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AN EXAMINATION OF THE REGULATORY REGIME FOR STEM CELL TECHNOLOGY IN NIGERIA: CHALLENGES AND PROSPECTS

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Abstract

Stem cell technology offers hope and treatment for a wide range of diseases by replacing damaged cells with new ones derived from stem cells. Recent years have witnessed exponential advancements in clinical trials revolving around stem cell-based therapies. Stem cell technology holds enormous potentials for regenerative medicine. However, harnessing the potentials is bedevilled with challenges. A major limitation to the advancement stem cell technology in Nigeria is insufficient regulatory framework. The controversy surrounding stem cell technology stems primarily from **ethical, medical, legal and political concerns.** The sourcing of stem cells constitutes a major challenge regarding their use in animals and humans. Religious and traditional beliefs constitute a great hindrance to the application of stem cell technology in Nigeria. Other challenges include inadequate investment in stem cell technology, commercialization of access to therapeutic care, lack of awareness and inconsistent power supply. This paper examines the regulatory regime for stem cell technology in Nigeria and discusses the challenges and prospects. The methodology employed is the doctrinal approach; which focuses on the letter of the law rather than the law in action. In view of the growing need for stem cells for therapeutic uses globally, it has become imperative to fix these challenges.

Keywords: Stem Cell, Ethical, Legal, Regulatory Framework, Challenges, Prospects

1.1 Introduction

The emergence of stem cell technology has brought hope to the medical field with the opportunities that regenerative medicine offers. To this end, human embryonic stem cells can now be manipulated to cure some of the most debilitating diseases of our times. The ability to transform somatic cells into pluripotent stem cells will ease the objections by some people towards the use of embryo derived stem cells. However, due to global differences of opinion on stem cell research, it is almost impossible to come up with standardised and uniform rules that will govern the research around the world. While there is rapid and continued progress in the field of stem cell technology, Africa is lagging behind with respect to being actively involved, despite the enormous benefits the continent stands to get. Hence, very few African countries (South Africa, Nigeria, Egypt, Algeria, Morocco and Tunisia) are actively involved in stem cell research and technology.[1]

Goabaone[2] believes that to succeed in promoting stem cell technology in Africa, there is a need to understand the ethical and moral issues that constitute a hindrance to the research. There is also the need to generally enhance stem cell education among the ordinary people of the continent; and to grow stem cell research and technology in Africa. According to him, investment in stem cell research will also have economic benefits because diseases have a significant impact on the economy of the continent by impacting negatively on industrial workforce.

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[1] Goabaone, G., "Stem Cell Research in Africa: Legislation and Challenges", *Journal of Regenerative Medicine (2018),* 7:1 DOI: 10.4172/2325-9620.1000142, available at www. http://hdl.handle.net/11427/26855, accessed on May 17, 2024.
[2] Ibid.

South Africa is considered to be ahead of the rest of Africa in stem cell research and technology.[3] It is perhaps for this reason that other Africans suffering from blood and cancer related disorders regularly visit South Africa in search of medical care. Active research has been reported in some African institutions such as Netcare Femina Hospital in Pretoria South Africa, University of Pretoria and University Cape Town. In Nigeria, there are stem cell research centres in Lagos and Abuja; and recently, the Kaduna State University in collaboration with the University of Indonesia (Universitas Indonesia) and AMA Foundation is spearheading research and training initiatives in stem cell technology.[4]

Stem cells have been the subject of significant controversy over the years. The controversy surrounding the subject largely arises from the fact that obtaining new lines of human embryonic stem cells necessitates the destruction of human embryos. This has led to a divided debate. Proponents on one side argue for the immense potential of stem cell lines in advancing scientific knowledge; and more importantly, alleviating human suffering. On the other side, there is a strong emphasis on the value and respect for human life. Both sides have valid points to defend, resulting in an ongoing debate without a consensus till date. As a result, stem cell research and technology remain entangled in complex issues involving legality, ethics and politics. Nevertheless, despite the ethical dilemmas it presents, scientists continue to pursue the research due to its potential benefits.

Nigeria lacks comprehensive and precise laws specifically addressing stem cell technology. In Nigeria, stem cell technology is governed by the National Health Act 2014 which is a broad legislation that also governs medical research, biotechnology and bioethics. The loopholes created by the statute (which is not as detailed as that of South Africa) have made obvious the need for Nigeria to

[3] Ballo, R., et al "A New Class of Stem Cells in South Africa: Introducing Induced Pluripotent Stem Cells," *South African Medical Journal (2013)* 103: 16-17, available at www. researchgate.net/publication/328576606, accessed on October 16, 2025.

[4] Msue, A., 'Kaduna, Indonesia Universities, Foundation Partner on Stem Cell Research', *Leadership Newspaper* of Friday January 12, 2024 <www. leadership.ng >accessed on March 24, 2024.

develop a *sui generis* legislation for stem cell technology. It is not doubt that clear laws encourage responsible research, attract investment and can position Nigeria as a leader in the field of stem cell technology. Comprehensive regulations also guarantee that research is conducted ethically, protecting participants and maintaining public trust.

1.2 The Regulatory Regime for Stem Cell Technology in Nigeria

The First Wealth is Health[5], but regrettably, several provisions of Nigeria's National Health Act 2014 as presently constituted do not portray Nigeria as a 'serious' country with regards to matters of health. One would think that the Act, being a sector specific legislation should be a deliberate attempt at repositioning Nigeria's health system. Section 1 (1)[6] which established for the Federation the National Health System empowers the System in paragraph (c) to *'provide for persons living in Nigeria the best possible health services within the limits of available resources….'* One would wonder the reason for the definite mention of 'persons living in Nigeria', but the bigger question is whether the health services offered in Nigeria's public health institutions represent the best possible health services within the limits of the nation's available resources?

Section 4 (1)[7] establishes National Council on Health as the highest policy making body in Nigeria on matters of health while section 5(1) (a) of the same Act grants the Council the 'responsibility for the protection, promotion, improvement and maintenance of the health of the citizens of Nigeria, and the formulation of policies and prescription of measures necessary for achieving the responsibilities specified under this paragraph'. In view of the need to improve and maintain the health of the citizens of Nigeria and the enormous benefits of stem cell technology, the National Council on Health ought to be proactive in the discharge

[5] Ralph Waldo Emerson (1860), American Essayist, Lecturer, Philosopher and Poet.
[6] National Health Act 2014.
[7] Ibid.

of its functions and formulate policies aimed at harnessing the potentials in stem cell technology.

It is shocking that there is no mention of the term 'stem cell' in the entire gamut of the National Health Act 2014. This is contrary to the position in the National Health Act 2003[8] of South Africa wherein the term 'stem cell' appeared four times.[9] The National Health Act 2014 leaves Nigeria nowhere in matters relating to stem cell technology; the Act is at best a watered down legislation and this is at the heart of the problems and challenges of stem cell technology in Nigeria.

Section 31[10] provides for the establishment, composition, tenure and responsibilities of the National Health Research Committee. The Committee which shall reflect federal character is charged with the promotion of health research and collation and documentation of information on the research activities of public and private health establishments. The principle of federal character, though a reflection of Nigeria's heterogenous nature, is often a clog in the wheels of national development. It is our belief that in seeking to satisfy the federal character requirement, the Committee will be populated by persons representing regions instead of hiring the best hands for the job.

Section 32[11] declares that notwithstanding anything to the contrary in any other law, every research or experimentation on a living person shall only be conducted in the manner prescribed by the relevant authority and with the written consent of the person after he shall have been informed of the objects of the research or experimentation and any possible effect on his health. The interpretation section however does not define the expression *'relevant authority'*. And where the research or experimentation is to be conducted on a minor for a therapeutic purpose, it must be in the best interest of the minor, in such a manner and on such conditions as may be prescribed by the National Health Research Ethics

[8] Act No. 61 2003.
[9] See sections 56 and 57, National Health Act 2003.
[10] National Health Act 2014.
[11] Ibid.

Committee and with the informed written consent of the parent or guardian of the minor.[12] However, where the research or experimentation to be conducted on the minor is for non-therapeutic purpose, it may only be conducted in such manner and on such conditions as may be prescribed by the National Ethics Committee and with the informed written consent of the parent or guardian of the minor.[13]

Section 33[14] provides for the establishment, composition, function and tenure of the National Health Research Ethics Committee. The committee membership includes inter alia 'one representative each of the Christian and Islamic faith'.[15] Although there is the need for the locality of laws, it is worrisome that religion has become a predominant consideration and is often taken too far in our national life. This is regardless of the prohibition of State Religion by the Constitution of the Federal Republic of Nigeria, 1999 (As Amended)[16].
Section 48[17] prohibits the removal of tissue, blood or blood product[18] 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 obtained in the prescribed manner. Such consent may however be waived for medical investigations and treatment in emergency cases.

Section 49[19] 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.

[12] Section 32 (2) National Health Act 2014.
[13] Section 32 (3) National Health Act 2014.
[14] National Health Act 2014.
[15] Section 33 (2) (f) of the National Health Act 2014.
[16] Section 10 thereof.
[17] National Health Act 2014.
[18] 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.
[19] National Health Act 2014.

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 such donation or to sell or trade in tissue, blood, blood products except for reasonable payments made in appropriate health establishment[20].

The National Health Act 2014[21] prohibits reproductive and therapeutic cloning of human kind. The provisions of section 50 is a direct proscription of stem cell technology in Nigeria while section 51 also bans the removal and transplantation of human tissue except in a hospital and by a medical practitioner. Section 52[22] provides that only a registered medical practitioner or dentist may remove any tissue from a living person, use tissue so removed for any of the purposes stated in this Act or transplant tissue so removed into another living person or administer blood or a blood product to or prescribe blood or a blood product for a living person.

Section 53 of the Act makes it an offence for a person who has donated tissue, blood or a blood product to receive any form of financial or other reward for such donation except the reimbursement of reasonable costs incurred while providing such donation. It is also an offence to sell or trade in tissue, blood, blood products except for reasonable payments made in appropriate health establishments for the procurement of tissues, blood or blood products. Section 54 provides for the allocation and use of human organs obtained from deceased persons for transplantation, or treatment, or medical or dental training or research, stating that such organs shall only be used and allocated in the prescribed manner. The responsibility to carry out such prescription however rests with the National Tertiary Health Institutions Standards Committee

[20] Section 53, National Health Act 2014.
[21] Sections 50 and 51.
[22] National Health Act 2014.

Section 64 of the National Health Act 2014 defines some terms which relate to stem cell and are important 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 and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete.
vii. Therapeutic cloning- the manipulation of genetic material from adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues.

Article 12 of the World Medical Association Declaration of Helsinki 2013, which is applicable to Nigeria also provides that medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualification. Such research requires the supervision of a competent and appropriately qualified physician or other health care professional.

The legal framework for stem cell technology in Nigeria leaves much to be desired and this explains the attendant slow pace of advancement of the technology in the country. The operation and practice of stem cell technology in Nigeria is inhibited by our laws.

1.3 Benefits of Stem Cell Technology

Before now, adults suffering from the congenital blood disorder sickle cell anemia, which causes organ damage and crippling pain along with an increased

risk of stroke, had only two treatment options to help them cope with the disease: drugs and blood transfusions. A new stem cell transplant has proven to be revolutionary in reversing the effects of even the severe forms of this disease. Johns Hopkins University reported a high success rate in bone marrow transplant in adults with nine out of ten patients showing no side effects from the treatment. A research conducted by the Northwestern University, United States of America also suggests that stem cell therapy is successful in treating rheumatoid arthritis with the patient experiencing tremendous relief from the symptoms like morning stiffness and pain[23]. Doctors and scientists have successfully used stem cells to help with oral problems like the decay of enamel on the teeth or to treat gums. Stem cells can also be used to create hepatocytes[24] which make up most of the cells in the liver, treat Parkinson's disease, multiple sclerosis[25] and several other medical conditions. Stem cell therapy has had positive results when used to regenerate the myelin[26] lost in patients affected with multiple sclerosis. These therapies have the potential to help millions.

There are a number of arguments in favour of and against human embryonic stem cell research as explored hereunder. The Australian Legislation Review Committee Report, otherwise known as the Lockhart Report[27] is a veritable source

[23] National Research Council 'Guideline for Human Embryonic Stem Research' 2005 cited in Agbedia, C. and Oshegbo, G., "The Challenges of Stem Cell Research in Nigeria" *International Journal of Advanced Nursing Studies,* 2 (2) (2013), available at <https://pdfs.semanticscholar.org/6ff2/86cceb7e085d5e174aa661055fc3bbca9596.pdf?_ga=2.88362459.1340411971.1581688034-1865349820.1581688034>, accessed on June 24, 2024.

[24] The hepatocyte is an important cell type in parenchymal tissues of the liver and involves in many liver functions, such as detoxification, carbohydrate metabolism, lipid metabolism, secretion of albumin, clotting factors and complements.

[25] Multiple sclerosis is a chronic, progressive disease involving damage to the sheaths of nerve cells in the brain and spinal cord, whose symptoms include numbness, impairment of speech and of muscular coordination, blurred vision, and severe fatigue, available at Definitions from Oxford Languages, accessed on June 9, 2024.

[26] A mixture of proteins and phospholipids forming a whitish insulating sheath around many nerve fibres, which increases the spread at which impulses are conducted, available at Definitions from Oxford Languages, accessed on June 9, 2024.

[27] This is an Australian government report written by an independent legislation review committee that contains important and comprehensive review of the Australian legislation relating to human

of these discussions, as many submissions to the Inquiry raised these arguments and dealt with them in the report. Most of the arguments are universal and thus relevant in this article.

Several stem cell therapies are possible with the development of stem cell research. There are several reports that have reviewed the outcome of the use of different types of stem cells in various clinical trials[28]. A few examples of stem cell technology cover spinal cord injury[29], glaucoma[30], cardiovascular disease[31], diabetes[32], liver injuries[33], corneal disease[34], osteoarthritis[35], graft-versus-host disease[36] and more recently therapeutic strategies for the management of COVID-

cloning and research involving human embryos, that is, the Prohibition of Human Cloning Act 2002 (PHC Act 2002) and the Research Involving Embryos Act 2002 (RIHE Act 2002).

[28] Kabat, M., et al: 'Trends in Mesenchymal Stem Cell Clinical Trials 2004-2018: Is Efficacy Optimal in a Narrow Dose Range?' *Stem Cells Translational Medicine (2020)* Volume 9, pp 17-27, available at www.https://doi.org/10.1002/sctm.19-0202, accessed on October 16, 2025.

[29] Shroff, G. and Gupta, R.: 'Human Embryonic Stem Cells in the Treatment of Patients with Spinal Cord Injury'. *Annals of Neurosciences (2015)*, 22 (4), pp. 208–216, available at www.https://dx.doi.org/10.5214/ans.0972.7531.220404, accessed on October 16, 2025.

[30] Zhou, S. et al. 'Differentiation of Human Embryonic Stem Cells into Cone Photoreceptors Through Simultaneous Inhibition of BMP, TGFβ and Wnt Signaling'. *Development (2015)* 142 (19), pp. 3294-306, available at www.https://pubmed.ncbi.nlm.nih.gov, accessed on June 7, 2025.

[31] Shiba, Y. et al.: 'Human ES-Cell Derived Cardiomyocytes Electrically Couple and Suppress Arrhythmias in Injured Hearts'. *Nature (2012)*, 489 (7415), pp. 322–325, available at www.https://doi.org/10.1038/nature11317, accessed on October 16, 2025.

[32] Bruin, J.E. et al: 'Treating Diet-Induced Diabetes and Obesity with Human Embryonic Stem Cell-Derived Pancreatic Progenitor Cells and Antidiabetic Drugs'. *Stem Cell Reports (2015)*. 4 (4), pp. 605–620, available at www.https://doi:10.1016/j.stemcr.2015.02.011, accessed on October 16, 2025.

[33] Avior, Y. et al: 'Microbial-Derived Lithocholic Acid and Vitamin K2 Drive the Metabolic Maturation of Pluripotent Stem Cells Derived and Fetal Hepatocytes'. *Hepatology (2015)*, 62 (1), pp. 265–278, available at www.https://doi:10.1002/hep.27803, accessed on October 16, 2025.

[34] Mahla, R.S.: 'Stem Cells Applications in Regenerative Medicine and Disease Therapeutics.' *International Journal of Cell Biology (2016),* available at www.https://doi10.1155/2016/ 6940283, accessed on October 17, 2025.

[35] Yubo, M., et al: 'Clinical Efficacy and Safety of Mesenchymal Stem Cell Transplantation for Osteoarthritis Treatment: A Meta-Analysis (2017), available at www.https:doi:10.1371/journal.pone.0175449, accessed on October 17, 2025.

[36] Zhao, L., et al: 'The Role of Mesenchymal Stem Cells in Hematopoietic Stem Cell Transplantation: Prevention and Treatment of Graft-Versus-Host Disease'. *Stem Cell Research and Therapy (2019)*10, pp 182*,* available at www.https://doi:10.1186/s13287-019-1287-9.

19 patients[37]. Stem cell technology has the potential to improve and accelerate drug screening, drug discovery, and pre-clinical assessment of new drugs[38]. Researchers and doctors hope stem cell research can help to:

1. Increase understanding of how diseases occur. By watching stem cells mature into cells in bones, heart muscle, nerves, and other organs and tissue, researchers and doctors may better understand how diseases and conditions develop.
2. Generate healthy cells to replace diseased cells (regenerative medicine). Stem cells can be guided into becoming specific cells that can be used to regenerate and repair diseased or damaged tissues in people. People who might benefit from stem cell therapies include those with spinal cord injuries, type-1 diabetes, Parkinson's disease, amyotrophic lateral sclerosis, Alzheimer's disease, heart disease, stroke, burns, cancer and osteoarthritis.
3. Stem cells may have the potential to be grown to become new tissue for use in transplant and regenerative medicine. Researchers continue to advance the knowledge on stem cells and their applications in transplant and regenerative medicine.
4. Test new drugs for safety and effectiveness. Before using investigational drugs in people, researchers can use some types of stem cells to test the drugs for safety and quality. This type of testing will most likely first have a direct impact on drug development first for cardiac toxicity testing[39].

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[37] Leng, Z., et al. 'Transplantation of ACE2-Mesenchymal Stem Cells Improves the Outcome of Patients with COVID-19 Pneumonia'. *Aging and Disease (2020)*, 11, pp 216-28, available at www.https://doil:10.14336/AD.2020.0228, accessed on October 17, 2025.

[38] Satish, S.K., et al, 'Stem Cells: A Model for Screening, Discovery and Development of Drugs. *Stem Cells Cloning* (2011), available at www.https://doi:10.2147/SCCAA.S16417, accessed on October 17, 2025

[39]Mayo Clinic, Stem Cells: What They Are and What They Do, <https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stemcells/art-20048117> accessed on November 11, 2019.

1.4 Challenges of Stem Cell Technology

This segment examines the challenges hindering the advancement of stem cell technology. Unclear legislations constitute a major setback to the growth of stem cell technology in Africa generally, and Nigeria in particular. It is also critical to explore ethical, philosophical and religious perspectives in order to formulate rules and establish regulations that respect the dignity and fundamental human rights of individuals[40].

Besides the global challenges to stem cell technology, the following are peculiar to Nigeria:

i. Belief System

Religious and traditional beliefs constitute a great hindrance to stem cell application in Nigeria. It is not in doubt that the human body is associated with some level of sacredness; which fact hinders the advancement of therapeutic research involving the human parts. The umbilical cord which for instance is seen as a disposable biological by-product owing to cultural beliefs; could have been harvested during delivery and kept in the cord blood bank for research and treatment purposes[41]. Cultural beliefs, no doubt have a massive impact on the perception and use of stem cells in Africa. In some African cultures, there is a level of sacredness attached to the human body which hinders research involving the use of body parts. For instance, some African tribes continue to bury the umbilical cord of a newly born child believing that this will prevent any spiritual

[40] Frazzetto, G.: 'Embryos, Cells and God'. *EMBO Reports*, 5 (6), pp 553-555, cited in 'Medico Legal and Ethical Study of Stem Cell' Research in India Srivastava, K., ANVESHA- *A Multidisciplinary E- Journal for all Researches (2004)* Vol. 1, June 2022, page 63, available at www.anveshaejournal.com, accessed on April 8, 2024.

[41] Olayanju, A.O. et al, 'Cord Blood Banking: The Prospects and Challenges of Implementation in Nigeria.' *Hematology and Transfusion International Journal (2017)*; 5(4):273-278, available at www. https://doi:10.15406/htij.2017.05.00126, accessed on October 17, 2025.

influence upon the child[42]. This position partly represents the culture of the Igbo people of South Eastern Nigeria.

ii. Commercialization of access to therapeutic care[43]

There is the tendency of commercializing access to stem cell technology. The concern here is the protection of the weak and the voiceless in the society. This is because the essence of stem cell research and therapy is to alleviate serious health challenges and provide cures for debilitating disease. This brings to mind the need to determine whether the distribution of costs and benefits is actually fair and according to the principle of justice within the Nigerian context. This is mostly because in Nigeria, the household is a major source of finance for the health sector and about half of the population of Nigerians live below the poverty line. Many are unable to pay for health services at the first point of call even before care is given. This situation has great implication on the individual, the healthcare provider and the society.

iii. Low or inadequate investment in stem cell research and technology

It is noteworthy that the level of investment in stem cell research and technology in Nigeria is abysmally low. This is a worrisome development resulting in over reliance on foreign discoveries in that area of study.

iv. Poor enforcement of ethical standards and provisions on stem cell technology

It is important to pay some attention to conflicts of interest. It has been argued[44]that when science is driven by profit maximization, ethics is often relegated into the background. Ethics are then regarded not as guidelines for good research, but rather as an obstacle to be overcome in the search for profit.

[42] Oosthuizen, H, 'Legal and Ethical Issues in Stem Cell Research in South Africa'. In Beran R Legal and Forensic Medicine. Springer, Berlin, Heidelberg, (2013), available at www.https://researchgate.net, accessed on October 17, 2025.

[43]Agbedia, C. and Oshegbo, G., (n 23).

[44]Robertson, J.A., 'Compensation and Egg Donation for Research Fertility and Sterility', *Science Direct,* Vol 86 No 6 (2006); 1573-1575, available at https://punmed.ncbi.nlm.nih.gov, accessed on June 28, 2023.

However, as highlighted in the 2005 report of the United Nations Task Force on Science, Technology, and Innovation, domestic innovation must be targeted towards local health needs. Though communicable diseases constitute major 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, and stroke, represent an increasing share of Nigerians' burden of disease. Stem cell research should therefore focus on preventive and treatment options. Nigerians must evaluate the appropriateness of stem cell technologies within our own national contexts and systematically identify and prioritize which applications are the most promising for improving the health of Nigerians. In all it is important that ethical assessment of stem cell research projects must be done to ensure that the basic clause of the Helsinki Declaration (respected and the well-being of the human subject) is adhered to.

v. Building capacity

There is a great and urgent need for capacity-building of health care professionals in stem cell research and technology. In building build capacity, Nigeria must seek help from countries that have shown higher levels of achievements in stem cell research and therapy. Brain drain in Nigeria is making a bad situation even worse as 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 organizations. Given this conundrum, a talent hunt strategy is a must to attract more talented young people to devote themselves to this area of life science.

vi. Need for appropriate and widespread advocacy for use of stem cell technology

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 to give patients a clear picture of the associated processes as well as counsel those whose health will be improved and those who will not benefit from it. To become adequately informed for this advocacy role, everyone must become involved in the global issues of the day. There is a need to familiarise with local and national political systems.

vii. 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 is able to give informed consent but the extent to which the consent form reflects the nature of the trials rather than 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 the giving of it. Furthermore, the desperate situations of patients make it easier for 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 the 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 obtains the consent must ensure the following: do a value clarification, be aware that their position of trust should not be in 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 code link to prove that the tissue was given with full consent. Conflict in confidentiality may occur in situations when embryo donated for research carry genetic abnormalities or microbial infections unknown to the donor. It becomes more complicated if a recipient later contracts

a disease that is 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 special sensitivity in handling private and personal patient circumstances/issues to balance clinical need and ethical choices. This is an attempt to avoid conflict in confidentiality.

viii. Ensuring equal access to treatment despite the sporadic achievement of IVF activity already underway in Nigeria, one hopes that the issue of accesses will be seriously considered given the country's economic inequity and fragile healthcare structure.

Chapman et al[45] 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 accesses to innovative novel and cost-effective means of treating disease and IVF. But in reality, some people may not benefit from embryonic stem cell technology services through social circumstances, geographical location or other factors. The current cost of IVF in Nigeria may make the clinical uses of this technique to be limited to the very wealthy. The health care injustice and inequality should be eradicated and advocated against by empowering the community on their right to care and calling attention of the government to inconsistency in the provision of health care resources at all levels. The responsibility to lessen this burden therefore rests with the government playing a stewardship role to put up strategies to reduce out-of pocket payments by removing public sector user fees, develop innovative ways to limit other health care costs (such as drug and transport cost), widen geographical access to health services and strengthening referral linkages.

[45]WHO Preventing Chronic Diseases; *A Vital Investment Geneva, Switzerland*; WHO Press, 2005.

ix. Protecting the rights of women

While the embryonic stem cell debate has been pre-occupied with the clinical and ethical advantages and disadvantages of embryonic stem cell technology, its social impacts in sustaining existing pattern of female oppression of the rights of women to their own eggs have been ignored. The argument here is that women who donate ova or embryos are at risk of exploitation in view of the huge 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 commoditized, and their acts of altruistic donation demeaned, if downstream users can develop commercial applications for stem cells developed from their ova and embryos. A related issue is the justification for financial incentive for women who donate eggs for research. Currently, there is a well-developed system for paying egg donors for infertility services and this should be extended to paying donors for eggs to be used in research as well. It is noteworthy that there is great resistance for payment. This could be a grave issue for women in that, 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.

x. Regulation of clinical trial

There is weak regulation of research on human subjects or better put the Federal government through the Ministry of Health has neglected strict regulation of medical research to guarantee that their goals benefit the citizenry.

Other challenges of stem cell technology in Nigeria include:

1. Lack of Awareness

In a study done on the awareness of bone marrow transplant for the treatment of sickle cell anaemia in tertiary health centres across some states in Nigeria, 64.5% of the respondents were not aware that bone marrow transplant can be used; this

percentage is low when compared to reports from developed countries[46]. Another major challenge is getting donors and this is due to low or lack of awareness.

2. Inconsistent Power Supply

Another major challenge facing companies, organizations and the health sector in Nigeria is unreliable and epileptic power supply. Stem cell research and banking obviously requires constant electricity supply to maintain and preserve the cells in the bank. For effective utilization of a stem cell therapy machines, there ought to be uninterrupted power supply. In a situation where there is no constant power supply it is impossible to store stem cells in the bank. As a result of the fluctuations of electricity, electrical devices that are used could even be damaged. In the case of private organizations that use either gas or fuel to power their electricity generating sets, they will incur more expenses.[47]

3. Shortage of Trained Personnel and Poor Funding

Medical stem cell therapy is a novel therapy which up till now, is not readily available in Nigeria and with very limited trained personnel. In Nigeria, the number of medical personnel such as the Medical Laboratory scientists, doctors, nurses, and other medical related professionals trained in stem cells technology are insignificant when compared to the country's population. Also, the statistics of health care growth in Nigeria is poor despite various commitment being made to fund the health sector. The advancement of medical research in Nigeria is slow due to poor funding in this area. This inadequate trained professional is obviously

[46] Kirby T., 'Nigeria's Bone Marrow Registry Offers New Hope to Patients'. World Report. 2012;379(9832): 2138, cited in Ogwunja, C., et al, 'The Review of Stem Cell Therapy in Nigeria: The Way Forward', *Journal of Complementary and Alternative Medical Research* 14(3): 7-17, 2021; Article no. JOCAMR.68516 ISSN: 2456-6276, available at www. researchgate.net/publication/ 352379897, accessed on May 17, 2024.

[47] Nwagu, M.U., et al, 'Cost and Financial Challenges of Accessing Bone Marrow Transplantation: Opinion Survey in a Nigerian Tertiary Institution.' *Asian Hematology Research Journal*. 2020;3(2):18-26 accessed on May 17, 2024.

traceable to poor or lack of funding for the training in this area of medicine, coupled with the brain-drain syndrome that has confronted the medical sector[48].

4. Inadequate Facilities and Building

The huge cost of purchasing and maintenance of facilities needed for stem cell technology poses another challenge. In most hospitals and laboratories in Nigeria, poor maintenance culture also affects the machines used. Stem cell research centres in Nigeria are in Lagos and Abuja. The insufficient number of stem cell centres make assessment of stem cells almost impossible as individuals will have to spend extra cost transportation to any of these two states. Besides purchasing standard equipment, it is also important to have backups for the equipment needed for stem cell therapy. It is also important to ensure that the diagnostic unit of the centre is standard particularly the Laboratory and Radio imaging technique.

5. Cost of Stem Cell Therapy

Accessibility also constitutes a major challenge for stem cell transplant in Nigeria, which is a result of lack of insurance coverage from government or private funds. In 2011, commendable efforts were made in pioneering Bone Marrow Transplant (BMT) at the University of Benin Teaching Hospital (UBTH), Nigeria. However, this procedure could not be sustained at the UBTC because of lack of political will from the Nigerian government. Presently, the cost of BMT which is done in only one private Hospital in Nigeria is a little above Thirty Nine Million Naira (39 Million Naira which is about 26000 USD)[49]. Drugs for stem cell therapy are very expensive to acquire in developing countries like Nigeria and the process of importing drugs into the country has proven difficult throughout the years.

[48] Nwannadi, I.A., et al, 'Umbilical Cord Blood Donation and Banking: Awareness Among Pregnant Women, in Makurdi, Nigeria', *Journal of Dental and Medical Sciences* 2014;13(1):16–19.

[49] See Nwagu MU, et al, "Cost and Financial Challenges of Accessing Bone Marrow Transplantation: Opinion Survey in a Nigerian tertiary institution." *Asian Hematology Research Journal*. 2020;3(2):18-26, (n. 47).

The global challenges of stem cell research and technology include:

1. Ability to introduce Tumor or Cancerous Cells

Aside from ethical problems regarding the source of embryonic stem cells, the greatest obstacle to clinical use of human embryonic stem cells-based therapy is safety concerns. The pluripotency that allows human embryonic stem cells to create hundreds of distinct cell types also makes them challenging to manage after in vivo transplantation. Teratomas, tumours that possess all three germ layers, may arise if undifferentiated human embryonic stem cells are implanted.[50]

Another major challenge facing stem cell research is the understanding of the mechanism of stem cell differentiation. That is, how can scientists be so sure that stem cells will form whatever tissue or organ they are induced to form inside the body and not something else. How can this be guaranteed? When cells are transplanted, their growth may become too difficult to control and these cells then develop into tumour cells in the patient. This possibly explains why in Tunisia for instance, the use of human embryos is ethically disapproved. Normally, if a fertilized egg is implanted into a uterus, it has the potential to develop into a genetically unique human being with genetic attributes. Similarly, some Muslims and Christians in Africa shun the use of embryo derived stem cells because they deem it unethical to cut short the right of an embryo to develop into a baby[51].

Klimanskaya[52] noted that stem cells transplant can introduce tumour and cancerous cells. Cancer and tumor are consequences that occur when cells divide abnormally. The challenge for scientists is to find a balance between directing cell growth into specialized tissues that can replace damaged ones and ensuring that cells do not excessively grow and become cancer cells[53].

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[50] Volarevic, V., et al., 'Ethical and Safety Issues of Stem Cell-Based Therapy.' *International Journal of Medical Sciences (2018)*, 15(1), pp 36–45.

[51] Nisbet, M.C.'The Polls-Trends: Public Opinion about Stem Cell Research and Human Cloning', *Public Opinion Quarterly (2004)* 68: 131-154.

[52] Klimanskaya I., et al, Human Embryonic Stem Cell Lines Derived From Single Blastomeres. *Nature (2006)*; 444:481-485.

[53] *Ibid.*

2. Immunological Rejection

This has over the years posed a serious challenge to successful stem cell transplants. Most times, a patient's immune system recognizes the transplanted stem cells as foreign and attacks them. In this case, drugs termed as immunosuppressive are given to recipients of the transplant to reduce the chances of rejection; this leaves the patient vulnerable to infection by any other viruses or microbes in the environment[54]. Other challenges include the recognition and proper isolation of stem cells from a patient's tissues and a major obstacle to successful stem cell transplantation is immunological rejection[55].

3. Identification of Stem Cells in Adult Tissues

Ogwunja[56] opined that another major challenge that continues to overwhelm scientists and researchers is the identification of stem cells in adult tissues. Adult tissues contain different types of cells, and this makes it difficult to locate stem cells in tissues that could contain thousands of different cells. The research involved is complex and even after cells are isolated, the process to successfully trigger differentiation into the desired cell type is usually a huge challenge for researchers. This requires an understanding of stem cell control and regulation that has yet to be fully gained[57].

As noted earlier, the good side of stem cell technology is that it has aided the understanding of causes of some diseases which has led to the development of novel therapies that aim to treat the underlying causes of illness rather than just its symptoms.

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[54] Ikehara, S., Grand Challenges in Stem Cell Treatments. Frontiers in Cell and Developmental Biology. 2013;1(2):1-2, available at www.https://doi:10.3389/fcell.2013.00002, accessed on October 17, 2025.

[55] Zakrzewski, W. et al. 'Stem Cells: Past, Present, and Future.' *Stem Cell Research Therapy (2019)*, 10 (68), available at www.https://doi:101186/s13287-019-1165-5, accessed on October 17, 2025.

[56] Ogwunja, C., et al, 'The Review of Stem Cell Therapy in Nigeria: The Way Forward,' *Journal of Complementary and Alternative Medical Research* 14(3): 7-17, 2021; Article no. JOCAMR.68516 ISSN: 2456-6276, available at www. researchgate.net/publication/ 352379897, accessed on May 17, 2024.

[57] *Ibid.*

Nigerians have surely faced excruciating pain in the healthcare industry throughout the years as a result of inadequate medical care and poor governance of healthcare institutions. This resulted in a shortage of stem cell therapy in the country a few years ago, despite the fact that other nations across the world were adopting this technology as a trend. In 2011, the first stem cell transplant on a seven (7) year-old child with sickle cell anaemia was a resounding success at the University of Benin Teaching Hospital (UBTH). Six successful stem cell transplants for sickle cell disease have been reported, and the first stem cell transplant using the Spectra Optia Apheresis machine was performed in July 2019 on a sixty-two (62) year-old patient with multiple myeloma[58].

As a consequence of these heart-warming achievements, the Nigerian government grew more interested in establishing several stem cell transplantation centres around the country. Seun Adebiyi, a leukaemia survivor, and his colleagues established the Bone Marrow Registry, Nigeria (BMRN) in 2012 as a significant step towards improving the global recovery statistics of Africans with blood disorders[59]. To expand the horizon of genetically diverse stem cell donors from Nigeria, BMRN plans to start the first umbilical cord blood bank in Africa thereby supporting Haematopoietic Stem Cell Transplantation (HSCT).

1.5 Conclusion

The capacity of stem cells to convert into many types of cells within the body is astonishing.

Notwithstanding the legal, ethical, financial, social, political, and religious challenges facing stem cell therapy in Nigeria, there is still hope for the nation's health sector to strive past these hurdles only if priority is placed on the well-

[58] Enogholase, G., 'Doctors in Benin Based Private Hospital Perform Stem Cells Transplant', *Vanguard Newspaper* of July 11, 2019, www.vanguardngr.com, accessed on October 17, 2025.

[59] Kirby, T. 'Nigeria's Bone Marrow Registry Offers New Hope to Patients.' *World Report.* 2012;379(9832): 2138, available at www.https://doi:10.1016/S0140-6736(12)60929, accessed on October 17, 2025.

being of citizenry rather than on the search for profit. In the course of this research, it was discovered that:

1. There is no comprehensive legislation dedicated to regulating stem cell research and therapy in Nigeria. The National Health Act 2014 and the Code of Medical Ethics of Nigeria 2008 do not contain clear, definite and decisive provisions on the regulation of stem cell technology in Nigeria. It is fundamental that the National Health Act 2014 fails to mention the term 'stem cell' throughout the entire legislation. Further to this is the limitation posed by the Act[60] in its prohibition of reproductive and therapeutic cloning of human kind. These shortcomings negatively impact the advancement and regulation of stem cell technology in Nigeria and can enable unethical practices in the field.
2. The poor funding and inadequate public awareness about stem cell technology and its potential benefits also hinder its adoption. Inadequate funding for research and development of stem cell technology constitutes a significant barrier, coupled with poor investment in the research, poor infrastructure, including inadequate laboratory facilities and equipment and shortage of trained professionals in the field which is compounded by the brain drain syndrome.
3. The cultural and religious values in Nigeria constitute another hindrance to the regulation of stem cell research and therapy, particularly regarding the use of embryonic stem cells. Some individuals and groups hold strong beliefs about the sanctity of human life, thus hampering research involving embryos or foetal tissue. Religious and cultural beliefs constitute a major limitation to the practice of stem cell technology in Nigeria. It is understandable that discussions regarding the human body are often associated with a high degree of sacredness; but the fact is that it limits the

[60] See section 50.

advancement of therapeutic research involving the human parts is worrisome.[61]

4. Section 31 of the National Health Act, 2014 which promotes the principle of federal character as a criterion for appointments into the National Health Research Committee could be counterproductive instead of seeking the best hands for the job. Section 33 (2) (f) of the National Health Act 2014 also appears to neglect other sectors of beliefs in Nigeria. Also, there is need to increase the term of office of members of the National Health Research Ethics Committee and make it renewable in view of the fact that some researches would require lengthy periods.

The ultimate question that should be asked is, is there any way out of the findings noted above? Undoubtedly, the situation adversely impacts the growth of stem cell technology in Nigeria and enables unethical practices in the field. From the foregoing discussion, it is believed that the following suggestions will help Nigeria achieve better regulation of stem cell technology, if implemented:

1. Enactment of (or an amendment of the National Health Act 2014, to ensure) a comprehensive *sui generis* legislation containing clear and definite provisions on stem cell technology in Nigeria, with permissible conducts and sanctions for breach stated, taking into considerations the in vitro fertilization (IVF) procedure, artificial cloning of cells, bone marrow transplant etc currently practiced in Nigeria and possible stem cell therapeutic procedures to be developed. We are of the view that a good piece of legislation is critical to the advancement of every sector of our national life and the National Health Act 2014 as presently constituted is inadequate. In the countries where stem cell technology is permitted, it is placed under strict public control by a centralized authority, following for instance, the pattern of the

[61] Olayanju, A.O. et al, (n. 41). See also Oosthuizen, H (n. 42).

United Kingdom licensing body - the Human Fertilization and Embryology Authority.

2. Increased public awareness and funding for stem cell technology. This will enable Nigeria harness its potential benefits and eliminate all hindrances to its adoption and growth. Advocacy will help in eradicating the hitch that traditional beliefs have imposed on stem cell technology in Nigeria. This can be achieved by enlightening everyone especially those in the rural areas and highly populated places like offices, markets, hospitals and schools on the gains of stem cell technology. Increased funding for stem cell technology and therapy, intense advocacy and enlightenment of the populace on the benefits of this area of research will no doubt help change the psyche of the people.
3. Nigerian government could harness stem cell research as a tool to boost its economy, by setting up more stem cell research centres across the country and expertise brought in from developed countries, with the aim of harbouring one of the largest stem cell centres that can cater for citizens and non-citizens. As most Africans are known for having lots of children especially in some parts of Nigeria where it is fashionable and symbolises one's status[62]. About five (5) million children are born yearly in Nigeria[63] It is therefore a huge potential to invest in cord blood banking as the stem cells isolated from them can serve as immune modulatory cells, used for bone regeneration. A donor registry and cord blood banking will open a revenue for improving the Nigerian economy.

It is also recommended that Section 31 of the National Health Act, 2014 should be amended to remove the principle of federal character as a criterion in appointments into the National Health Research Committee as this could influence the Minister into choosing from tribes instead of the best hands in the

[62] Nigeria - Families in Nigeria – Poverty, Family, and Children, available at JRank Articles <https:search.app/1PRcjdbuNxdjo2ea6, accessed on 28th May 2021.
[63] Nwannadi, I.A., et al, (n. 48).

required field to deliver on the job. it Furthermore, section 33 (2) of the National Health Act 2014 should also be amended to either delete paragraph (f) or include other sectors of beliefs in Nigeria; and section 33 (3) of the same Act also amended 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 of time required in achieving specialized researches of this nature.