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Organ Transplantation Tourism: Upholding the Donee's Right to Qualitative Health Care

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Abstract

Transplantation involves transferring an organ, tissue or cells (OTCs) from one person (donor) to another (recipient). With all of the achievements of medical science as regards organ transplantation, organ shortage is a major global challenge facing transplantation. The rise in demand for organ transplants, especially in developed countries, is the basis for organ transplantation and tourism. The spread of illegal transplant tourism is causing horrific abuses. Added to this is the risk of transmission of infections or malignancies to recipients of solid organs, tissues, and eye grafts. However, it has been difficult to track donors of organs, tissues and cells and their medical history, making it difficult to guarantee patients' safety. The paper, discusses organ transplantation tourism, recognising it as a reason for human trafficking. In doing this, it looks into the legal framework for organ transplantation and the right to health, acknowledging that what started with all good intentions, as a lifesaving procedure, has developed into a global problem for which urgent international collaboration is required. Therefore, it raises the issue of post-operation infection, as a possible public health concern. Lastly, the paper suggests coding and tracking as a means of controlling the spread of post-transplantation infections, by keeping a tab on what is donated, who gets what and the destinations of each donated organ.

Subject Areas

Law

Keywords

Organ Donations, Organ Transplantation, Organ Tourism, Post Transplantation Infections, Coding, Tracking

1. Introduction

An organ is a fully differentiated structural and functional unit in a human being

or animal that is specialized for some particular function [1]. Transplantation involves transferring an organ, tissue or cells (OTCs) from one person (donor) to another (recipient).

Successive attempts at tissue or organ transplantation and various fantastic descriptions of such transplantation were recorded many centuries ago [2]. For instance, in 300 BC the Christian Arabs saints, Cosmas and Damian were said to have successfully transplanted the leg of a deceased person several days earlier to replace a diseased leg of another person. However, in 1954, the first successful kidney transplant was performed in Boston, USA [3]. The transplant was performed between identical twins, overcoming the main difficulty in performing successful organ transplants at that time—the immunological discrepancies between donors and recipients—which inevitably led to activation of the alloimmune response, resulting in rejection and loss of the graft. In Nigeria, the first kidney transplantation was done at St. Nicholas Hospital, Lagos, in 2000.

Organ transplantation is now a well-established clinical therapy for saving lives and improving the quality of lives of thousands of patients every year. The efficacy of organ transplantation as a successful therapeutic procedure is obvious from the volume carried out annually. The Global Observatory on Donation and Transplantation noted that in 2019, 153,863 people worldwide receive a solid organ transplant, out of these, 40,608 were from deceased organ donors [4]. In addition, this is the large number and variety of tissues and cells which are implanted on a routine basis to treat a wide range of pathologies, many of which are life-limiting. Though unascertainable, the number of tissue transplant is considerably higher than the number of organ transplants. This is due to the fact that the number of large tissues that can be transplanted is high and there are numerous amounts of uses that tissues can be put into. For instance, corneal transplants restore vision; heart valve transplants involve lower morbidity rates than porcine or artificial valves; bone is used to repair damage due to trauma, cancer or degeneration; dural matter transplants are used to protect the brain after a traumatic head injury leaving it exposed to infection; joints and tendons are transplanted to restore mobility and independence; and skin is used extensively in the treatment of burns. Fat and other tissues are used both in reconstructive and cosmetic surgery.

Be that as it may, the demand for organs outweighs its supply, giving rise to organ commodification. This has led many to seek organs in countries other than theirs. On the other hand, some poor people see organ commodification as a means of earning money to meet their needs. Others have been forcefully made to donate their organs. These have given rise to a global issue that has necessitated global action, for protecting the donors, on the one hand and the upholding the right to qualitative healthcare of the recipient of the organs, cells and tissues on the other.

This paper looks into human organ donations, organ tourism and transplantation, acknowledging that what started with all good intentions, as a lifesaving procedure, has developed into a global problem for which urgent international

collaboration is required. In doing this, it raises the issue of transplant tourism in relation to the OTCs (objects) "donated" and transplanted, and the inability to guarantee their quality, despite the state's obligation to uphold the right to qualitative health. Lastly, the paper examines matters relating to post-transplantation infections, a possible consequence of organ transplantation, which could ultimately create a public health crisis. And it suggests coding and tracking as a means of curbing the spread of post-transplantation infections.

2. Organ Donation and Transplantation in Nigeria

Organ donation is the donation of biological tissue or any organ of the human body, by 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 and social history, of which are suitable for transplantation. Such procedures are termed *allotransplantations*, as opposed to *xenotransplantation*, which is the transfer of animal organs into human bodies. *Autotransplantation*, another form of transplantation involves the transfer of tissue or organs from one part of an individual to another part of the same individual. However, this surgical replacement of a malfunctioning organ by another human organ, raises ethical issues such as personhood, bodily integrity, attitude towards the dead and social, and symbolic value of human body parts. It is important to note that organs are usually taken from "brain-dead" individuals. Consequently, organ and tissue donation involve making a decision about how someone's body is to be treated after death.

As noted earlier, most transplanted organs are taken from dead donors. Before organs are removed from any donor, the medically accepted brain death criteria must be applied. This is a legal pronouncement by a qualified person that further medical care is not appropriate and that a patient should be considered dead under the law. The specific criteria used to pronounce legal death are variable and often depend on certain circumstances in order to pronounce a person legally dead.

Kidney transplantation has now become the treatment of choice for end-stage renal disease, and is the commonest solid organ transplantation being carried out in the world at the moment. In developing countries like Nigeria and Pakistan, it is the only solid organ Transplantation that is practiced [5].

In Nigeria, as well as some other Sub-Saharan African countries, organ donation and transplantation are yet to become a routine form of medical treatment [6]. The procedure is being done in a few private and teaching hospitals in Nigeria, with varying degrees of capacity, for performing organ transplantation. The treatments are however expensive and most Nigerian patients in need of organ transplant seek treatment abroad. The number of organs required to satisfy the needs of transplantation far exceeds the number of cadaveric organs available, creating a need for organs from living donors. This situation in its part has created legal and ethical issues, which will be discussed in this paper. Moreover,

organ donation networks and infrastructures are not yet well-developed in Nigeria. A vast majority of Nigerian patients in need of transplantation services, especially renal patients, travel abroad for treatment. It is public knowledge that, India is the preferred destination of most transplant patients in Nigeria because of its relatively more efficient healthcare system, cheaper cost of transplant services, and the availability of organ donors and brokers. Thus, *transplant tourism* is a medical metaphor that is beginning to take a tight hold in Nigeria.[1]

Transplant tourism is the practice of potential organ transplantation recipients, traveling abroad to purchase the needed organ and undergo the procedure. The demand for organs for transplant far outweighs the supply. Consequently, people, especially from low-income nations, offer their body parts for sale [7]. According to WHO, "transplant tourism" refers to patients travelling across the borders to be transplanted elsewhere [8]. It occurs in two different circumstances, namely, where there is a long waiting list for the organ, (this is usually the situation in developed countries), and in countries with little or no regulations on organ commodification (the situation in developing, low/medium income countries).

3. Legal Framework for Organ Donation and Transplantation

The legal framework for organ donations and transportation will be discussed under two sub heads.

3.1. Legal Framework for Organ Donation and Transplantation in Nigeria

The legislation that makes direct and comprehensive provision with respect to organ donation and transplantation in Nigeria is the National Health Act, 2014. The Act prohibits the provision of organ transplant services except in a duly authorized hospital and with the written permission of the medical practitioner in charge of clinical services at that hospital [9]. Section 53 provides that; only duly qualified and registered medical and dental practitioners are authorized to render transplantation services. The Act further prohibits any form of commercialization of human organs. It is therefore, an offence punishable with imprisonment or fine (or both) for a person *who has donated tissue … to receive any form of financial or other reward for such donation* or *to sell or trade in tissue*[2]. However, the Act exempts reimbursements for reasonable costs incurred by a donor in connection with organ donation[3]. The Act in its part establishes two sources of organs for transplantation: living and cadaveric donors.[4]

[1]Nwabueze R N. (2015) Organ Donation and Transplantation. In Iyioha I O and Nwabueze R N. Comparative Health Law and Policy: Critical Perspective on Nigerian and Global Health Law. Routledge. London. p. 219.

[2]Section 54 National Health Act, 2014.

[3]Section 54 (1) (a) National Health Act, 2014.

[4]Sections 48, 49, 55, 56, and 57 National Health Act.

By virtue of Section 49 of the Act the donor's consent must be in writing. The Act should not be interpreted to intend to exclude the country's illiterate population, from benefiting from organ donation and transplantation programme. This provision can therefore be interpreted to mean that, where Section 3 of the Illiterates Protection Act 1920 has been complied with, the donor's consent will be upheld. Section 3 of the *Illiterates Protection Act* provides that where a person writes a letter or document at the request of, on behalf of, or in the name of an illiterate person, then the writer must write their name and address on the document in order for the illiterate person to be bound by the document. The provision of Section 3, will however not apply to documents prepared by legal practitioners at the request of or on behalf of an illiterate person. Thus, transplant centres and potential recipients should ensure that, in the case of potential illiterate donors, there is compliance with the *Illiterates Protection Act*.

Of immerse legal implication on organ donation and transplantation are the provisions regarding the right to health and by extension, the right to life. These rights are based on the principle of respect for the individual and the assumption that each person is a moral and rational being who deserves to be treated with dignity. The Nigerian 1999 Constitution recognizes and upholds these rights. The right to life is founded on the premise of life being sacrosanct. Consequently, it is inviolable, inalienable and indivisible. Section 33 guarantees the right to life [10]. It can be said to be a natural right (that is, a right that a person has by virtue of the fact that he is a human being. It provides that,

every person has the right to life, and no one shall be deprived of his life, except in execution of the sentence of a court in respect of a criminal offence of which he has been found guilty in Nigeria.

Furthermore, Section 34 guarantees the right to human dignity. Section 34 (1) (a) provides that,

every individual is entitled to respect of the dignity of his person and accordingly no person shall be subjected to torture or to inhuman or degrading treatment.

The right to health, in its part, is recognized by almost all countries of the world and provided for by many international Conventions, Declarations and Treaties. It is the right to the enjoyment of the highest attainable standard of physical and mental health [11]. Health, on the other hand, is the state of being sound or whole in body, mind, or soul; the freedom from pain or sickness [12]. According to the preamble of the WHO Constitution, it is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". The 1948 Universal Declaration of Human Rights, states that health is a part of the right to an adequate standard of living [13]. In addition, the Commission on Human Rights in its resolution 2002/31[5], created the mandate of Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

[5]General Comment 14 to the ICESCR.

The right to health is an inclusive right, as it contains freedoms and entitlements [14]. The "freedoms" include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference such as the right to be free from torture, non-consensual medical treatment and experimentation.[6] On the other hand, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.[7] This right covers two areas, the underlying determinants, which include, water, sanitation, food, nutrition, housing, healthy occupation and environmental conditions, education and information, and healthcare. In upholding the right to health, all services, goods, and facilities must be available, accessible, acceptable and of good quality. That is, they must be scientifically and medically appropriate and of good quality.[8]

The elements of the right to health are:

1) Availability: entailing sufficiency in quantity of functioning public health and health care facilities, goods and services, and programmes;

2) Accessibility: health facilities, goods and services must be accessible to everyone. Accessibility is four folds, namely, non-discrimination, physical accessibility, economical accessibility (affordability) and accessible information;

3) Acceptability: all health facilities, goods and services must be respectful of medical ethics and culturally appropriate as well as sensitive to gender and life cycle requirements;

4) Quality: health facilities, goods and services must be scientifically and medically appropriate and of good quality.

The right imposes a duty on each state party

to take whatever steps that are necessary to ensure that everyone has access to health facilities, goods and services so that they can enjoy, as soon as possible, the highest attainable standard of physical and mental health.[9]

State parties, therefore, have an obligation to respect, protect and fulfill. They are not to interfere with the enjoyment of the right to health. They are however to ensure that third parties (non-state actors) do not infringe on the enjoyment of the right to health, by regulating non-state actors. Consequently, state parties ought to enact legislations against counterfeiting, which they must make provision for enforcement. Lastly, state parties must take positive steps to realize the right to health by adopting appropriate legislative, administrative, budgetary, judicial, promotional measures. They are to adopt "national strategies that ensure that all citizens enjoy the right to health indicators and bench marks". In addition, available resources, in the most cost-effective way, should be identified to ensure that enjoyment of this right. The National Health Strategies and Plan of Action should be "based on the principles of accountability, transparency, and

[6]The Right to the Highest Attainable Standard of Health, UN. Doc. E/C: 4th Dec, 2000: ICESCR, Gen. Comment 14 (2000).

[7]See General Comment 14, note 44.

[8]"The Right to the Highest Attainable Standard of Health, UN. Doc. E/C, 4th Dec, 2000: ICESR, General Comment 14 (2000).

[9]WHO Factsheet No.323 of November, 2012.

independent judiciary, given a good governance is essential to the effective implementation of all human rights, including the realization of the right to health.

The right to health therefore includes access to timely, acceptable, and affordable health care of appropriate quality and implies that governments must provide an environment in which everyone can, to a considerable extent enjoy healthy living. Such conditions range from ensuring availability of qualitative health services, healthy and safe working conditions, adequate housing and nutritious food. It should however be noted that the right to health does not mean the right to be healthy.[10]

The right to health is also recognized in several regional instruments, such as the African Charter on Human and Peoples Rights[11]; the Additional Protocol in Art. 16 of the 1981 American Protocol to the American Convention on Human Rights in the area of Economic, Social and Cultural Rights, also known as Art.10 of the Protocol of San Salvador, 1988; Art. 11 of the European Social Charter, 1961, revised in 1996; Part B of the American Convention on Human Rights, 1969; the European Convention for the Promotion of Human Rights and Fundamental Freedom, 1950.

Chapter Four of the 1999 Constitution of the Federal Republic of Nigeria makes provision for the fundamental human rights recognized by the Constitution. The right to life is the first right provided for in the chapter but the right to health is not mentioned in the Chapter. The Constitution however makes provision for the right to health under its chapter two. The difference between chapter two and chapter four is that the rights provided for under chapter four are enforceable in courts of law while those provided for under chapter two are deemed to be Fundamental Objectives and Directive Principles of State Policy which are not enforceable in courts. Rather, the country is enjoined to carry out its duties and responsibilities as stated in the chapter. Thus, although the Constitution denies legal recognition of the right to health as well as other social and economic (socio-economic) rights, the domestication of the African Charter in 1983 has introduced monumental changes to the legal status of these rights in the country. No longer may constitutional denial of legal recognition to these rights be relied upon to shield the government or its agencies from obligations regarding the right. More specifically, article 16 of the Charter guarantees the right to health.

Nigeria recognizes the right to health and has committed itself to its protection as a result of ratifying relevant international treaties and domestic legislation mandating specific conduct with respect to the health of individuals within its jurisdiction. These include the International Covenant on Economic, Social and Cultural Rights (ICESCR), 1976; Convention on the Elimination of all Forms of Discrimination (CERD), 1969; the Convention on the Elimination of

[10]The role of the government is to uphold its citizens' right to health by providing facilities and product conducive for healthy living. However, being healthy is the responsibility of each citizen.

[11]Section 17(3) (d) of the 1999 Constitution of the Federal Republic of Nigeria provides that: The State shall direct its policy towards ensuring that there are adequate medical and health facilities for all persons.

all Forms of Discrimination against Women (CEDAW), 2011 and the Convention on the Rights of the Child (CRC), 1990; the International Covenant on Civil and Political Rights (ICCPR), 1996 and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

In addition, Nigeria has ratified Conventions of the International Labour Organizations (ILO), some of which contain provisions on the health of workers.[12] In all, Nigeria has ratified forty (40) ILO conventions, out of which thirty (30) are in force, while ten (10) have been denunciated.[13] Nigeria is also a party to the Geneva Conventions and Additional Protocols, 1949-2005, that prescribe rules for conduct of warfare, including health-related obligations. Nigeria also adheres to several non-binding instruments/standards that address health issues, such as the 1993 Vienna Declaration and Programme of Action, 1993 UN International Conference on Population and Development and the 1995 Beijing Declaration and Platform for Action (UN Fourth World Conference on Women). At a regional level, Nigeria is a party to the African Charter on Human and Peoples' Rights (African Charter), the African Charter on the Rights and Welfare of the Child and the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, 1995.

3.2. International Legal Framework and Initiatives for Organ Donation and Transplantation

International framework for organ donations and trafficking is made up of resolutions and guidelines. These will be discussed here.

Trafficking in human organs, has been identified as one of the causes of human trafficking.[14] The United Nations (UN) considers trafficking with human organs a cause for human trafficking in a supplementary protocol to its "Convention against Transnational Organized Crime" of 2000. By UN resolution titled, "Strengthening and Promoting Effective Measures and International Cooperation on Organ Donation and Transplantation to Prevent and Combat Trafficking in Persons for The Purpose of Organ Removal and Trafficking in Human Organs".[15] Member States are to prevent and combat organ trafficking, in line with their obligations under international and national law, and to uphold accountability. Member States also have the responsibility of strengthening legislative frameworks, adopt laws necessary to guarantee that the donation of organs was guided by clinical criteria and ethical norms and ensure equitable access to human organ transplantation based on non-discrimination. The World Health Organization (WHO) was directed to develop international guidelines on the health, criminal and human rights aspects of those crimes.

In 1991, through its "Guiding Principles on Human Cell, Tissue and Organ Transplantation", the World Health Organization (WHO) expressed its disap-

[12]Example include ILO Convention C155—Occupational Safety and Health Convention of 1981.
[13]"Ratification for Nigeria". Retrieved from http://www.ilo.org/ on 17th March, 2015.
[14]Supplementary protocol to the UN Convention against Transnational Organized Crime 2000.
[15]Document A/71/L.80.

proval of commercialised organ commodification and trade.[16] In response to the increase of commodification of organs, the World Health Assembly, reviewed the 1991 Guiding Principles.[17] The 2004 edition, amongst others, made provisions requiring member states to implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and its traceability; cooperate in the formulation of recommendations and guidelines to harmonize global practices in the procurement, processing and transplantation of human cells, tissues and organs, including development of minimum criteria for suitability of donors of tissues and cells; consider setting up ethics commissions to ensure the ethics of cell, tissue and organ transplantation; and extend the use of living kidney donations when possible, in addition to donations from deceased donors.[18] The 2004 Guiding Principles were further reviewed in 2010.

The 2010 version of the Guiding Principles, clearly made a distinction between the compensation due to an organ donor, for expenses incurred in course of living donation, and financial incentive which exceeds such restitution[19]. The latter is to be prohibited. In addition, they made provisions for an orderly, ethical and acceptable framework for acquisition and transplantation of human cells, tissues and organs for therapeutic purposes, addressed issues of access, quality, safety and ethics in transplantation. They however do not apply to transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes, or to blood or blood constituents collected for transfusion purposes.

Another initiative by the UN is the United Nations Global Initiative to Fight Human Trafficking (UN.GIFT), identified three (3) types of illegal organ trade, namely,

1) Where persons are forced or deceived into giving up an organ.

2) Where person, who voluntarily sold their organ, but are not paid in accordance to prior agreement.

3) Where organs are removed, in an alleged therapeutic intervention, from persons without their consent.

The UN.GIFT was conceived to promote the global fight on human trafficking, on the basis of international agreements reached at the UN [15]. It was launched in March 2007 as a collaborative effort by the International Labour Organization (ILO), the Office of the United Nations High Commissioner for Human Rights (OHCHR), the United Nations Children's Fund (UNICEF), the United Nations Office on Drugs and Crime (UNODC), the International Organization for Migration (IOM) and the Organization for Security and Cooperation in Europe (OSCE). UN.GIFT aims at mobilising state and non-state actors to eradicate human trafficking by reducing both the vulnerability of potential victims and the demand for exploitation in all its forms; ensuring adequate protection and support to those who fall victim; and supporting the efficient prose-

[16]WHA 44.25.

[17]WHA 57.18 of 2004.

[18]Art. 1 WHA 57.18.

[19]WHA 63.22.

cution of the criminals involved, while respecting the fundamental human rights of all persons.

In order to curb these unethical activities and their consequences, the Transplantation Society (TTS) and the International Society of Nephrology (ISN) convened an International Summit on Organ Transplantation Tourism and Trafficking in Istanbul in April 2008. The summit reached a consensus on the Declaration of Istanbul [16]. The outcome was the Declaration of Istanbul, which essentially seeks to protect the ethics, dignity and practice of organ transplantation. It restates that organ trafficking and transplantation tourism violate the principles of equity, justice and respect for human dignity. The Declaration deals with the mechanism, ethics, appropriateness, penalties and proposals on organ transplantation.

In addition, it distinguished between travelling for transplantation, and transplant tourism by means of the following:

travel for transplantation is the movement of organs, *donors*, *recipients or transplant professionals across jurisdictional borders for transplantation purposes. Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources* (*organs*, *professionals and transplant centres*) *devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population* [17].

The practical basis for concern arises when the destination country places its own resident patient population at disadvantage for gaining access to the list because lucrative arrangements for patients from the client countries simultaneously claim an allocation priority. Meanwhile, in the client country, readily available access to organs (in the destination country) prevents deceased-donor programs from gaining widespread support. Be that as it may, some tourist transplantations are ethical.

The *Istanbul Declaration* made additional provisions for where tourist transplantation may be ethical. Firstly, where a live donor is involved. The declaration, makes provisions for, where the recipient has a dual citizenship and wishes to undergo transplantation from a live donor that is a family member in a country of citizenship that is not their residence, and where the donor and recipient are genetically related and wish to undergo transplantation in a country not of their residence. The second category is deceased donors. There are provisions for situations where there exists official regulated bilateral or multilateral organ sharing programmes, based on reciprocated organ sharing programmes, which exist between or among countries or jurisdictions. The essence of the Declaration of Istanbul is so that the benefits of transplantation be maximized and shared equitably with those in need, without reliance on unethical and exploitative practices that have harmed poor and powerless persons around the world. These efforts have contributed to the considerable progress made in countries around the world since 2008.

With regards to international legal instruments, they can be grouped into soft

laws and hard laws. Soft laws refer to rules that are neither strictly binding in nature nor completely lacking legal significance. It encompassed non-binding or voluntary resolutions, recommendations, code of conduct and standards. Hard laws on its part, are the actual binding legal instruments and laws. They give parties binding responsibilities as well as rights. Most of the instruments dealing with organ donation and transplantation are however soft laws.

4. Tracking and Tracing a Global Problem: Upholding the Right to Qualitative Healthcare for the Recipient of an Organ, Cell or Tissue in a Transplant Tourism Situation

With all of the achievements of medical science as regards organ transplantation, organ shortage is a major global challenge facing transplantation. A means for meeting this need is through altruistic donation. This involves donations by living, sometimes unrelated, volunteers. Globally, it has been considered as a major source of donated organs. The source has however been expanded, due to the need for money by poor people. Given the rise in demand for organ transplants, especially in developed countries, one which is higher than the available supply, a small but growing number of the world's poor people are offering their body parts for transaction, and kidneys are the most commonly purchased organs [18]. This is the basis for organ transplantation and organ tourism.

The practical basis for concern arises when the destination country places its own resident patient population at disadvantage for gaining access to the list because lucrative arrangements for patients from the client countries simultaneously claim an allocation priority. Meanwhile, in the client country, readily available access to organs (in the destination country) prevents deceased-donor programs from gaining widespread support. According to Sugg [19], the spread of illegal transplant tourism is causing horrific abuses. It is pertinent to find a way to stop it. Organ shortage, though local problem, has become a global problem.

In 2010, the Guardian reported on the scandal of the Kosovan black market in organ transplant [20]. In 2008 a young Turkish man, Yilman Altun, fainted in a queue at Kosovo's Pristina airport. He had just had a kidney removed for transplant purposes, by the organ ring Medicus. He was one among various *desperate Russians*, *Moldovans*, *Kazakhs and Turks … lured into the capital* "*with the false promise of payments*" *for their kidneys*. The ring allegedly involved Turkish surgeon Yusuf Sonmez, who was arrested in January 2011, and several eminent Kosovan doctors. Sonmez was involved in an organ ring whose source was outright murder. A handful of Serbian captives "were moved to a farmhouse in Fushë-Krujë, a town north of the Albanian capital, Tirana", and were shot in the head so that one or more organs could be removed, undamaged, and sold for transplant.

The dangers of organ tourism are illustrated, to an extent, in the example giving above. This is coupled with the fact that, patients are traveling abroad to receive organ transplants and the risk of importing new diseases in immunosup-

pressed recipients is amplified. While this story may represent what happens globally, it also reveals three key factors common to the trade in human organs. Firstly, the donors are paid very little of the amount originally promised. Secondly, they received little or no effective aftercare. This negligent act has been found to make the difference between recovery and a life of permanent, crippling ill-health. Thirdly, the ring that lures them in is thoroughly global, involving wealthy patients from Canada, Germany and Poland, Israel and other developed nations.

Health tourism, the "parent" of organ tourism, was originated in the United States in the 1930s in New Mexico [21]. The essence of modern health tourism is to maintain health and repair health, and features fitness activities and medical care programs to meet the purpose of relaxing and rejuvenating [22]. The insufficiency of transplantable organs, cells and tissues has paved the way for the growth of transplant tourism, just as the increase in the number of elderly people, the proportion of sub-health population, and the world's diseases, has led to health tourism has resulted in the rapid development of health tourism, in the 21st century [23].

A prime destination for these organs is the US. According to Gutierrez [24], the average kidney transplant, costs $259,000 in the US in 2008, netting between $80,000 and $100,000 in insurance reimbursements for hospitals and doctors. Gutierrez adds that, in July 2009, 44 US residents were arrested on charges of organ trafficking. Meanwhile, a notable problem caused by transplant tourism is ensuring safety of both the donor and the recipient and the quality of the OTs. Given that OTCs cross national boundaries, in a bid to increase availability, it is difficult to monitor and ensure appropriate access and safety both nationally and globally. The lucrative nature of trading in "body parts" has generated also unethical behaviour.

Noting the global increase in allogeneic transplantation of cells, tissues and organs, the World Health Organization (WHO) [25], urged member states, to implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and traceability, to cooperate in the formulation of recommendations and guidelines to harmonize global practices in the procurement, processing and transplantation of human cells, tissues and organs, including development of minimum criteria for suitability of donors of tissues and cells, to consider setting up ethics commissions to ensure the ethics of cell, tissue and organ transplantation, to extend the use of living kidney donations when possible, in addition to donations from deceased donors and to take measures to protect the poorest and vulnerable groups from "transplant tourism" and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs.

The risk of transmission of infections or malignancies to recipients of solid organs, tissues, and eye grafts is not in doubt [26]. Infectious pathogens can include viruses, bacteria, parasites and prions. The risks of amplification of trans-

mission are further increased when there are multiple recipients from a common donor. This is possible because, as many as 100 tissues and organs can be recovered from a single donor [27]. Due to the organ shortage in particular, donors with known high-risk behaviour, such as prisoners are sometimes accepted for organ transplantation which can result in multiple infectious risks [28]. Other adverse events such as malignancies, reactions to toxins, unexpected malfunction, adverse immunological responses and immune mediated disease transmissions and administrative errors can occur.

Another factor resulting in inability to track organs and tissues is the lack of a formal communication. For instance, a report in 2005 [29] described a number of hepatitis C virus (HCV) transmissions to several organ and tissue recipients from a single donor. This case generated much publicity because there were 91 grafts produced from the donor (7 organs, 2 corneas and 82 other tissues), 44 transplants and 40 recipients in 16 states and 2 other countries over a period of 22 months. The entire tissue recipient infections would have been prevented if recognition of infection in the organ recipients had resulted in notification of the tissue bank before tissue was processed or released. More than 6 months elapsed between recognition of the organ recipient infections, donor linkage, and the time that tissue was processed.

The role of patient safety efforts is to drive that risk to the lowest level reasonably achievable without unduly decreasing the availability of these life saving resources, so that the overall benefit outweighs risk. Risk must also be assessed using vigilance and surveillance programmes which to date have not been universally developed for tissues and cells and are insufficiently developed for organs through regional organ sharing programmes such as UNOS in the U.S. [27]. The U.S. does require mandatory reporting of infectious adverse reactions to the FDA by regulated establishments, and eye banks accredited by the EBAA comply with requirements to electronically report adverse reaction, including those due to biologic dysfunction. The success of this reporting is made possible since eye banks typically distribute ocular tissue directly to the surgeon and identify the recipient prior to transplantation. A critical component of a biovigilance system is constructive feedback to ongoing analysis efforts.

The World Health Organization (WHO) guideline on adverse event reporting emphasizes that the effectiveness of surveillance systems should be measured not only by transplant outcome data reporting and analysis, but also by the use of such systems to improve patient safety through active response to data that are generated [30]. It is important to mention that vigilance and surveillance of tissues and cells used in transplantation is relatively new globally. As noted earlier, transplant tourism is saddled with scandalous and unethical practices. In addition, there is not a uniform system for tracking many tissues, with the exception of corneal tissue, or to detect adverse events from their use. In fact, most of the reported infectious transmissions from tissue transplants have included the inability to identify common recipients of tissues from the same donor.

Previous experience gained from managing adverse events and reactions has

led to a widespread understanding of the need for traceability—the ability to track from donor to recipient and vice versa in order to ensure that all individuals associated with an event or reaction can be identified. Full traceability goes well beyond the single strand of information following the path of one product from donor to recipient, and becomes a complex web where multiple products are produced, pooled products are prepared, donors can make multiple donations of different biologic materials and multiple agencies can be involved in the procurement of organs and tissues. This web of information has multiple data owners, frequently extends across continents, and has to be retained for long periods of time, and in a format that allows rapid retrieval demands the use of computer data storage. It is therefore essential to ensure that a complete and secure information trail across the multiple computerized systems is employed, as well as a means of uniquely identifying each donation, and each product prepared from that donation. Given that OTCs travel worldwide, it is therefore clear that uniqueness of identification at national or regional level will not suffice.

WHO in its Guiding Principles, discussed above, recognized the significant global circulation of certain human tissues and cells and the substantial role played by a commercial market in many of these tissue and cell products. In addition, the essence of transparency in these activities, to ensure public support and understanding was stressed. The documents, noted that, a key element of oversight includes effective systems of vigilance and surveillance worldwide, which requires, as an essential prerequisite, a robust system for traceability of donated material from donor to recipient.

The WHO has clearly stated its position concerning coding and traceability of cells, tissues and organs. At the Second Global Consultation on Regulatory Requirements for Human Cells and Tissues for Transplantation in 2006, the WHO represented that in the era of globalization of cells and tissue transplantation, the need for common product names and definitions for unique product identification was essential.

Principle 10 of the WHO Guiding Principles on Human Cell Tissue and Organ Transplantation provided for the necessity of detailed assessment of transplantation procedures as well as of the outcome of transplanted human cells, tissues and organs, for full traceability. The WHO subsequently developed the Aide-Memoires specifying basic requirements in this field. The Aide-Me'moire on "Access to Safe and Effective Cells and Tissues for Transplantation" provides an overview for National Health Authorities, but also for all stakeholders, of all key aspects to be considered and requirements to be met for the setting up and/or the oversight of human cell and tissue transplantation services [31].

"Traceability" has been defined as, the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the reci-

pient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells.

In order to trace and track OTCs, a coding system is needed. A coding system is a means by which distinct items within a system can be uniquely identified and consistently characterized to all participants within that system. It requires as a minimum a means to allocate identifiers in a manner that avoids duplication, and a standard reference for describing items. For a manufactured drug identification of the manufacturer and the unique lot number assigned by that manufacturer is sufficient to trace back to the manufacturing records for the batch. It is important to recognize that a coding system does not itself provide traceability, but provides the information infrastructure on which effective traceability can be built. Coding and traceability are not the same but one supports the other.

The Radio Frequency ID (RFID) has been used globally and in Nigeria as a means of combating drug counterfeiting. It is a serialisation/track and trace technology, used for tracking and tracing of medicines and medical products. This involves assigning a unique ID to each stock unit during manufacture. This ID remains with the drug, through supply chain till consumption. The ID is made up, amongst others of, product name, strength, lot number and expiry date. Alternatively, it could take the form of a unique pack coding which enables access to the same information held on a secure database.

It has been used for tracking items through supply chain, to each point where there is the facility for data capture, providing traceability with regards to history of any item, subject to limitation of number of control points and enabling authentication of the data at any time, by implication, of the pack of unit on which it is applied. It is believed that this could successfully be applied to control the cross border spread of post-transplantation infections, thereby preventing a global health issue.

5. Recommendations and Conclusion

With regards to transplantation tourism, efforts should be made to encourage the introduction of a standardized international coding system for donation identification numbers for all donated human biologic products. The focus should also be placed on global traceability for all donated human biologic products. In addition, communication between international stakeholders to develop consensus on common grounds should be encouraged, as well as promoting suitable international forums to be established to expand the international terminology for donated human biologic materials. Furthermore, any move towards adopting globally unique identification should be compatible with a well-established standard coding system so that the progression towards automated data capture and computerized records can be achieved.

The essence of organ transplantation is to improve health and prolong the life of the recipient. Therefore, it is important to ensure that the process of harvest-

ing organs is as safe as possible, and that both the living donor and recipient are followed up to detect and manage any short- or long-term sequelae [32]. The competence of the medical/surgical team responsible for the transplant process should also be of the highest order, so as to ensure outcomes comparable with those in developed countries. The National Health Act 2014 has made specific provisions in this regard. These have been discussed earlier. Also worthy of consideration are issues relating to the economic aspects of the procedure, ensuring that acceptable world standards are not compromised. It is also essential to ensure that all material information is available to the parties concerned.

There are serious ethical, legal and social issues relating to organ transplantation that need to be addressed. Many countries of the world have put in place transplant laws and regulations as the case may be, but commercial organ sale and transplant tourism remain a booming business in various parts of the world, even in first-world countries. In the developing world, with the current level of corruption and poverty, there is a need to redouble efforts to monitor transplant activities. Professional bodies should take the lead in this regard. Furthermore, there is a need for governments to engage in public consultation and community awareness concerning organ donation in living and deceased persons.

There is clearly no easy solution to either the modern black market in organs or local shortages. Some have argued that paid donations should be legalized: partly to regulate them, and partly to ease global supply problems. In China, the state allows organs to be harvested from executed criminals, if they or relatives grant consent. One clear message of transplant tourism does indeed seem to be that, to stop abuses abroad, we need to improve charity at home.

As noted earlier, a coding system is essential for effective tracing and tracking, as both support each other and are of utmost importance to patient safety.

Originality and Plagiarism

Originality is strictly preserved whereas plagiarism is dispirited.

Conflicts of Interest

The author declares no conflicts of interest.

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