on grounds that it was indecent and obscene. Doodeward sued to have it back. The Court held that Doodeward could have the corpse back, because it had been subjected to “...the lawful exercise of work or skill so...that it has acquired some attributes differentiating it from a mere corpse awaiting burial...” Therefore, since the body had been preserved in a bottle with spirit, it had ceased to be a mere corpse and the law could therefore protect it.

In the English case of *R v Kelly & Lindsay*,<sup>126</sup> where parts of a corpse had been stolen from the Royal College of Surgeons and exhibited in a London art gallery, the Queens Bench held that since Kelly had subjected the parts of the corpse to skilled work, they had acquired property rights and therefore capable of being stolen. He was convicted to serve a prison sentence of 9 months. In the more recent case of *AB and Others v Leeds Teaching Hospital NHS Trust*,<sup>127</sup> regarding the preservation of body organs, the English High Court held that the “...evidence in the lead cases shows that to dissect and fix an organ from a child’s body requires work and a great deal of skill, the more so in the case of a very small baby [...]. The subsequent production of blocks and slides is also a skilful operation requiring work and expertise of trained scientists...”

The analysis of these cases shows that the common law position is that a corpse does

---

120 United Nations. The Universal Declaration of Human Rights. New York: United Nations; 1948. [Accessed April 3, 2023]. Available from: <http://www.un.org/en/documents/udhr/>.

121 Pattinson SD. *Medical Law and Ethics*. Third Edition. London: Sweet and Maxwell; 2009. Property in human organs and tissue; pp. 516–525.

122 Locke J. The Second Treatise of Civil Government 1690 and Austin, TX: *Constitution Society*; 1998. [Accessed April 3, 2023]. Of property. Available from: <http://www.constitution.org/jl/2ndtreat.htm>.

123 Munzer S. *A Theory of Property*. New York: Cambridge University Press; 1990. p. 41.

124 Haynes, 1614, 12 Co. Rep 112.

125 1908, 6 CLR 406.

126 Q.B. 621 (1999).

127 [2004] EWHC 644.

not have property rights, but there are exceptions to this rule: If someone subjects the corpse or parts thereof to some skill or act then it can acquire property rights.<sup>128</sup> Corpses on morgues are subjected to multiple skills like embalming, mummifying, and other preparatory procedures. It is possible for the next of kin of the deceased to claim these bodies as owners.

Kenyan Law is not clear on this issue of property rights on cells, tissues, and organs. The Human Tissue Act is completely silent on the existence of rights, if any, in a corpse or any part of it. the Health Act is also silent on this issue. Courts have, however, weighed in on the question of property rights in corpses or parts of corpses. In *Mary Nyang'anyi Nyaigero & another v Karen Hospital Limited & another*,<sup>129</sup> Justice Serگون of the High Court stated that “...There is no dispute that a dead body has no property value hence it cannot be used as a collateral to secure a debt. The continued detention of a dead body will continue to attract morgue charges instead to the utter detriment of the deceased’s estate [...] Having come to the conclusion that there is no property in a dead body, therefore it doesn’t make sense for the respondents to continue detaining the deceased’s body.”<sup>130</sup> This was a matter where the Karen Hospital had held the body of the deceased as a lien to demand payment of the outstanding hospital bills. The judge was relying on *Ludindi Venant & Another v Pandya Memorial Hospital*,<sup>131</sup> where Retired Justice Philip Waki had stated that

with utmost respect to the hospital, that on any view it would be equally repugnant to public policy to sanction the use of dead bodies as objects in the game of Commercial ping pong [...] For it is trite law that there is no property in a dead body. It cannot be offered or held as security for payment of a debt. It cannot be auctioned if there is a default. It cannot be used to earn rental income in a cold-room. In sum there is no legal basis for detaining it, and it would be callous and sadistic to hold otherwise

Similarly, in *Joan Akoth Ajuang & another v Michael Owuor Osodo the Chief Ukwala Location & 3 others; Law Society of Kenya & another*,<sup>132</sup> Justice Aburili held that:

I reiterate that Kenyan Law does not guarantee specific rights to the dead but provides for the protection of the dignity of every person. However, Article 28 of the Constitution provides that every person has inherent dignity and the right to have that dignity respected and protected. Whereas there are no proprietary rights in a dead body, one does not cease being a human once dead, only the state of life is altered.<sup>133</sup>

Several other courts have held a similar position. For example, courts have held that “...

---

<sup>128</sup> Hakimian R, Korn D. ‘Ownership and use of tissue specimens for research’. *JAMA*. 2004;292(20):2500–2505.

<sup>129</sup> [2016] eKLR.

<sup>130</sup> Ibid, at Para 14 and 15.

<sup>131</sup> [1998] eKLR.

<sup>132</sup> [2020] eKLR.

<sup>133</sup> Ibid, at Para 173.



wishes or a will on how the deceased's remains will be disposed of upon death are not, as a general rule binding because, in the first place, there is no property in a dead body and secondly, because a dead person cannot take part in the decision of his or her own burial",<sup>134</sup> and that "there is no property in a corpse which a testator can validly dispose of by his will, the executor's obligation is to give effect to the deceased wishes in relation to the disposition of his corpse as far as practicable. The executor is not bound to give effect to those wishes or in conflict with the personal law of the deceased."<sup>135</sup> There is clearly an urgent need to clarify, through statute law, whether donors retain property rights in the cells, tissues, or organs that they donate to those in need, whether they are alive or not.

With regard to cells, tissue and organs donated by persons who are still alive, courts across the globe have held that donors retain no property rights in those cells, tissues or organs. In the landmark case of *Moore v. Regents of the University of California*,<sup>136</sup> John Moore sought treatment for hairy-cell leukaemia and was attended to by Dr David Golde of the University of California. The physician recommended that Moore's spleen be removed for therapeutic purposes. Golde and fellow researcher Shirley Quan decided to use Moore's spleen tissue for further scientific study because they considered it to be of "...great value in a number of commercial and scientific efforts..."<sup>137</sup> They never disclosed this intention to Moore. After several years of research, during which they required Moore to travel to California for 'further tests' when in fact they were drawing more samples for further research, they succeeded in developing a cell line from Moore's t-lymphocytes for which they obtained a patent worth an estimated USD 3 Billion. Moore sought to recover a share of these proceeds, but the Supreme Court of California held that the cell line was a product of invention, and not the donor. Therefore, the court held that "the court held that individuals do not have an ownership interest in their cells after the cells are removed from their bodies."<sup>138</sup> However, the court recognised the existence of a duty imposed on physicians to disclose any interests, commercial or otherwise, that they might have with human tissue, cells and organs.

Subsequent courts in the US have held a similar position. For example, in *Greenberg v. Miami Children's Hospital Research Institute*,<sup>139</sup> the Greenberg family had donated blood and tissue samples to Dr. Rueben Matalon and the Miami Children's Hospital Research Institute for use in developing a prenatal genetic test in the study of Canavan disease, a rare and fatal genetic disease that occurs most frequently in Ashkenazi Jewish

<sup>134</sup> *SAN v GW* [2020] eKLR.

<sup>135</sup> Kwach J. in *Pauline Ndeti Kinyota Maingi vs Rael Kinyota Maingi* Nairobi CACA No. 66 of 1984.

<sup>136</sup> 51 Cal. 3d 120; 271 Cal. Rptr. 146.

<sup>137</sup> Gitter DM. 'Ownership of human tissue: a proposal for federal recognition of human research participants' property rights in their biological material.' Wash Lee Law Rev. 2004;61(1):257-345. See also Hakimian R, Korn D. 'Ownership and use of tissue specimens for research.' JAMA. 2004;292(20):2500-2505.

<sup>138</sup> Ibid.

<sup>139</sup> 264 F. Supp. 2d 1064.

families. The physician and the school secured a patent for which annual royalties reached an estimated \$375,000. The Court recognised that medical researchers have a duty to informed consent, but declared to extend his duty to disclosure of economic interests as this would have a pernicious effect on medical research, in that “it would give each donor complete control over how medical research is used and who benefits from that research.” The Eighth Circuit Court of Appeals stated the same position in *Washington University v. Catalona*,<sup>140</sup> where a physician William Catalona, collected over 30,000 tissue samples during the treatment of prostate cancer while working for Washington University. When he decided to leave Washington University to join North-western University, he asked the patients to allow him to transfer the samples to his new station but Washington University declined. In a suit that ensued, the Court held that the patients had no ownership rights to the samples and therefore had no power to authorise Catalona to transfer them to his new location.

The above cases demonstrate that whereas donors have a right to decide whether to donate their cells, tissue, or organs, that right vanishes after the donation. They do not retain any ownership rights to those cells, tissue, or organs. However, any commercial interests must be disclosed to the potential donor. The potential donor will then make an informed decision on whether to donate or not because once they donate, any benefits accruing from the donation are beyond his/her control.

#### **4.0 Organ Trafficking and Transplant Tourism**

Demand for organs, tissues and cells is outpacing the supply, and transplantation is gradually falling victim of its own success. This has eventually led patients to source for the organs, cells and tissues illegally and outside the established legal and policy frameworks. The increased demand for these human parts has led to increased prices, and, to fill in the gap that the altruistic and regulated market has left, a black market has been developed, with a view to generating profits through illegal means. There is evidence to the effect that due to poverty, people are offering their organs, tissue and cells for sale in international markets. Criminal networks have continued to exploit the most vulnerable populations, particularly migrants, because of the absence of comprehensive regulatory frameworks. Studies have shown this this illegal black market generates approximately USD 1.5 billion every year. For example, in 2017, it was reported that organ trafficking was prevalent in Lebanon, with Syrian refugees engaging in this trade to sustain themselves together with their families.<sup>141</sup>

---

<sup>140</sup> 490 F3d 667 (8th Cir 2007).

<sup>141</sup> Magdalena Mis, (2017), “Organ trafficking ‘booming’ in Lebanon as desperate Syrians sell kidneys, eyes: BBC”, Reuters. Available at <https://www.reuters.com/article/us-mideast-crisis-syria-trafficking/organ-trafficking-booming-in-lebanon-as-desperate-syrians-sell-kidneys-eyes-bbc-idUSKBN17S1V8>, accessed on April 7, 2023.



In 2018, the International Labour Organisation reported that an approximated 40 million people had fallen victim to organ trafficking, most of which cases were a result of forced labour, illegal migration practises, and sexual exploitation.<sup>142</sup> The Global Observatory on Donation and Transplantation estimates that 12,000 organs are illegally trafficked annually.<sup>143</sup> Migrants are the most vulnerable, and they can be attacked while enroute to their host destinations or while in refuge in those destinations. Most of them are victims of war or are immigrants in search of greener pastures.<sup>144</sup> This black market for organ trafficking is complete with medical tourism bureaus domiciled in large cities across the world, organ hunters, and rogue surgeons, although some legitimate surgeons may also be misled to perform the operation by the parties who misrepresent themselves as legitimate donors and recipients.<sup>145</sup> The most popular destinations are in Asian countries such as Philippines, China, Pakistan, and India. Recipients tend to be from developed economies like the United States of America, Australia, Japan, and Saudi Arabia.

Transplant tourism raises several ethical issues. First, it leads to exploitation of the vulnerable members of the population. Most of these people are those languishing in poverty. Others are victims of political violence in search of refuge in developed countries, while others are victims of negligent medication where their attending medical personnel end up removing their organs without their consent.<sup>146</sup> Transplant tourism is also a violation of the transplantation principles that the human body should not be commodified. Donors are also likely to suffer post-donation effects, especially where inadequate immunosuppression and antimicrobial prophylaxis was not undertaken during the surgery.<sup>147</sup> This poses an additional burden on medical resources as this becomes a new victim of medication, yet they were healthy before the donation.

Against this background, the Declaration of Istanbul on Organ Trafficking and Transplant Tourism<sup>148</sup> was passed in 2008. The Declaration recognises that the prevailing

---

142 United Nations Office on Drugs and Crime (2018), *Global Report on Trafficking in Persons, 2018*, available at [https://www.unodc.org/documents/data-and-analysis/glotip/2018/GLOTiP\\_2018\\_BOOK\\_web\\_small.pdf](https://www.unodc.org/documents/data-and-analysis/glotip/2018/GLOTiP_2018_BOOK_web_small.pdf), accessed on April 7, 2023. See also Broumand B., Saidi R.F. 'New definition of transplant tourism.' *Int. J. Organ Transplant. Med.* 2017; 8:49.

143 Global Observatory on Donation and Transplantation . 'Organ Donation and Transplantation Activities 2014.' Organización Nacional de Trasplantes; Madrid: 2016. [accessed on April 7, 2023]. Available online: <http://www.transplant-observatory.org/data-reports-2014/>.

144 Forsyth A. Meeting an Organ Trafficker Who Preys on Syrian Refugees. Available at <https://www.bbc.com/news/magazine-39272511>, accessed on April 7, 2023.

145 Odedra A, Green ST, Bazaz R. 'United Kingdom and Republic of Ireland renal physicians' experiences of patients undergoing renal transplants abroad: a questionnaire-based cross-sectional survey.' *Travel Med Infect Dis.* 2014;12(6 Pt B):702-706. doi: 10.1016/j.tmaid.2014.04.002.

146 Cohen IG. 'Transplant tourism: the ethics and regulation of international markets for organs'. *J Law Med Ethics.* 2013;41(1):269-285. doi:10.1111/jlme.12018.

147 Gerard Thomas Flaherty; Nizrull Nasir; Conor M. Gormley; and Suyash Pandey, (2021), 'Transplant Tourism and Organ Trafficking: Current Practices, Controversies and Solutions', *Int J Travel Med Glob Health.* 2021 Sep;9(3):102-106.

148 Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 1008. Available at [https://www.declarationofistanbul.org/images/documents/doi\\_2008\\_Arabic-English.pdf](https://www.declarationofistanbul.org/images/documents/doi_2008_Arabic-English.pdf), accessed on April 7, 2023.

unethical practices on transplant tourism are a consequence of global shortage of organs transplantation and therefore calls upon participating nations to ensure that there are sound programs and practices to prevent organ failure among their populations. Thus, individual countries must implement sound practices for the screening, prevention and treatment of organ failure. It also recognises that deceased people organs have a therapeutic potential and such donations should be promoted to minimise the burden that living donors have. Most importantly, the Declaration recognises that ‘organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should be prohibited.’<sup>149</sup> Therefore, all forms of advertising, soliciting, or brokering for the purpose of transplant commercialism, organ trafficking, or transplant tourism should be banned by individual countries. Countries should also impose penalties for such acts as medically screening donors or organs, or transplanting organs that aid, encourage, or use the products of, organ trafficking or transplant tourism.

Kenya has not responded to this Declaration through legislative frameworks. The Human Tissue Act is not responsive to these emerging issues as it predates the Declaration. Section 80(1) of the Health Act states that “No person shall remove tissue or gametes from a human being for transplantation in another human being or carry out the transplantation of such tissue or gametes except in a duly authorised health facility, and on the written authority of the medical practitioner or the person from whom the tissue or gametes are removed, in the prescribed manner.” The medical practitioner mentioned above shall not be the lead participant in a transplant for which he or she has granted authorization under that subsection. This is meant to curb unethical practices where the medical practitioner could have colluded with participants in the black market to authorise organ transplant.

The closest Kenyan Law comes to outlawing organ trafficking and transplant tourism is through the Counter-Trafficking in Persons Act.<sup>150</sup> Section 9 of this Act states that where, in the course of trafficking persons under the Act, a suffers any permanent or life-threatening bodily harm or dies, the offender shall be liable to imprisonment for life. Under section 10, persons who engage in human trafficking for organised crime shall also be liable for imprisonment for life. Organ trafficking is both unethical and a crime. Persons engaged in this act can be prosecuted under this Act.

## **5.0 Xenotransplantation and Related Ethical and Legal Concerns**

Due to the continued shortage in supply of organs, tissues, and cells to meet the growing demand, researchers are exploring the potential to get these organs from non-human primates. While this may potentially be the solution to the prevailing problem of shortage

---

<sup>149</sup> See article 6, *ibid*.

<sup>150</sup> Cap 61, Laws of Kenya (Now No 8 of 2010).

of supply of these organs, there is the potential risk of triggering increased zoonotic infections.<sup>151</sup> The pig, for example, has been considered as a potential donor. Preliminary empirical studies have established a close anatomical and physiological compatibility with humans. Pigs also reproduce rapidly, so it would be easy to replace them.<sup>152</sup> The risk of triggering increased zoonotic infection has triggered further research on preventing and mitigating immune rejection and therefore inducing tolerance to the xenograft and reducing the need for relying on immunosuppression in the long term.

Xenotransplantation raises various legal and ethical questions. The ethical question on xenotransplantation is three-pronged: the emotional, the deontological and consequentialism.<sup>153</sup> On the emotional front, people think that getting tissue from pigs means crossing the moral boundary. Proponents of xenotransplantation feel that it is better to get those tissues, organs and cells from these animals to save the life of a person who is facing death due to organ failure.<sup>154</sup> Whereas emotional debates are not anchored on academic thinking or empirical findings, they are decisive.<sup>155</sup>

The consequentialist debate is about the results of xenotransplantation. Consequentialists seek to maximise the benefits of an action and minimise the harm the action is likely to cause. For example, there is a risk of death for a patient who does not get the xenograft, especially if the human equivalent is also not available. Hence, getting the xenograft is a benefit to this person. On the other hand, the transplantation may fail, and the patient may contract a zoonotic disease in the process. For example, the results for initial renal allografts were very poor.<sup>156</sup> Similarly, results for initial kidney allografts were also very poor.<sup>157</sup> But the consequentialist can argue that this was justified as it paved the way for modern xenotransplantation.

The deontological debate is about the authority in rules or guidelines. The question is: what authority does the body that is the source of the rules or guidelines have? Suppose there are guidelines and/or rules on xenotransplantation, what authority does the developer of these rules and/or guidelines have?<sup>158</sup> Can any body develop satisfactory rules on getting

---

151 Siems C, Huddleston S, John R. 'A brief history of xenotransplantation.' *Ann Thorac Surg* 2022; 113: 706–710. See also George AJT, Lechler RI. 'Xenotransplantation: will pigs fly?' In: Polak JM, Hench LL, Kemp P (eds). *Future strategies for tissue and organ replacement*. London: Imperial College Press, 2002, pp. 215–236

152 Bayliss G. Practical ethical concerns in allocation of pig kidneys to humans. *Clin Kidney J* 2022; sfac125. See also Sachs DH, Galli C. Genetic manipulation in pigs. *Curr Opin Organ Transpl* 2009; 14: 148–153 and Cooper DK, Ekser B, Ramsoondar J, et al. The role of genetically engineered pigs in xenotransplantation research. *J Pathol* 2016; 238: 288–299.

153 Jorqui-Azofra M. 'Regulation of clinical xenotransplantation: A reappraisal of the legal, ethical, and social aspects involved.' *Methods Mol Biol* 2020; 2110: 315–358.

154 Hurst DJ, Padilla LA, Cooper DKC, et al. Scientific and psychosocial ethical considerations for initial clinical trials of kidney xenotransplantation. *Xenotransplantation* 2022; 29: e12722.

155 Rachels J, Rachels S. *The elements of moral philosophy*. 5 ed. New York: McGraw-Hill, 2007.

156 Brent L. *A history of transplant immunology*. San Diego: Academic Press, 1997.

157 Tilney NL. *Transplant. From myth to reality*. New Haven: Yale University Press, 2003.

158 O'Neill O. A simplified account of Kant's ethics. In: Cahn SM (ed). *Exploring ethics: An introductory anthology*. Oxford: Oxford University Press, 2009, pp. 411–415.

organs from non-human primates? And how authoritative is that body and the rules that they will have developed? One solution to settling this debate is establishing principles.<sup>159</sup> The World Health Organisation and related organs are yet to develop guiding principles on xenotransplantation. The two Kenyan pieces of legislation relating to organ, tissue and cell transplant are also silent on xenotransplantation. The scientific community in the country has also remained docile on these issues and is most likely monitoring global trends to take a position.

## **6.0 Conclusion**

Human organ, tissue and cell transplantation raises several ethical and legal issues that Kenyan Law and by extension global law is yet to address. Kenyan Law is silent on such questions as property rights of the donor, tissue banking, organ trafficking, and xenotransplantation. Any continued silence would mean that law-making organs are not alive to these emerging paradigms on regulation of human organ, tissue, and cell transplantation. The most relevant statute, the Human Tissue Act, is not outdated and, even if it was not outdated, only covers deceased donors. The Health Act adds very little regulation on this area and is silent on the emerging paradigms that this paper has raised. It is high time that the Human Tissue Transfer Act is repealed and replaced with a statute to be referred to as the Human Organ, Tissue and Cell Transfer Act. The new Act should address the emerging trends that this paper has raised.

---

159 Beauchamp TL, Childress JF. Principles of biomedical ethics. 4th ed. Oxford: Oxford University Press, 1994.