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Assessing the Legal Framework for Consent in Human Organ Donation and Transplantation in England (U.K.): Lessons for Nigeria

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Abstract

Organ donation and transplantation has become one of the most crucial development in the field of Medicine, saving lives as well as improving the quality of life of many patients.[1] Organ donation and transplantation is removing an organ from one person ie the donor and surgically placing it on another ie the recipient, whose organ has failed. Organs that can be donated are: kidneys, heart, liver, pancreas, intestines, lungs, bones marrow, skin and cornea.[2] It must be noted that a person's organ(s) cannot or should not be harvested without his consent or the consent of a close relation in case of a deceased donor. This research work delved into the legal framework for donor's consent to organ donation and transplantation in the England and how Nigeria can learn from the English legal framework for consent. The doctrinal method of research was employed which entails the use of laws, text books, journals, dictionaries, newspaper publications and other secondary sources. The work found that the legal framework for consent to organ donation in England is comprehensive and efficient. It is recommended that Nigeria should follow suit by amending the National Health Act[3].

Keywords: *consent, England, human organ, Nigeria, organ donation, transplantation*

1. Introduction

Organ donation and transplantation is an applaudable scientific innovation. Even though the donation of organs is commendable, obtaining the consent of the organ donor or his relative in case of a minor or a dead donor, is very crucial to transplant medicine, otherwise the procedure will be marred by illegality. The legality or otherwise of the mode of consent obtained prior to organ donation and transplantation will go a long way in determining whether the harvesting of a donor's organ(s) is actionable or not. Many western countries including the United Kingdom have established legal framework on consent to organ donation and transplantation. In England, the Human Tissue Act[4] and the Organ Donation (Deemed Consent) Act are the major legislations that provides for consent as a condition precedent to organ donation. While the Human Tissue Act tends to support informed consent, the Organ Donation (Deemed Consent) Act tilts to the side of presumed or deemed consent. In Nigeria, the National Health Act generally provides for a legal framework for the regulation development and management of a national health system and set standards for rendering health services in Nigeria. Part VI of the National Health Act also provides for the control of use of blood, blood products, tissue and gametes in humans, but made a blanket

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[1] A.A. Bakari et al, Organ Transplantation: Legal, Ethical and Islamic Perspective in Nigeria. (Niger Journal of surgery, July 2012)

[2] https://www.my.clevelandclinic.org/health/articles/11750-organ-donation-and-transplantation last accessed on 18/04/2023

[3] Act No. 8 of 2014

[4] 2004

provision for consent to organ donation and at the same time sabotaged the said provision by creating a very porous exception to that rule.

2. Definition of 'Consent', 'Human Organ', 'Organ Donation' and 'Transplantation'

It is pertinent to clarify relevant key terms used in this research work such as consent, human organ and transplantation.

"Consent" implies agreement or acquiescence.[5] Consent in medical parlance means that a person must give permission before they receive any type of medical treatment or intervention, test or examination. This must be done on the basis of an explanation by a clinician. Consent from a patient is required notwithstanding the nature of the procedure to be performed. The three ingredients for a valid consent are: it must be voluntary, informed and the person consenting must have mental capacity to do so.[6]

According to the Medical Dictionary, consent means a voluntary agreement with an action proposed by another. Consent is an act of reason, the person giving consent must be of sufficient mental capacity and be in possession of all essential information in order to give valid consent. A person who is an infant, is mentally incompetent, or is under the influence of drugs is incapable of giving consent. Consent must also be free from coercion, fraud and financial enticement.

According to Gillon,[7] 'Consent means a voluntary uncoerced decision, made by a sufficiently competent or autonomous person on the basis of adequate information and deliberation, to accept rather than reject some proper course of action that will affect him or her'. It can be gleaned from the foregoing that consent to organ donation entails explaining to the donor the pros and cons of organ donation and getting the approval of the said donor before embarking on organ harvest, otherwise the procedure will ultimately amount to the tort of assault and battery.

Human Organ is defined as a self-contained group of tissues that performs a specific function in the body. The heart, liver and stomach are examples of organs in humans. The word organ comes from the latin word *organum*, which means 'instrument'. This in turn comes from the Greek word *opyavov* (*organon*), which refers to a musical instrument or 'organ of the body'.[8]

Organ Donation is the donation or giving of biological tissue or an organ of the human body, from a living or dead person to a living recipient in need of a transplantation. Transplantable organs and Tissues are removed in a surgical procedure following a determination based on the donor's medical history, of which are suitable for transplantation. Allotransplantations is the transfer of organ(s) from one human being to another, while xenotransplantations is the transfer of animal organs into human bodies.[9]

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[5] S.I. Salihu, Transplantation of Human Organ: The Need for Right to Consent and the Nigerian National Health Act 2014. https://www.researchgate.net/publication/320347066_%27Transplantation_of_Human_organ_in_Nigerian_A_critique_of_National_Health_Act_2014_on_Donor/ Accessed on 30/4/2023

[6] www.nhs.uk>conditions>consent-to-treatment. Accessed on 30/4/2023

[7] Yinka Olomojobi. Medical & Health Law: The Right to Health. P. 173. Princeton & Associates Publishing Co. Ltd, Ikeja Lagos: Gillon, Philosophical Medical Ethics, P113

[8] Biology Dictionary. https://biologydictionary.net>organ accessed on 30/4/2023

[9] https://www.bc.edu>research_sites>cpi>pdfaccessed on 30/4/2023

Transplantation involves the transfer of cells, tissues, or solid organs from one human to another, to replace the structure or function of comparable injured or diseased body components that are defective or of inadequate function. Organs can be harvested from deceased or living persons.[10]

3. Types of Consent

The right to self-determination is embedded in the principle of autonomy, such that any invasion of the human body without prior consent is both tortious and criminal in nature. It then follows that any medical personnel who touches a patient without consent can be held liable in the tort of battery and also in the criminal offence of assault. In **Schloendorff v. Society of New York Hospital**,[11]**Cardozo J** held thus:

> *Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without the patient's consent commits an assault.*[12]

There are two types of consent recognisable in medical law, viz: presumed consent and informed consent.

3.1 Informed Consent

According to Faden and Beauchamp[13], informed consent is an autonomous action by a subject or a patient that authorises a professional either to involve the patient in research or to initiate a medical plan for the patient or both. For consent to be said to be informed, it means that a patient or even an organ donor have been told the benefits and risks of the procedure and the patient have the mental capacity to comprehend the information and make rational decisions and thereafter give a voluntary consent which is devoid of threat of punishment or any form of coercion or reward.

Exceptions to informed consent include the case of an incapacitated patient, life threatening emergency with inadequate time to obtain consent and where the patient voluntarily waives his right to give consent.[14] These exceptions usually comes in as defences in the face of a legal battle.

It is worthy of note that English courts have in some cases, given approval for the donation of organ by persons who lack mental capacity to give an informed consent to organ donation, this happened in ***Re-Y (Adult Patient) Transplant; Bone Marrow***.[15]

It must be noted that the English legal framework for informed consent is the Human Tissue Act.[16] Under the HTAct, informed consent is the fundamental principle for the donation of human organs, tissue and materials for transplant. Also, it is illegal under the HTAct to use an organ donated for the purpose of transplantation, for research or any other purpose.

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[10] T.L. Beauchamp et al, Contemporary Issues in Bioethics P 424 8th edition, (Wadsworth Cengage learning publishers USA).

[11] 105 NE.92 (NY, 1914)

[12] G.T. Laurie et al, eds, Law and Medical Ethics P. 65, Eleventh Ed (Oxford University Press UK 2018): Yinka Olomojobi. Medical & Health Law: The Right to Health. P. 173. (Princeton & Associates Publishing Co. Ltd, Ikeja Lagos, 2019)

[13] T.L. Beauchamp et al, P 79.

[14] P. Shah et al, Informed Consent. Article is available at www.ncbi.nlm.nih.gov/books/NBKL430827/. accessed on 4th May 2023

[15] (1997) Fam 110 (as cited by J. Herring op cite)

[16] Otherwise known as HTAct 2004

Noteworthy is the fact that the doctrine of self-autonomy is the underlying justification for the requirement of informed consent prior to medical interventions. In the English case of **Chester v Afshar**[17] the House of Lords stated that the right to self-autonomy with respect to choosing treatment is part of modern medicine. The situation is usually complex where a patient cannot make an informed consent by reason of unconsciousness, it is in such circumstance that the doctrine of necessity comes to play.

Furthermore, it is axiomatic that consent is directly interwoven with the human right of dignity of the person and self-determination. These principles of human dignity, respect and self-determination was further enunciated in the case of **Airedale NHS Trust v Bland,**[18]wherein **lord Goff** held thus:

> *"principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult of sound mind refuses, however unreasonable, to consent to treatment or care by which his life might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it be in his best interest to do so"*[19]

This research work agrees with the view of Prof Jonathan Herring,[20] that an organ donor have full legal right to dictate how the donated organ should be used. It is pertinent to mention that an organ donor must be informed of the exact nature of the procedure to be performed on him or her while removing the organ and the attendant consequences thereof.

3.2 Presumed or Deemed Consent

Presumed or deemed consent is a legislative framework that requires citizens of the England to place their names on a national 'opt out' register if the citizen do not wish to be an organ donor upon demise. Deemed consent is also known as 'opt out' system and means that unless a deceased person had expressed a wish in life not to be an organ donor, then consent will be assumed. Organ harvesting can be done with or without consulting the family members of the deceased.[21] In other words, all adults in England are now considered to have agreed to be an organ donor once they die unless they recorded a decision not to donate or are in one of the excluded groups. The presumed consent is provided for in the Organ Donation (Deemed Consent) Act.[22] In the event that a person living in England neglects to put his name in the national health service register on organ donation or make a will stipulating his intention not to donate his organ(s) upon death, then such silence is termed an acquiescence or 'opt in' by the law.

Albeit, there are a few exceptions to the principle of presumed consent viz:

(a) If the deceased person is under the age of eighteen (18), then presumed consent will not apply.

[17] (2004)UKHL 4
[18](1993) 1 ALL ER 821
[19]Y. Olomojobi P. 177 op cit.
[20]Op cit
[21]https://www.rcpjournals.org>content.clinmedicine accessed on 4th May 2023
[22]2019

(b) The deceased person lacked the capacity to give consent for a sufficient long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed.[23]

(c) If the deceased person had not been resident in England for a period of at least twelve months immediately before dying as to have known the legal regime or related his wishes to his relatives with regard to organ donation.

(d) Section 27(4) of the Organ Donation (Deemed Consent) Act[24] provides an exception to the general rule of presumed consent, if a person in a qualifying relationship to the deceased person can show that immediately before death, the deceased would not have consented to organ donation, such information must be such that a reasonable person can believe same. According to section 27(4) of the Act,[25] persons in a qualifying relation with a deceased person are: Spouse or Partner, parent or child, brother or sister, grandparent or grandchild, child of a person falling under paragraph (c) stepfather or stepmother, half-brother or half-sister and friend of longstanding.[26]

4. Legal Framework for Consent to Organ Donation in England

It must be born in mind that human organs can be harvested from both the living and the dead or cadaver. A living donor is an individual who donates his organ for transplant into the body of another person whose organ(s) is no longer functioning properly. Living kidney donation is the most rampant of living organ transplant. Living organ donors have been categorized into adult donor, child donor and persons lacking capacity. Different legal considerations apply to the child donor and persons lacking capacity.

In England, statutory regulation of consent preceding organ donation and transplantation is governed by the Human Tissue Act[27], The Human Tissue (Scotland) Act[28] and the Mental Capacity Act[29]. The institution that controls organ donation and the attendant issue of consent is the Human Tissue Authority which is a creation of the Human Tissue Act.[30] The HTAct[31] also provides for sanctions where a live organ donation is carried out without consent, thus:

Section 33(1) Subject to Subsections (3) and (5), a person commits an offence if-

a) He removes any transplantable material from the body of a living person intending that the material be used for the purpose of transplantation, and

b) When he removes the material, he knows or reasonably be expected to know that the person from whose body he removes the material is alive.

(2) Subject to subsections (3) and (5) a person commits an offence if-

[23]Human Tissue Act 2004, Section 3 (10)
[24]2019
[25]*Ibid*
[26]J. Herring op cite
[27] HTAct 2004
[28]2006
[29]2005
[30]The Human Tissue Authority was created under part 2 of the Human Tissue Act 2004.
[31]Section 33

(a) he uses for the purpose of transplantation any transplantable material which has come from the body of a living person, and

(b) when he does so, he knows, or might reasonably be expected to know, that the transplantable material has come from the body of a living person.

(3) The secretary of state may by regulations provide that subsections (1) or (2) shall not apply in a case where-

(a) the authority is satisfied-

(i) that no reward has been or is to be given in contravention of section 32, and

(ii) that such other conditions as are specified in the regulation are complied with.

(4) Regulations under subsection (3) shall include provisions for decision of the authority in relation to matters which fall to be decided by it under the regulations to be subject, in such circumstances as the regulation may provide, to reconsideration in accordance with such procedure as the regulations may provide.

(5) where under subsection (3) an exception from subsection (1) or (2) is in force, a person does not commit an offence under that subsection if he reasonably believes that the exception applies.

(6) A person guilty of an offence under this section is liable on summary conviction

(a) to imprisonment for a term not exceeding 51 weeks, or

(b) to a fine not exceeding level 5 on the standard scale, or

(c) to both[32]

Noteworthy is the fact that transplantable materials is defined as 'an organ or part of an organ if it is to be used for the same purpose as the entire organ in the human body, bone marrow and peripheral blood stem cells, where that material is removed from the body of a living person with the intention that it be transplanted into another person'[33]

On the other hand, the statutory framework for the donation of organs by deceased persons is the Organ Donation (Deemed consent) Act[34] which is also referred to as Max and Keira's Law. Under the Organ Donation (Deemed Consent) Act, all individuals living in England and Wales who are 18 years old and above are deemed potential organ and tissue donors after death, unless they:

a) Make a decision that they do not want to be a donor

b) Have appointed a representative to make a decision on their behalf after death.

a) Are an excepted adult. An excepted adult is a person who had not been ordinarily resident in the United Kingdom for a period of at least 12 months immediately before their death

[32]Available at Legislation.gov.uk. accessed on 4th May 2023

[33]This definition of transplantable material was given by the Secretary of State to the government of the United Kingdom at Regulation 10 of Statutory Instruments 2006 No 1659. The Human Tissue Act 2004 (persons who lack capacity to consent and transplant) Regulations 2006. Available at www.legislation.gov.uk. Accessed on 4th May 2023

[34]2019

> or a person who lacks the capacity to understand the concept of deemed consent for a significant period before their demise.[35]

It is pertinent to note that any person who had expressed consent to donate his/her organ(s) upon demise, either verbally or in writing, cannot have their consent deemed. The deemed consent law is applicable to organs and materials used for transplantation, such as hearts, lungs, kidneys and eyes.[36] It does not apply to novel transplants, such as face, hand, limbs or uterus.[37]

4.1. Legal Considerations for the Child Donor

Undeniably, most cases of organ or tissue donation are usually not medically beneficial to the child donor, especially where the donated tissue is not regenerative in nature. According to section 1 of the Family Law Reform Act,[38] a child is any person under the age of (18) eighteen. At section 8 of the Family Law Reform Act, it provides that a child age 16 or 17 can validly consent to treatment and the consent will be seen as same with that of an adult. Generally, persons under the age of 18 are not competent to give consent to organ donation unless the court declares the child donor competent to give such consent. The courts in the United Kingdom have termed such declaration of competence of a child as '*Gillick Competence*'. The term *Gillick competence* was gleaned from the case of **GILLICK V. WEST NORFOLK & WISBECK AREA HEALTH AUTHORITY.**[39] The facts of the Gillick case is that a mother with five daughters under the age of 16 sought a declaration that it would be unlawful for a doctor to prescribe contraceptives to girls under 16 without the knowledge or consent of the parents. The court held thus:

> *"I am not disposed to hold now, for the first time, that a girl age less than 16 lacks the power to give valid consent to contraceptive advice or treatment merely on account of her age."*

The court's decision in Gillick's case thus interfered with parental authority, control, rights and duties, over their children who are below the age of eighteen. What this portends is that once the court declares a child "Gillick Competent", then, the child can validly give consent to have his organ harvested for transplantation. For a child to be declared Gillick competent, the court will be convinced that the child is mature to:

i. Understand the nature and implications of the decision.
ii. Comprehend the outcome of not pursuing the decision;
iii. Retain the information for a long time so as to arrive at a conclusion on whether to proceed with the procedure or not;
iv. Weigh up the information and arrive at a decision
v. Communicate his choice or decision.[40]

Furthermore, the aforementioned case birthed the usage of the notion of 'mature minor', but it is still debatable that a minor cannot legally consent to organ donation. It must be noted that in some

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[35]D.P.T Price, Legal Framework Governing Deceased Organ Donation in the U.K. (British Journal of Anaesthesia 108 (Si): i68-i72 (2012) Available at www.bjanaesthesia.org/article/s0007-0912(17)32168-2/.pdf accessed on 11th May 2023

[36]J. Herring P.501 op cit

[37]https://nhsbtdbe.blob.core.windows.net>donationspdf accessed on 11th May 2023

[38] 1969

[39](1985)3 ALL ER 402 or (1986) AC 112 HL

[40]J. Herring op cit

cases, the courts considers the donation of an organ by a minor to be in the public interest and also in the interest of the minor donor who may be a sibling to the recipient. In such cases, it is considered that it is in the interest of the child donor that a member of her family be saved. This legal reasoning was brought to the fore in **Strunk v. Strunk**.[41] In Strunk's case, the donor, who was an adult had a mental age of a six year old, was chosen by his family to donate a kidney to his sick brother. The court held that it would be in the donor's interest for his brother's life to be saved. The surgery was allowed even though the donor was not in a position to give consent.

4.2. Legal Considerations for Donors Lacking Capacity

The English statutory framework for consent to organ donation of an incapacitated person is the Mental Capacity Act[42] and the Human Tissue Act[43]. An incapacitated person have been defined under the MCA[44] as a person lacking capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to a matter because of an impairment of or a disturbance in the functioning of, the mind or brain.

Section 3(1) of the MCA provides thus 'For the purpose of section 2, a person is unable to make a decision for himself if he is unable; (a) to understand the information relevant to the decision, or (b) to retain that information, (c) to use or weigh that information as part of the process of making the decision, or (d) to communicate his decision (whether by talking, using sign language or any other means).'

An incapacitated donor can make a decision to donate by making an advance decision before the incapacitation,[45] by donating a power of attorney to another person who then makes decisions on his behalf,[46] and an application can be made to the court in respect of the incapacitated donor. When an application with regard to organ donation by an incapacitated person is brought before the court, the court usually takes a decision in line with section 1(5) of the MCA. Section 1(5) of the MCA provides thus: 'An act done or a decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interest'

The aforementioned principle was followed in **Re Y (Adult patient) Transplant: Bone Marrow,**[47] Y, a female, aged 25 suffered mental and physical impairment, she resided in a community home, but was regularly visited by her mother, Y's sister suffered from a bone marrow disorder and her only chance of survival was a bone marrow donation. Y was declared a suitable donor by medical professionals but lacked the mental acumen to give consent to the donation of her bone marrow. Y's sister sought a declaration authorizing the harvest of Y's bone marrow. The court granted the declaration. The sound reasoning behind the judgment is that by making the donation to her sister, it would benefit Y's mother, who was very vital to Y's wellbeing. Y's mother was not in good health, partly due to anxiety over Y's sister's health. The evidence before the court showed that if Y's sister were to die, it would be fatal to Y's mother. Because of the foregoing evidence before the court, the declaratory order was made authorizing the donation of Y's bone

[41] 445 SW 2d 145 (Ky, 1969): https://www.quimbee.com accessed on 18th May 2023
[42] The MCA 2005
[43]known as the HTAct 2004
[44]Section 2(1) of the MCA 2005
[45]Pursuant to section 24 of the Mental Capacity Act 2005
[46]Pursuant to section 9 of the Mental Capacity Act 2005
[47]Supra

marrow for transplant, even though Y lacked the mental competence to have given an informed consent.

5. The Nigerian Perspective On Consent To Organ Donation And Lessons

The legislative framework that governs consent to organ donation in Nigeria is the National Health Act[48]. The National Health Act at section 48 provided thus:

Section 48(1) Subject to the provision of section 53, a person shall not remove tissue, blood or blood product from the body of another living person for any purpose except;

a) With the informed consent of the person from whom the tissue, blood or blood product is removed granted in prescribed manner;

b) That the consent clause may be waived for medical investigations and treatment in emergency cases, and

c) In accordance with prescribed protocols by the appropriate authority.

(2) A person shall not remove tissue which is not replaceable by natural processes from a person younger than eighteen years.

(3) A person who contravenes the provisions of this section or fails to comply therewith is guilty of an offence and liable on conviction as follows:

(a) in the case of tissue, a fine of ₦1,000,000 or imprisonment of not less than two years or both fine and imprisonment; and

(b) in the case of blood or blood products, a fine of ₦1,000,000 or imprisonment for a term not exceeding one year or both fine and imprisonment.

Even though section 48 (1) (a) of the National Health Act provides for obtaining donor's consent prior to organ donation but the same law swiftly made a somersault and provided at section 48 (1) (b) thus 'that the consent clause may be waived for medical investigations and treatment in emergency cases'. This provision of the Act indeed created a lacuna as that section can be exploited for nefarious activities and organised crime The National Health Act did not limit the type of medical investigations contemplated. No effort was made to define and streamline what would be seen as an emergency case that will warrant the harvest of the organ or tissue of a Nigerian citizen, without obtaining his or her informed consent.

Furthermore, it is noteworthy that commercialisation of organ donation nullifies consent. Section 51 National Health Act prohibits the commercialisation of human organs, if a person is involved in the sale, procurement or distribution of human organs, such person is liable to a fine of one hundred thousand naira or not less than one year imprisonment or both. In order words, going by the provisions of the aforementioned law, Ike Ekweremadu, Nigeria's erstwhile deputy senate president, committed an offence worthy of fine of one hundred thousand naira or imprisonment for not less than one year or both. The Old Bailey Court of London, found that informed consent

[48]2014

was lacking on the part of the donor and he thus entered into 'an emotionally cold transaction' with the donor.[49]

The provisions of National Health Act pertaining to consent of organ donors leaves more to be desired as same is a sharp contrast to its English counterpart. It is the researcher's view that the National Assembly must rise up to this urgent challenge and amend the National Health Act in order to close up the gaps therein. The Act is long overdue for review and necessary amendment because of advancements in medical field.

6. Conclusion

The legal framework for organ donation in the England has been found to be efficacious in regulating issues surrounding consent to organ donation. On the other hand, Nigeria's legal framework for organ donation i.e the National Health Act merely provided for consent in case of living organ donation and neglected other intricate circumstances that may arise in organ donation, like when a minor, an incapacitated person and/or a deceased person is to donate organ(s). How then can the Nigerian transplant surgeon deal with such yawning gap in our law in the absence of any rules of engagement in that regard? It is recommended that Nigeria's National Assembly should amend the National Health Act or create a new body of laws which will encompass the emerging issues surrounding organ donation and consent thereof in order to close the existing vacuum in our legal regime.

[49] I. Onoh, Organ Harvesting: UK Court Sentences Ekweremadu, Wife Today. 23/3/2023. Available at https://leadership.ng/organ-harvesting-uk-court-sentences-ekweremadu-wife-today/ accessed on 18th May 2023