

MEDICO-LEGAL AND ETHICAL ISSUES IN STEM CELL RESEARCH IN NIGERIA

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Abstract

The growing need and importance of stem cell research and therapeutic uses cannot be overemphasised worldwide. Stem cells are regarded as master cells because they are cells from which all other cells with specialised functions are generated. However, their sourcing, use and disposal have continued to raise ethical, medical and legal issues. This paper critically examined the medical, ethical and legal issues regarding stem cell research globally and particularly in Nigeria. The methodology employed is the doctrinal approach. The paper relied principally on international agreements on stem cell research, like the World Medical Associations Helsinki Declaration 2013, stem cell research laws and regulations of advanced legal climes like the United Kingdom, and Nigerian legislations including the National Health Act 2014 and the Code of Medical Ethics in Nigeria 2008. The paper found that the existing international legislation on stem cell research does not contain stiff sanctions for breach. It is recommended that a comprehensive sui generis legislation on stem cell research, permissible conduct and sanctions for violation be made, taking into consideration the IVF, artificial cloning of cells currently practised in Nigeria, and possible stem cell therapy procedures to be developed.

Keywords and phrases: Ethical, Medical, Legal, Stem Cell Research.

Introduction

There is a growing interest globally in discovering and developing a permanent source of tissues capable of generating any type of cell to avoid the problem of transplant rejection. Therefore, stem cell research has become a dominant theme in biomedical research. Its prominence is due not only to the potential of employing stem cells in the treatment of many otherwise intractable diseases but also to the public furor that has arisen because of the use of human embryos as the source of many lines of cells. Stem cell research has gained notoriety in medical research and therapy. However, it has proved a political, ethical, and legal minefield, creating challenges for policymakers and regulatory bodies.¹

The debate over the source and use of stem cells has been particularly acrimonious in some political and religious circles.² It is instructive that intense research activity has been taking place in laboratories worldwide beneath the public aspect of the debate and discussion about stem cells. As a result, a new field called regenerative medicine has been created in the past two decades. A prime goal of regenerative medicine is to restore damaged tissues and organs through the applications of stem cell therapy, especially in situations where natural biological regenerative processes are insufficient.³ A significant consideration in stem cell therapy is the source of stem cells, which has given rise to substantial debates on the subject matter. Against this backdrop, this paper discusses the medical, ethical and legal issues regarding stem cell research globally and particularly in Nigeria.

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¹ Corrigan, O. and others, 'Ethical Legal and Social Issues in Stem Cell Research and Therapy' *Cambridge Genetics Knowledge Park* [2006] 1-31.

² Carlson, B.M., 'Stem Cell Anthology; Stem Cell Biology, Tissue Engineering, Cloning, Regenerative Medicine and Biology' *Elsevier* [2010].

³ *Ibid*

Conceptualising Cell and Stem Cell

All living organisms, from the simplest to the most complex, consist of a unit of space enclosed by a membrane. This unit of space is called a cell. Cells are the smallest, structural and functional unit of an organism which is characteristically microscopic.⁴ One of the outstanding characteristics of cells is the ability to replicate, transferring the cell's hereditary genomic information to progeny.⁵ A cell is referred to as a fundamental unit of life. There are two types of cells: the prokaryotic and the eukaryotic cells and these differences are mainly based on the presence and absence of a nucleus in the cell.⁶

Robert Hooke first described cells in 1665 after he observed a honeycomb of tiny compartments.⁷ He remarked that they looked strangely similar to *cellular*, the Latin word for small rooms.⁸ Among all living organisms, some are unicellular, consisting of only one cell capable of performing all life functions: amoeba, algae, bacteria, fungi and protists. Others are multi-cellular, composed of different types of cells with specialised functions, for example, plants, animals, human beings, and birds. A cell is the lowest level of biological organisation with the ability to survive and reproduce provided it has access to a usable energy source, the necessary raw materials and appropriate environmental conditions.⁹

Stem cells are cells that can renew themselves and differentiate into specialised cell types.¹⁰ Stem cells found in the early mammalian embryo at around 5-7 days after fertilisation can give rise to all the different cell types of the organism. These embryonic stem cells are said to be pluripotent (that is, capable of giving rise to several different cell types). Stem cells are also found in the foetus, umbilical cord blood, and tissues of the adult organism.¹¹

A generic definition for stem cells is "self-renewing populations of cells that undergo symmetric and asymmetric divisions to self-renew or differentiate into multiple kinds of differentiated progeny"¹². The first dichotomy in the classification of stem cells is between embryonic and adult stem cells. Embryonic stem cells are derived from the inner cell mass of a 5-day embryo, otherwise known as a blastocyst. They have been described as totipotent¹³ because a single cell from the inner cell mass can, in theory, go on to form any of the differentiated cell types in the body. Adult stem cells are cells in the postnatal body that retain stem cell properties throughout life.

Medical, Legal and Ethical Issues in Stem Cell Research

The medical, legal and ethical issues on stem cell research are intertwined such that a discussion of one will inadvertently lead to a discussion of the others. For example, human embryonic cell research is ethically controversial because it entails the destruction of human embryos. The critical medical, legal and ethical questions associated with the research include whether it is permissible to destroy a human embryo and whether we should clone human embryos for therapeutic cloning research.

⁴ BYJUS, 'Difference between Cell and Tissue' <<https://byjus.com/biology/difference-between-cell-and-tissue/>> accessed 28 June, 2022.

⁵ Devlin, T.M. *Textbook of Biochemistry with Clinical Correlations* (John Wiley & Sons, 2011).

⁶ *Ibid*

⁷ Raven, P.H. & Johnson, G.B., *Biology, Second Edition* (Times Mirror/Mosby College Publishing, 1989).

⁸ *Ibid*.

⁹ Russel, P.J. and others, *Biology: The Dynamic Science*, First Edition (1st edn, Thompson Brooks/Cole, 2008).

¹⁰ Biehl, J.K. & Russel, B., 'Introduction to Stem Cell Therapy' <www.ncbi.nlm.nih.gov/pmc/articles/PMC4104807> accessed June 16, 2022.

¹¹ Corrigan (n1) 1

¹² Carlson (n2) 44.

¹³ That is capable of giving rise to any cell type or a complete embryo.

Medically, there is a consensus in the scientific community that a human embryonic stem cell holds great promise for developing new treatments for a variety of serious and untreatable disease conditions.¹⁴ Stem cell researchers hope that it might be possible to use stem cells, or specialised cell types differentiated from them, to repair organs and tissues damaged by injury or by degenerative or autoimmune diseases, including Parkinson's disease, sickle cell, cancer, bone marrow diseases, multiple sclerosis and type-1 diabetes. Other applications for stem cells are also being investigated, for instance, as sources of differentiated cell types for drug screening and toxicity testing or as vehicles for drug delivery. Research on stem cells also has the potential to yield new insights into the molecular control of cell differentiation.¹⁵ The question is, is it permissible to destroy a human embryo?

Human embryonic stem cell lines are made by chemically and physically disaggregating an early blastocyst embryo and removing its inner cell mass. This embryo at this stage comprises approximately 200 cells, including an outer layer of differentiated placental material, and undifferentiated (pluripotent) cells of inner cell mass.¹⁶ This procedure implies that the embryo dies; hence the question: can we intentionally kill a developing human being at this stage to expand scientific knowledge and potentially provide medical benefits? At the end of the spectrum is the school of thought that believes that human life begins at conception in moral terms. For those holding this view, the early embryo is morally no different from a child or an adult human being and cannot be used in research that is not to its benefit; and it cannot be used without its consent.¹⁷ It can be argued that this amounts to an artificially induced termination of pregnancy, otherwise known as abortion.

Abortion

Suffice it to state that the Nigerian Constitution is pro-life. Hence it contains specific provisions to the effect that every person has a right to life, and nobody should be intentionally 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.¹⁸ As noted by Abugu,¹⁹ abortion is a criminal offence in Nigeria, except where such abortion is carried out to save the life of the pregnant woman. Furthermore, a non-therapeutic abortion is also considered a severe infraction of medical and dental practitioners' professional code of conduct. In this regard, a doctor who is guilty of inducing or improperly procuring a non-therapeutic abortion would be liable to a charge of infamous conduct in a professional respect.²⁰ This offence may lead to striking off the name of the medical practitioner from the register. Unfortunately, this prohibition of abortion appears to be respected more in the breach than in the observance, as it now forms part of the daily routine of many medical practitioners.

In 1984, a survey to assess the incidence of abortion revealed that in Lagos Metropolis, 125 abortions or treatments of incomplete abortions were recorded in a month, and 81 were recorded in Oyo State within a month. In Kaduna state, where information was difficult to obtain, 103 cases were recorded in the preceding year. This is even though, in 1981, the Nigerian Society for Gynecology and Obstetrics sponsored a Termination of Pregnancy Bill in the House of

¹⁴ Carlson (n2) 349.

¹⁵ Corrigan (n1) 1.

¹⁶ Carlson (n2) 349.

¹⁷ Carlson (n2) 349.

¹⁸ Section 33, Constitution of the Federal Republic of Nigeria, 1999 (As Altered).

¹⁹ Abugu, U. *Principles and Practice of Medical Law and Ethics* (Page link Nigeria Ltd, 2018). See also sections 228, 229, 230, and 297 of the Criminal Code and section 232 of the Penal Code.

²⁰ Rule 60 of Code of Medical Ethics in Nigeria, 2004.

Representatives, but the bill did not pass.²¹ Abugu²² also noted that the Declaration of Lisbon, 1981²³ states the rights of a patient to include but is not limited to the right to die in dignity. This is no doubt connected to the Fundamental Human Rights enshrined in sections 33, 34, 35, 37 and 38 of the Constitution.²⁴ It is submitted, flowing from the above position that an embryo is no different from a child or an adult human being and should not be used in research that is not to its benefit; and without its consent; that such embryo should in the least be allowed to die in dignity.

Consent

Other principal rights due to a patient are the rights to autonomy and self-determination, and consent. The Medical and Dental Council of Nigeria urges all practitioners to ensure that, as far as possible, permission is obtained before any procedure is carried out on a patient.²⁵ The ethical and legal application of any treatment or procedure requires the patient or the person legally responsible for the patient to give consent. Consent must be informed in the sense that it must be obtained without coercion, inducement or deception. The procedure must be explained to the patient in plain language that they are fully conversant with, if necessary, through an interpreter. In the case of a minor, consent should be given by the parent or guardian. Carrying out a procedure on a patient without permission would be litigable and culpable and could be trespass or assault.²⁶

In cases involving assisted reproductive technology, otherwise known as assisted conception, an exciting development in the issue of consent is what happens when a consenting partner dies. In recent years, the British court ruled that a woman could not use her partner's semen after his death. The woman was, however, allowed to use the semen in another country and had a child from her dead husband²⁷. In considering whether an adult may, as a matter of law, validly consent to the removal of one of his organs for transplantation, Kennedy and Grubb²⁸ cited the following quotation from Jesse Dukeminier²⁹ as follows:

Mayhem is the crime of intentionally and maliciously maiming or disfiguring a person. At common law, mayhem was limited only to the deprivation of such of a man's organs, as may render him less able to fight to defend himself or to annoy his adversary. Included were a man's hand, his finger, his foot, his testicle or his eye. The significance of the organs in fighting is irrelevant today. Modern statutes have extended the crime of mayhem to disfiguring in general and to the disfiguring of women and men. Moreover, under current law, it is possible to contend that surgically removing an internal organ from a person constitutes mayhem.

Again the question arises whether, if removing a kidney for transplantation is mayhem, consent by the donor is a defence against the charge. Only two cases are remotely relevant, and the victim's consent had no effect in both of those cases. In *Wright's Case*, recorded by Lord Coke in 1603, a strong and lustie rogue' directed his companion to cut off the rogue's left hand so that he might get out of work and beg more effectively. The rogue and his companion were convicted of mayhem;

²¹ Okagbue, I, 'Pregnancy Termination and the Law in Nigeria' *Stud Fam Plann* [1990] <<https://pubmed.ncbi.nlm.nih.gov/2219225/>> accessed 16 February 2022.

²² Abugu (n 18) 122

²³ Adopted by the 13th World Medical Assembly Lisbon, Bali, Indonesia, September 1995. <<https://dl.med.or.jp/dlmedia/wma/lisbon2005e.pdf>>. Accessed 21 April 2022.

²⁴ Constitution of the Federal Republic of Nigeria, 1999 (As Altered).

²⁵ Abugu (n18) 126. See also Rule 21, Code of Medical Ethics in Nigeria, 2008.

²⁶ Giwa-Osagie, O. 'Medico-Legal Aspects of Assisted Reproductive Technology (Assisted Conception)' in *Compendium of Medical Law under the Commonwealth & United States Legal Systems with Treatise on Assisted Conception* (Maiyati Chambers, 2016).

²⁷ *Ibid.*

²⁸ Kennedy, I. and Grubb, A. *Medical Law: Text and Materials* (Butterworths, 1989).

²⁹ Jesse Dukeminier 'Supplying Organs for Transplantation' *Michigan Law Review* [1970] (68) (5) 811-865.

consent was held as no defence to the crime. In *State v Bass*, a man wanted his fingers cut off to collect insurance money. With full knowledge of the purpose, a physician deadened four fingers of the man's left hand, which another man cut off using an electric saw. The physician was convicted of being an accessory to mayhem. The court held that consent of the person was no defence to the charge....

There is a direct prohibition of medical practice for persons not registered with the Medical and Dental Practitioners Council of Nigeria.³⁰ In addition, Rule 2³¹ states, among other things, that the Medical and Dental Council of Nigeria recognises Acupuncture, Homeopathy, Manipulative Medicine and Naturopathy as modes of alternative medicine practices. Rule 15³² declares as follows:

Alternative medicine practitioners are, by their training, not to use any instrument too, or by any means whatsoever, to penetrate the human body, that is, physically get beneath the skin except for the remedial purposes of administering intravenous drip infusions or for diagnostic intentions by obtaining blood for laboratory tests or administer intramuscular preparations of homoeopathic injectable remedies, vitamin B complex preparations, or in the average utilisation of acupuncture needles, or the administration of injectables approved for use in alternative medicine. But on the other hand, physical penetration beneath or beyond the skin for surgery, excision, or replacement of body parts or any embedded material by a registered alternative medicine practitioner is infamous in professional respect.

The effect of the above provision is that an alternative medicine practitioner is prohibited from carrying out any form of excision or replacement of any part of the human body, whether for research or therapeutic purposes. Abugu was right when he stated that a registered alternative medical practitioner could only practice within the narrow limit of homoeopathy, osteopathy and acupuncture.³³

Stem Cell Research in the United Kingdom

The United Kingdom (UK) has adopted a positive stance on the use of stem cell research, and this is easily noticeable through detailed and dedicated regulations like:

- i. The Human Fertilisation and Embryonic Act 1990 with Regulations under it;
- ii. Human Reproductive Cloning Act 2002 prohibits anyone from placing an embryo in a woman if it has been created anyway other than by fertilization
- iii. The Human Tissue Act 2004
- iv. UK Stem Cell Bank is a national stem cell bank to manage stem cell resources under an ethical governance framework
- v. EU Tissue Directive applicable to it and Convention on Human Rights and Biomedicine³⁴.

Research on human embryos is only allowed for specific purposes, outlined in the Human Fertilisation and Embryology Act (1990) and the subsequent Human Fertilisation and Embryology (Research Purposes) Regulations 200.

³⁰ Section 18 (1) of the Medical and Dental Practitioners Act, Cap M8, Laws of Federation of Nigeria, 2004

³¹ Rules of Professional Conduct for Alternative Medicine Practitioners in Nigeria, 2002.

³² *Ibid*

³³ Abugu (n18) 50.

³⁴ Bernard L. and Parham, L., 'Ethical Issues in Stem Cell Research, *Endocrine Reviews* [2009] (30) (3): 204–213. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726839/>> accessed 22 January 2020.

The International Society for Stem Cell Research (ISSCR) endorses the goals of stem cell scientists. It promotes innovation in research, education, and the free exchange of scientific ideas and research materials. The ISSCR Task Force is charged with formulating guidelines that articulate ethical principles and rules of behaviour for the performance of human stem cell research. The International Society for Stem Cell Research (ISSCR) was founded in 2002. It is an independent, non-profit organisation and aims to foster the exchange of information on stem cell research³⁵.

Medical, Legal and Regulatory Framework of Stem Cell Research in Nigeria

Stem cell research and therapy is a highly specialised area growing rapidly in Nigeria. Although there is no comprehensive legislation dedicated to regulating its use in the therapeutic cure, there are however pockets of important legal provisions for its regulation in the National Health Act 2014, the Code of Medical Ethics of Nigeria and the World Medical Associations Helsinki Declaration 2013 on Ethical Principles for Medical Research involving Human subjects. Section 64 of the National Health Act 2014 defines some terms related to stem cells and is essential in understanding some of its provisions in discussing stem cell research. They are:

- i. Blood product –any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells
- ii. Oocyte –a developing egg cell
- iii. Embryo- human offspring in the first eight weeks from conception
- iv. Gamete- either of the two generative cells essential for human reproduction
- v. Zygote –the product of a union of a male and female gamete
- vi. Tissue –human tissue includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete.
- viii. Therapeutic cloning- the manipulation of genetic material from an adult, zygotic or embryonic cells to alter, for therapeutic purposes, the function of cells or tissues.

Article 12 of the Helsinki Declaration 2013 provides that medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualification. In addition, such research requires the supervision of a competent and appropriately qualified physician or other health care professional.

Other Provisions under the National Health Act 2014

The National Health Act 2014³⁶ provides for the establishment of the National Health Research Committee (otherwise known as "the Research Committee") with a membership of not more than thirteen (13) persons. The Act further provides that the Research Committee's composition shall reflect federal character.³⁷ Much as the federal character principle is entrenched in our laws and intended to foster unity by ensuring the participation of different ethnic nationalities in Nigeria, it is our humble view that the principle of federal character still constitutes a significant setback to the development of various sectors of our national life. For instance, since the Act in section 31(4)(b) provides that the secretary of the Research Committee shall be the Director of Health Planning and Research in the Federal Ministry of Health, there would be a need to ensure federal character when appointing the Chairman who shall be "an acknowledged health researcher and be accomplished and renowned in a health discipline"³⁸. This could lead to the best brains being left out in such appointments.

³⁵ *Ibid*

³⁶ Section 31(1) of the National Health Act 2014.

³⁷ Section 31(3) of the National Health Act 2014.

³⁸ Section 31(4)(a) of the National Health Act, 2014.

It is instructive that the Act³⁹ is conservative and protective as it provides as follows:

- (1) Notwithstanding anything to the contrary in any other law, every research or experimentation on a living person shall only be conducted-
 - (a) in the manner prescribed by the relevant authority; and
 - (b) with the person's written consent after being informed of the research objects and any possible effect on his health.
- (2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or investigation may only be undertaken-
 - (a) if it is in the best interest of the minor;
 - (b) in such manner and on such conditions as may be prescribed by the National Health Research Ethics Committee; and
 - (c) with the informed written consent of the parent or guardian of the minor
- (3) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be undertaken-
 - (a) in such a manner and on such conditions as may be prescribed by the National Ethics Committee; and
 - (b) with the informed written consent of the parent or guardian of the minor.

Section 33⁴⁰ which provides for the establishment and composition of the National Ethics Committee, includes 'one representative each of the Christian and Islamic faith'⁴¹. We believe that such inclusion points to the peculiarity of the Nigerian society in terms of religion and fails in its effort to accommodate other religious groups in the country. Section 48⁴² prohibits the removal of tissue, blood or blood product⁴³ from the body of another living person for any purpose except with the informed consent of the person from whom the tissue, blood or blood product is removed and obtained in the prescribed manner. Such permission may, however, be waived for medical investigations and treatment in emergency cases.

Section 49⁴⁴ provides for mandatory use of tissue removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed. Any contravention of this attracts a fine or imprisonment. It is, therefore, an offence for a person who has donated tissue, blood or a blood product to receive any form of financial reward except for the reimbursement of reasonable costs incurred by him to provide a such donation or to sell or trade-in tissue, blood, blood products except for reasonable payments made in appropriate health establishment⁴⁵.

Cloning

Whether we are willing to support human cloning for stem cell research arises in connection with a specific stem cell technology known as "human therapeutic cloning". It involves the deliberate creation of an embryo by somatic cell nuclear transfer technology (cloning) to produce an immunologically compatible cell line.⁴⁶

³⁹ Section 32, National Health Act 2014.

⁴⁰ National Health Act 2014.

⁴¹ Section 33(2)(f) of the National Health Act 2014.

⁴² National Health Act.

⁴³ The Interpretation Section 64, National Health Act 2014 defines "blood product" as any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells.

⁴⁴ National Health Act.

⁴⁵ Section 53, National Health Act 2014.

⁴⁶ Carlson (n8) 351.

Scientists have cloned stem cells from human skin and egg cells in the laboratory. This is significant because the process could eventually be used to produce organs or other parts that are genetically identical to the patient's own and, therefore, pose no risk of rejection when transplanted.⁴⁷ However, section 50⁴⁸ expressly prohibits reproductive, therapeutic cloning of humankind in Nigeria. Other restrictive provisions include sections 51, 52, 54, 55 and 56.⁴⁹

Other legal and ethical issues which could be triggered by stem cell research include:

- (i) Paternity rights,
- (ii) Ownership rights,
- (iii) Patent rights
- (iv) Religious and Superstitious considerations.

Challenges of Stem Cell Research in Nigeria

i. Commercialisation of access to therapeutic care⁵⁰

There is a tendency to commercialise access to stem cell research. The concern here is the protection of the weak and the voiceless in society. This is because the essence of stem cell research and therapy is to alleviate severe health challenges and provide cures for the debilitating disease. This brings to mind the need to determine whether the distribution of costs and benefits is fair and according to the principle of justice within the Nigerian context. This is primarily because, in Nigeria, the household is a significant source of finance for the health sector; about half of the Nigerians live below the poverty line. As a result, many cannot pay for health services at the first point of call, even before care is given. This situation has significant implications for the individual, the healthcare provider and society.

ii. Low or inadequate investment in stem cell research. It is noteworthy that Nigeria's level of investment in stem cell research is abysmally low. This is a worrisome development resulting in overreliance on foreign discoveries in that study area.

iii. Poor enforcement of ethical standards and provisions on Stem cell research.

It is essential to pay some attention to conflicts of interest. It has been argued⁵¹ Ethics is often relegated to the background when science is driven by profit maximisation. Ethics are then regarded not as guidelines for good research but rather as an obstacle to be overcome in the search for profit. However, as highlighted in the 2005 United Nations Task Force on Science, Technology, and Innovation report, domestic innovation must be targeted toward local health needs. Though communicable diseases constitute significant causes of mortality and morbidity in the country, there are reasons to believe that non-communicable diseases such as hypertension, diabetes mellitus, coronary and rheumatic heart disease, sickle cell disease, cancers, mental health, blindness, stroke, represent an increasing share of Nigerians' burden of disease. Stem cell research should therefore focus on preventive and treatment options. Furthermore, Nigerians must evaluate the

⁴⁷ Karl, T. 'Cloning Stem Cells: How to Grow Spare Parts' <<https://www.livescience.com/32079-how-stem-cloning-works-infographic.html>> accessed 11 July 2022.

⁴⁸ National Health Act 2014.

⁴⁹ *Ibid*

⁵⁰ Agbedia, C. and Oshegbo, G., 'The Challenges of Stem Cell Research in Nigeria' *International Journal of Advanced Nursing Studies* [2013] (2) (2) <https://pdfs.semanticscholar.org/6ff2/86cceb7e085d5e174aa661055fc3bbca9596.pdf?_ga=2.88362459.1340411971.1581688034-1865349820.1581688034> accessed 28 September, 2022.

⁵¹ Robertson, J.A., 'Compensation and Egg Donation for Research Fertility and Sterility' *National Library of Medicine* [2006] (86) (6), 1573-1575.

appropriateness of stem cell technologies within our national contexts and systematically identify and prioritise which applications are the most promising for improving the health of Nigerians. Finally, an ethical assessment of stem cell research projects must be done to ensure that the primary clause of the Helsinki Declaration (respected and the well-being of the human subject) is adhered to.

iv. Building capacity

There is a great and urgent need for capacity-building of health care professionals in stem cell research and therapy. In building build capacity, Nigeria must seek help from countries that have shown higher achievements in stem cell research and therapy. Brain drain in Nigeria is making a bad situation even worse. Health care professionals, especially nurses, are increasingly being lured by employment opportunities in more affluent countries. Additionally, there is the issue of "the internal brain drain," i.e. health professionals abandoning the public health sector for more lucrative and career-enhancing positions in the private health sector, foreign-funded health research projects, banks and medical positions within non-governmental organisations. Given this conundrum, a talent hunt strategy is a must to attract more talented young people to devote themselves to this life science area.

v. Appropriate and widespread advocacy for the use of stem cell therapy

Embryonic Stem Research is about rights to life, longevity and health; nurses must understand the biology of the process and its ethical issues. Understanding the scientific aspects will help nurses give patients a clear picture of the associated procedures and counsel those whose health will be improved and those who will not benefit from it. To become adequately informed about this advocacy role, everyone must become involved in the global issues of the day. In addition, there is a need to be familiarised with local and national political systems.

vi. Informed consent

In embryonic stem cell research, consent must be gained from both female and male donors. The main ethical challenge that nurses face is not whether the patient can give informed consent but the extent to which the consent form reflects the nature of the trials rather than the nature of the treatment procedure. The premise is that embryonic stem cell research is presented as holding out the hope to alleviate the suffering to the extent that the person giving the consent may influence it. Furthermore, the desperate situations of patients make it easier for a health worker to manipulate their opinions. The ethical rights of each patient group should be paramount in a health care environment. To guard couples going through IVF against intrusion or pressure from their doctor, it has been suggested that someone other than the doctor treating them should obtain consent. This is because the patients' values may undergo subtle manipulation by staff. In obtaining consent for clinical trials, nurses and any health worker who receives the consent must ensure the following: do a value clarification, be aware that their position of trust should not conflict with the patient's needs and be ready to support the final decision of the patients. Thus, returning autonomy to the patient through the process of empowerment. There is also the issue of confidentiality.

When tissue/eggs are donated, the donor usually remains anonymous but can be traced through a coded link to prove that the tissue was given with full consent. Conflict in confidentiality may occur in situations when embryos donated for research carry genetic abnormalities or microbial infections unknown to the donor. It becomes more complicated

- if a recipient later contracts a disease linked to the tissue. The question arises as to whether the donor should be told. Morally it is expected that those receiving donated tissue have a right to know that it is safe. In such situations, the nurse will need particular sensitivity in handling private and personal patient circumstances/issues to balance the clinical need and ethical choices. This is an attempt to avoid conflict in confidentiality.
- vii. Ensuring equal access to treatment despite the sporadic achievement of IVF activity already underway in Nigeria, one hopes that the issue of access will be seriously considered given the country's economic inequity and fragile healthcare structure. Chapman et al⁵² explained that "good access exists when patients can get the right service at the right time in the right place." An egalitarian approach implies that all persons should have access to innovative, novel and cost-effective means of treating disease and IVF. But in reality, some people may not benefit from embryonic stem cell research services through social circumstances, geographical location or other factors. The current cost of IVF in Nigeria may limit the clinical uses of this technique to the very wealthy. Health care injustice and inequality should be eradicated and advocated against by empowering the community on their right to care and calling the government's attention to inconsistency in providing health care resources at all levels. The responsibility to lessen this burden, therefore, rests with the government playing a stewardship role in putting up strategies to reduce out-of-pocket payments by removing public sector user fees and developing innovative ways to limit other health care costs (such as drug and transport costs), widen geographical access to health services and strengthening referral linkages.
- viii. Protecting the rights of women
While the embryonic stem cell debate has been preoccupied with the clinical and ethical advantages and disadvantages of embryonic stem cell research, its social impacts in sustaining the existing pattern of female oppression of women's rights to their eggs have been ignored. The argument is that women who donate ova or embryos are at risk of exploitation, given the enormous financial benefit to medical practitioners who appropriate their reproductive labour for research and commercial benefits. Moreover, women's body parts are at risk of being commoditised, and their acts of altruistic donation are demeaned if downstream users can develop commercial applications for stem cells generated from their ova and embryos. A related issue is a justification for financial incentives for women who donate eggs for research. Currently, there is a well-developed system for paying egg donors for infertility services. Logically, this should be extended to paying donors for eggs to be used in research. Yet there is excellent resistance to payment. This could be a grave issue for women because the procedure involves the injection of various compounds, such as hormones and can be uncomfortable and intrusive. The premise is that if a woman has had to pay for IVF treatment, she is entitled to some financial recompense for the egg donation. The argument here is that nurses must champion the course that women who donate eggs deserve to be paid for their efforts.
- ix. Regulation of clinical trial
There is weak regulation of research on human subjects, and the Federal government, through the Ministry of Health, has neglected strict regulation of medical research to guarantee that its goals benefit the citizenry.

⁵² WHO Preventing Chronic Diseases; A Vital Investment Geneva, Switzerland; WHO Press, 2005.

Conclusion and Recommendations

The need for stem cell research and therapy cannot be emphasised in the development of medicine worldwide. Through this, medical researchers have attained an increased understanding of how diseases occur and how to manage them. Healthy cells could be generated to replace diseased cells, and cells which have the potentials to be grown to become new tissues for use in transplant and regenerative medicine have become handy. This has provided cures for incurable ailments like sickle cell anaemia, cancer, bone marrow diseases and diabetes. Stem cell research holds enormous potential for the growth and development of medical research and cures. However, the medico-legal and ethical issues still constitute a significant concern in stem cell research and therapy, particularly in Nigeria.

Most ethical issues arise from personal convictions, morals, beliefs and sometimes superstitions. Unfortunately, the existing international legislation on stem cell research does not contain stiff sanctions for breach. In Nigeria, issues of stem cells are regulated in piecemeal legislations; under the National Health Act 2014, The Code of Medical Ethics in Nigeria 2008 and international best practices. In addition, there is a tendency to commercialise access to stem cell research and therapy. Similarly, inadequate investment in this area of research by government and agencies, poor enforcement of ethical standards and the need to build capacity.

Against the foregoing, it is recommended that:

- a) a comprehensive sui generis legislation on stem cell research, permissible conduct and sanctions for breach be made, taking into consideration the IVF and artificial cloning of cells currently practised in Nigeria and possible stem cell therapy procedures to be developed. Furthermore, in the countries where it is permitted, it should be placed under strict public control by a centralised authority - following, for instance, the pattern of the UK licensing body (the Human Fertilization and Embryology Authority).
- b) There should be increased funding for stem cell research and therapy, intense advocacy and enlightenment of the populace on the benefits of this area of research and therapy. This will help change the psyche of the people.
- c) Section 31 of the National Health Act, 2014 should be amended to remove the principle of federal character as a criterion in appointments to the National Health Research Committee. This could influence the Minister into choosing from tribes instead of the best hands in the required field.
- d) Section 33 (2) of the National Health Act 2014 should be amended to either delete paragraph (f) or include other sectors of beliefs in Nigeria; and subsection (3) of the same Act to increase the term of office of members of the National Health Research Ethics Committee to a renewable term of five (5) years. This is necessary owing to the long period required to achieve specialised research.