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Quest for Legislative Intervention in Stem Cell Research and Therapy in Nigeria: Lessons from United Kingdom and South Africa

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Summary

Introduction: Stem cell research, which examines the therapeutic applications of human stem cells for disease treatment, is actively conducted worldwide. In response to this, many jurisdictions have developed regulatory frameworks that define permissible stem cell applications and establish mechanisms for compliance. Nigeria is yet to enact such laws, though reports indicate that a small number of stem cell research centres do operate in the country. In the absence of regulation, unethical practices may thrive. This study examined regulatory approaches to stem cell research in the United Kingdom (UK) and South Africa and assessed stakeholder perspectives on stem cell research in Nigeria.

Materials & Methods: The study adopted a qualitative approach and a multi-stage recruitment strategy to identify and document the opinions of 30 stakeholders from Lagos, Oyo, and the Federal Capital Territory (FCT), using in-depth and key informant interview guides.

Results: The study found that a permissive legal framework, strictly implemented, has enhanced stem cell research in the UK, while South Africa has a more liberal framework that is not strictly implemented. The latter has encouraged unethical practices leading to increased stem cell tourism in South Africa. Findings from stakeholders in Nigeria showed apathy towards stem cell research among some, although the majority supported its practice in Nigeria subject to necessary regulation.

Conclusion: Based on the study's findings, a permissive legal regime is preferable to a restrictive one for stem cell research in Nigeria, provided it is supported by clear enforcement and effective regulatory oversight.

Keywords: Biomedical Research, Cell and Tissue Based Therapy, Humans, Nigeria, South Africa, Stem Cell Research.

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INTRODUCTION

Many recent technological advancements have focused on resolving health-related challenges. This is in part due to the increased prevalence, in the twenty-first century, of diseases and debilitating conditions such as Parkinson's disease, neurological disorders, cancers, diabetes, cardiovascular diseases, and vision impairments, among a host of others. While various modes of treatment have, to an extent, succeeded in treating them, it has been discovered that stem cell therapy can be very effective in the management and cure of some of these diseases. Stem cells possess the unique ability to self-renew and differentiate into numerous specific cell lineages, and expansive stem cell therapy research has, over the years, revealed amazing treatment options for regenerative diseases, injuries, and other body system malfunctions. Recent advances in medical and biological technologies have paved the way for the increasing success of stem cell therapy, the continued success of which necessitates ongoing stem cell research [1, 2].

Stem cell research refers to investigation into the use of human stem cells as a treatment, prevention, or intervention for debilitating diseases and health conditions. It is also described as research conducted on cells obtained from the inner cell mass of an embryo at a very early stage of development [3, 4]. Irving [5] describes stem cell research as that carried out on primordial cells of a human being which are capable of becoming all or many of the 210 different kinds of tissues in the human body. It has also been defined as research that enables inquiry into how undifferentiated cells with the ability to self-replicate for indefinite periods self-replicate into any cell type in the human body. Stem cells can be derived from a number of sources, including foetal tissue or embryonic tissue obtained from human tissue after an abortion; human embryos formed through in-vitro fertilisation; umbilical cord blood obtained from a neonate; cloned chimera embryos formed through human somatic cell transfer; and adult cells derived from human bone marrow, blood, or skin [6].

Embryo stem cell research has generated considerable controversy over the years, for many reasons. First, it sets the quest for medical knowledge, through biomedical research, against the ethical obligation to safeguard all forms of human life, albeit early human life. Second, this type of research raises questions as to what constitutes a human person, and the ultimate value of human beings. It also highlights the nature of the duties owed to humans and the rights bestowed on them as they advance through the different stages of life [7].

In Nigeria, stem cell research is gradually gaining popularity and acceptance, despite being hampered over the years by cultural and religious beliefs [8]. This acceptance is promoted by a gradual increase in understanding of the manifold potential benefits of such research. Stem cell research as it is currently conducted in Nigeria is regulated by the National Health Act of 2014, which makes very few provisions for stem cell research itself. In the absence of laws governing such research, the development of an ethical code of conduct may be helpful for researchers. However, this may not be sufficiently detailed to address legislative gaps. As observed by Slabbert et al. [9], despite the existence in many countries of regulations governing research with human subjects, as well as medical malpractice and licencing laws in some jurisdictions, guidelines in general are not specific to stem cell therapy. In reaction to the adverse events arising from unfounded claims in stem cell research, the scientific community has risen to the challenge of developing guidelines for stem cell research; however, not everybody abides by these [10].

In instances of legal adjudication on matters relating to stem cell research and practice, issues can only be determined where there are detailed regulations on stem cell research. This study undertakes a comparative analysis of stem cell research regulations in the United Kingdom (UK)

DOI: 10.52609/jmlph.v6i2.251 | E-mail: folakemiajagunna1@gmail.com and South Africa, the findings of which will endeavour to guide the practice of stem cell research in Nigeria.

This article is divided into six parts. Part I introduces the discussions in the article, Part II discusses the methodology adopted for this research, Part III examines stem cell research practices in Nigeria, Part IV examines the regulatory frameworks governing stem cell research in the UK and South Africa respectively, Part V reports on the study's findings, and Part VI concludes the article.

METHODS

Study Design

This research employed an exploratory and comparative design. Because stem cell research remains relatively new and under-examined in Nigeria, a qualitative approach was used to capture the perspectives of key stakeholders on emerging ethical, regulatory, and practical issues. In parallel, a doctrinal desk-based review was conducted to examine the legal and policy frameworks governing stem cell research in the UK and South Africa. The qualitative interviews provided contextual insights into local experiences and perceived regulatory gaps, while the comparative legal review offered substantive examples of how other jurisdictions structure their regulatory regimes. Together, these components formed an integrated analytical framework through which stakeholder views were interpreted alongside documented regulatory models to assess their relevance for the Nigerian context.

Identification of studies and data extraction

The United Kingdom was purposively selected for the comparative study because it is the first jurisdiction in the world to enact all-encompassing legislation on all aspects of assisted reproduction, including stem cell research, and therefore has detailed regulations and policies regarding stem cell research [11]. South Africa was purposively selected because it is ahead of many African countries where stem cell research is concerned, and is reported to be more advanced than most African countries in terms of credible research infrastructure [12]. Unlike the UK and Nigeria, South Africa operates a hybrid common law system influenced by other legal systems including Germanic law, Roman-Dutch law, and indigenous African customary law [13]. This combination of legal influences on the South African system makes it ideal for a comparative study. In addition, the UK and South Africa are both countries of commonwealth origin, as is Nigeria.

The following regulations governing stem cell research were identified: in the UK, the Human Fertilisation and Embryology Act 1990, Human Fertilisation and Embryology (Research Purposes) Regulation 2001, and Human Fertilisation and Embryology Act 2008; and in South Africa, the National Constitution of South Africa 1996, National Health Act 2003, Medicine Control Act 101 of 1965, and the Consumer Protection Act 68 of 2008. These laws were reviewed, and the decisional processes and underlying policies examined. The impact of the regulations in their respective jurisdictions revealed the gaps between law and social reality, highlighting potential areas of focus for a possible stem cell research framework in Nigeria.

In addition, key informant and in-depth interviews were conducted with stakeholders in the assisted reproductive technology (ART) field in Nigeria to elicit their opinions on the practice of stem cell research in Nigeria. In all, a total of 30 participants were interviewed, using interview guides. The stakeholders were purposively selected and included two laboratory specialists (an embryologist and a nurse), nine medical practitioners, four religious leaders, and fifteen women who had attended IVF clinics. This selection represents a cross section of stakeholders in the IVF field who have direct or indirect input into stem cell research. The participants were selected from Lagos, Abuja and Ibadan, the cities with the highest numbers of fertility clinics in

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Nigeria. Narratives from these semi-structured interviews were subjected to content analysis after recurring themes were identified.

Study Area

This research was carried out in Lagos State, Oyo State, and the Federal Capital Territory (FCT) Abuja, but predominantly in Ibadan, Oyo State's capital. Ibadan is historically recognised as the largest traditional city in sub-Saharan Africa, and lies in the south-western part of Nigeria. Ibadan city is about 145 km north of Lagos, and has eleven local government areas (LGAs), including Ibadan North, Ibadan South, Ibadan Northwest, Ibadan Southwest, and Ibadan Northeast LGA (these are situated in the metropolitan core of the city). Akinyele, Oluyole, Egbeda, Ido, Lagelu, and Ona-Ara LGA are located in the outer core and are predominantly peri-urban or rural settlements.

Lagos State, also situated in the south-western part of the country, covers an area of approximately 358,862 hectares, and is bounded by Ogun State and the Benin Republic. As of 2020, Lagos State has 20 LGAs, of which Ikoyi, Lekki, Ikeja, Surulere, Victoria Island and Agege are home to a significant number of the state's fertility centres.

The FCT Abuja, north of the Rivers Niger and Benue, is the administrative capital of Nigeria, bounded by Kogi, Nasarawa, Kaduna, and Niger States to the south west, north east, north west, and west, respectively [14]. FCT Abuja has six LGAs: Kwali, Bwari, Gwagwalada, Kuje, Abaji, and Abuja Municipal Area Council. Of these, Abuja Municipal Area Council has the largest concentration of healthcare facilities, most of them private.

Study Population and Participant Selection

A multi-stage recruitment strategy, combining purposive and snowball sampling techniques, was employed for participant selection. In the first stage, fertility clinics located within selected LGAs in Ibadan, Lagos, and Abuja were mapped and purposively selected based on the presence of registered IVF services and accessibility for fieldwork. From these clinics, eligible professional respondents including medical doctors, an embryologist, and a nurse were identified through clinic staff lists, professional networks, and direct contact. A total of nine medical doctors were interviewed: two each from fertility clinics in Ibadan Southwest, Oluyole, and Ibadan North LGAs; two from clinics in Ikeja and Lagos Island LGAs in Lagos State; and one from Abuja Municipal LGA in the FCT. Two laboratory specialists (a nurse and an embryologist) were also selected from among the same facilities. Key informant interviews (KII) were conducted with all respondents in this category.

In the second stage, religious leaders were recruited through community gatekeepers, denominational councils, and mosque committees to ensure representation of Christian, Islamic, and traditional faiths. Four religious leaders were interviewed, including one Anglican cleric representing orthodox Christianity, one Pentecostal minister representing non-orthodox Christianity, one Islamic cleric, and one traditional religious leader. KIIs were conducted with all respondents in this group.

In the final stage, women who had undergone IVF treatment were recruited, using snowball sampling due to the sensitive nature of infertility and the need to maintain confidentiality. Initial contacts obtained from the fertility clinics referred additional eligible women who had previously received IVF services. Fifteen women were interviewed based on their willingness to participate and ability to provide detailed responses. In-depth interviews were held with respondents in this category, irrespective of their specific locations within the study area.

Instruments for data collection

Semi-structured interview guides were developed for each of the stakeholder groups, guided by an extensive literature review of the subject matter and designed to explore ethical, legal, social, and experiential perspectives on stem cell research and its relevance in Nigeria. The guides were tailored to the role and lived experiences of each

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participant category. The in-depth interview guides (Attachment A) were used to interview the women who had undergone IVF, while the key informant interview guides (Attachment B) were used to interview the IVF doctors, religious leaders, nurse and embryologist. Sets of open-ended questions were developed for the researcher's use and, where necessary, the researcher asked probing questions to elicit more detailed information from the respondents.

For medical personnel, questions focused on clinical practice, bioethical considerations, and regulatory perspectives (e.g., "Do you feel embryos should be specifically created for advanced scientific research?", and "What is your view on stem cell regulation in Nigeria?"). For women who had undergone IVF, questions explored personal experiences and perceptions of embryo value and ownership (e.g., "Do you regard the embryo as property or as a human being?", and "Should your leftover embryos be used for research and possible treatment?"). For religious leaders, questions addressed doctrinal, moral, and theological viewpoints on the status and treatment of the embryo within the traditions of their faith.

To ensure both depth and breadth of the interview data, the study employed some strategies beyond the use of probing. Open-ended questions were used to allow participants to provide detailed narratives in their own words, while follow-up questions were introduced to clarify emerging issues and encourage elaboration on complex themes. The interview guide was structured around key thematic areas to ensure that all relevant regulatory, ethical, and practical dimensions of stem cell research were consistently explored across participants. The interviews were conducted until saturation point was reached, whereupon no new information was imparted, thereby ensuring adequate coverage of perspectives. In addition, reflexive notes were taken after each interview to capture contextual import and to refine subsequent questioning where necessary.

The researcher had no prior relationships with participating clinics, thereby reducing relational bias. Nonetheless, the researcher's academic role may have influenced participants' responses. To mitigate this, interviews were conducted using open-ended, non-directive questions, with emphasis on confidentiality and voluntary participation. Reflexive documentation was maintained after each interview to evaluate the researcher's influence, interrogate assumptions, and reduce the impact of power asymmetries.

Ethical Considerations

All ethical considerations were observed in this research; this included seeking the respondents' informed consent after the study had been clearly explained to them. The respondents were also assured of their confidentiality and anonymity. No name was required, and the tape recorder was used only after respondents consented for the researcher to use it. The respondents were informed that they could decide to end their participation whenever they no longer wished to continue. Interviews with the IVF recipients were held in privacy. Ethical approval was obtained from the University of Ibadan Social Sciences and Humanities Ethical Review Committee (Approval No: 30177059).

Data collection period

Data were collected over a period of six months, from April to September 2020.

Data analysis and management

Information obtained from the interviews was carefully reviewed and stored. Electronic data were saved using secure digital software to ensure confidentiality. The narratives from these interviews were transcribed verbatim, and themes identified from the discussions were subjected to content analysis using Atlas Ti software for coding and analysis.

The interview transcripts were analysed using thematic analysis. The process began with inductive coding to identify concepts emerging directly from participants' accounts, followed by deductive coding guided by literature on stem cell regulation. These two approaches were combined to create a comprehensive coding framework. Although only one researcher conducted the coding, analytic transparency was maintained through detailed note-keeping and an audit trail documenting coding decisions and theme development. Attention was given to identifying and integrating deviant cases to ensure that minority or contradictory perspectives were not overlooked.

The doctrinal review followed a systematic examination of statutes, policy documents, and regulatory guidelines governing stem cell research in the UK and South Africa. Relevant provisions were analysed for their conceptual clarity, regulatory scope, oversight mechanisms, and applicability to the Nigerian context. Findings from the doctrinal analysis were then triangulated with the interview themes to identify areas of convergence, highlight regulatory gaps, and inform the development of recommendations tailored to Nigeria.

LITERATURE REVIEW

Stem cell research in Nigeria

Nigerians have suffered rigorous torments with regard to healthcare over the years, due to poor medical care and mismanagement of health facilities by authorities. This has led to the absence of stem cell therapy in the country until relatively recently, even while the technology was trending in other nations. However, a remarkable breakthrough was recorded in 2011 when the first stem cell transplant, on a seven-year-old sickle cell anaemia patient, proved successful at the University of Benin Teaching Hospital (UBTH). Since then, six successful stem cell transplants have reportedly been undertaken for sickle cell disease, and in July 2019 the first stem cell transplant for multiple myeloma was carried out on a 62-year-old patient. These heart-warming achievements heightened the interest of the Nigerian Government in the construction of several stem cell transplant centres across the country. The establishment in 2012 of the Bone Marrow Registry Nigeria (BMRN) was a great stride led by a leukaemia survivor, Seun Adebiyi, and his team with the aim of increasing global recovery statistics of Africans with blood disorders. A pioneering Bone Marrow Transplant Unit was said to have been established in Nigeria at UBTH; however, the unit could not be sustained due to a lack of political will on the part of the Nigerian Government [8].

Health research in Nigeria, including stem cell research, has remained uncoordinated and often dictated partly by the whims of researchers and institutions, or is largely donor driven. In light of this, the Nigerian National Health Act of 2014 was passed to provide a regulatory framework for the development and management of a national health system and to set standards for health services in Nigeria. The Act is meant to regulate both public and private spheres of the country's health services, and Parts IV and VI deal with regulations that are indirectly related to stem cell research. While Part IV deals with national health research and information, part VI deals with the control of human blood, blood products, tissue, and gametes. Section 32 of the National Health Act prescribes the manner for conducting all research or experimentation on all living persons for therapeutic and non-therapeutic purposes. The applicability of the provisions of S32 to stem cell research in Nigeria can only be justified if the embryo were to be classified as living person. It is submitted here that an embryo remains at best what it is because it does not possess the characteristics of a living person. However, where stem cells for research have been sourced from the bone marrow or skin of adults, then the provisions of S32 become applicable. Section 48 makes it mandatory to obtain informed consent from a donor where tissue, blood, or blood products are to be removed from the body of a living person, and criminalises removal of tissue for commercial purposes. From the analysis above, it can be seen that the National Health Act 2014 is scant on

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detailed provisions relating to stem cell research.

Stem cell research in the United Kingdom

In the UK, there are two separate exploratory practices involving the use of human embryos. The first entails embryo research with the view to gaining deeper insights into embryo growth, reproductive issues, and genetic disease. The second is concerned with inquiries into the uses of embryonic stem cells, requiring the use of embryos for continued research. Both these types of research are carried out and regulated under statute [15]. The Human Fertilisation and Embryology (HFE) Act 1990 establishes the Human Fertilisation and Embryology Authority (HFEA) as the governing body for assisted fertility treatments and other purposes connected with human embryo use in the UK [17]. It should be noted that this fertility authority is recognised as the first of such regulatory bodies in the world. The functions of the Authority include oversight over the duties and obligations of all parties involved in ART processes; this includes obligations towards the fertilised embryo. Generally, the Authority has the mandate to grant licences to ART providers in the jurisdiction, as well as granting licences to storage facilities and research centres where embryo research is conducted. The Authority is also empowered to revoke licences where applicable. The second schedule to the HFE Act itemises the requirements under which the Authority approves licences. The regulations governing stem cell research in the UK are described in more detail in the legislations below.

Human Fertilisation and Embryology Act 1990

The Human Fertilisation and Embryology (HFE) Act establishes the legal framework that regulates infertility treatments and other related medical services in the UK. It was passed to bring under a single legislation three main aspects of assisted reproduction; namely, the formation and use of human embryos outside the mother's body, the collection and use of donated human reproductive materials, and the storage of these reproductive materials. The Act governs human embryo use in scientific research. Under its provisions, researchers are permitted to carry out human embryological research for specific reasons, including to gain deeper insight into the origin of hereditary and genetic diseases, and to promote discoveries in infertility treatments and improvements in IVF conception techniques. The scope of the provisions also enables IVF researchers to determine whether an embryo has any genetic mutations before implantation. The guidelines contained in the Act were amended in 2001 to permit human embryonic research specifically for advancing understanding about embryonic development; to gather more information about life-threatening diseases; and to allow for the application of such information in life-threatening conditions [18].

The HFEA carefully deliberates research applications on a specific project basis, and grants licences only after considering the competence of the clinical and/or research team. The Authority also requires that all research must have local independent ethics committee approval and the consent (for the specific purposes of the research project) of the embryo donors, who must have received counselling prior to giving informed consent. The Act establishes the main duties of the HFEA: to regulate and license the clinical practice of assisted reproduction (for example, in vitro fertilisation), the storage of gametes and embryos, and research on embryos. It also collates records of procedures, keeps a register of all individuals born as a result of assisted conception procedures, and inspects and licenses premises.

It should be noted that the HFE Act only permits investigational research on human embryos prior to the development of a primitive streak, which is a basic embryonic feature that usually appears fourteen days post-fertilisation. Embryo research involving the generation of human embryonic stem cell lines is also under the statutory regulation of the Authority (HFEA). Embryonic stem cell lines, which are stem cells derived from the early embryo, are not regarded as embryos; as such,

DOI: 10.52609/jmlph.v6i2.251 | E-mail: folakemiajagunna1@gmail.com research involving such cells is not subject to the same laws under the HFE Act. However, due to the fact that their creation involves damage to human embryos, a Steering Committee was established to safeguard the conduct of such research under standard operating procedures. These operating procedures must be transparent to the relevant regulatory and scientific bodies as well as comply with HFEA regulations. [19].

The HFEA has published a Code of Practice that regulates licenced centres and provides guidance for IVF clinics to ensure that their operational services are efficient and in line with regulations. The Code of Practice also serves as a practical guideline for patients, donors, donor-conceived individuals, clinicians, and researchers. The document comprises three main sections: compulsory provisions, interpretation of the compulsory provisions, and guidance.

Human Fertilisation and Embryology (Research Purposes) Regulations 2001

The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 came into force on January 31, 2001, among other reasons to expand the scope for which research licences may be authorised. Before these regulations were enacted, there had been extensive arguments and deliberations between opponents of embryo research and those who championed its ability to offer a better quality of life for sufferers of distressing and long-term illnesses, whose only hope lay in science and embryo research in particular. The Warnock Committee's recommendation of 1984 reflected the need for a strict regulatory framework within which research could be conducted, and to take account of the advances in medicine anticipated by both the Warnock Committee and, later, by Parliament in 1990. Thus, the amendments captured in the 2001 regulations may be seen as the offspring of the Warnock Committee's recommendations. The HFE Act of 1990 had strictly provided that embryonic research may be conducted only until the first signs of neural development—that is, at the very latest, after 14 days. It penalised the use of an embryo after such time, making it an offence punishable by up to 10 years' imprisonment or an unlimited fine, or both. The 1990 Act had also instituted essential safeguards to ensure that any approved research was necessary and was to be conducted only for the approved purposes. It is on record that the HFEA, within the first ten years of the 1990 Act, received 130 applications to conduct research, and rejected 17 of those—more than 10 per cent [20].

The conditions set forth for embryo research in the 1990 Act were clear, and included conditions such as infertility, contraception, and congenital disease, including cystic fibrosis and haemophilia. The question before the House when the 2001 amendment was proposed was whether those purposes should be extended to include other serious diseases, such as Parkinson's disease, Alzheimer's disease, cancer, and diabetes [21].

Human Fertilisation and Embryology Act 2008

The HFE Act of 2008 was enacted principally to amend the HFE Act of 1990 and the Surrogacy Arrangements Act of 1985. It makes provisions for persons who are to be regarded under the law as parents of a child. Section 11 of the 2008 Act introduces a new Schedule 2, which is an amendment to Schedule 2 of the 1990 Act. This amendment permits activities such as embryo testing, and extends the purposes for which a research licence may be granted to include the creation and use of human admixed embryos for the purposes of research. The list of permitted research purposes had previously been extended by the Human Fertilisation and Embryology (Research Purposes) Regulations of 2001; the provisions of the 2008 Act consolidated all of the permitted purposes listed in both the 1990 Act and the 2001 Regulations. The 2008 Act also made three significant changes to the previous position on licensable research using embryos: a new paragraph, 3A (2)(a), expands the list of licensable purposes to include research undertaken to increase knowledge not only about serious diseases, but also about other serious medical conditions [22].

The 2008 Act followed a government decision to review the 1990 Act via public consultation, as it had become apparent that the existing legislation could not keep pace with the upsurge in scientific and technological advancement. Some of the challenges associated with the 1990 Act had been emphasised in the House of Commons Science and Technology Committee report in 2005. It was proposed that the restructured Act maintain the existing framework governing ART and embryo research in the UK.

Stem cell research in South Africa

Since the introduction in 1970 of stem cell transplant in South Africa, the country has seen various successful stem cell treatments [24]. Stem cell research is undertaken in the firm belief that knowledge of stem cell applications can help to address local health needs. Stem cell research as practiced in South Africa is somewhat complicated by the many regulations that directly or indirectly affect the conduct of stem cell research and treatment. Section 27 of the South African Constitution guarantees all South Africans the right to access health and social care services and urges the state to take reasonable legislative and other available measures to achieve these rights within the available resources. By inference, the provisions in this section of the Constitution form the grundnorm for health care in the jurisdiction. It can thus be argued that the state has a duty to provide health care within its resources. Insofar as stem cell research and therapy are regarded as regenerative medicine, they can be subsumed under this provision [25]. However, the primary legislation on stem cell research and treatment is the National Health Act of 2003. This and other regulations guiding the conduct of stem cell research are examined below.

National Health Act 61 of 2003

The South African National Health Act of 2003 has as its aim the provision of a uniform health system within South Africa. It thus takes into consideration the obligations contained in the National Constitution of South Africa and other laws with regard to health services provision. According to the Act, the term *embryo* refers to a human offspring in the first eight weeks from conception [26]. Although the Act itself was enacted in 2003, Chapter 8, which contains provisions on human tissues, came into existence in 2012. Section 56 (1) thereof permits the use of tissue, blood products, or gametes removed from living persons only for approved medical or dental purposes. S56 (2) prohibits the withdrawal of certain categories of tissue from living persons in contemplation of subsection 1 except by authorisation of the Minister of Health. By these provisions, placenta, embryonic foetal tissue, stem cells, or umbilical cord can only be removed from a person when authorised by the Minister, who may also impose any conditions for such removal. S57 (4) authorises research on stem cells and zygotes subject to the following conditions:

- That the stem cells are not more than fourteen days old;
- Upon a written application that guarantees that the proposed research will be documented for record purposes;
- That consent has been obtained from the donor of the stem cells.

Informed consent is mandatory in stem cell research, founded on the individual’s right to autonomy and self-determination [27]. This principle has been enshrined in South African law for several decades and was confirmed by the South African courts in the case of *Stoffberg v Elliot*. The principle is further enshrined in Section 12 (2) of the South African Constitution of 1996, while Section 7 of the National Health Act recognises the statutory requirement of informed consent. As it relates to stem cell research, an individual must consent to receive treatment using stem cell therapy after being fully informed about the nature and consequences of the treatment and the risks involved, and where any tissue is to be removed from the body of an individual for stem

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cell research, informed consent must be obtained to do so.

An ambiguity that clouds the interpretation of South Africa's National Health Act relates to the provisions above. The Act's definition of an embryo and the provisions applicable to it infer that stem cell research can be carried out on embryos up to 14 days; however, it is silent on whether research can be conducted on embryos from 14 days up to 8 weeks [28].

Medicine Control Act 101 of 1965

The Medicine Control Act categorises stem cell therapy as biological medicine, and also requires that any biological medicine must be registered with the Medicine Control Council. This Act deals more with the clinical translation of stem cell therapy than with the research aspect of stem cells [29]. Despite the provisions of this regulation, unregulated and unproven stem cell therapy has continued in South Africa; a trend that has led to increased stem cell tourism to the country [30].

Consumer Protection Act 68 of 2008

The Consumer Protection Act 68 of 2008 applies to transactions in South Africa that involve the supply of goods and services in exchange for some form of consideration. The Act exempts certain transactions; nonetheless, patients are considered consumers under the Act, thus making it applicable to the provision of health care services. By inference, the provision of stem cell therapy can be subsumed under health care provision and the Consumer Protection Act applies. In this wise, the rights of consumers as contained in the Act will extend to stem cell therapy treatments in South Africa [31].

In examining the South African policies on stem cell research, Mnisi [32] identified two principles that stand out regarding the governance thereof. One is the principle of subsidiarity, which suggests that one should favour the less belligerent means of realising a set goal. In applying this principle, embryo stem cell research should be undertaken only where there are no alternatives. The principle also assumes that if the human embryo has a higher ethical status compared with other stem cell alternatives, it should be considered unsuitable for stem cell research and treatment. The second principle is that of proportionality, which suggests that the destruction of embryos should serve important and worthwhile goals. If the subsidiarity argument is sustained, there ought to be suitable alternatives that possess a lower status than human embryos for use in stem cell research. These include animal material and induced pluripotent cells. On these grounds, Mnisi endorsed stem cell research in South Africa.

Regulations relating to the use of Human Biological Material 2012

These regulations were issued by the Minister of Health pursuant to Section 68 of the National Health Act 61 of 2003, and define stem cell research as the use of stem cells for therapeutic purposes. Section 2 defines the range of persons competent to remove human biological material for genetic testing or research purposes, while Sections 3 and 4 spell out the procedure for obtaining informed consent prior to removal of biological material from the body of another person and from deceased persons, respectively. Section 7 permits the use, for research purposes, of excess embryos from IVF procedures and umbilical cord blood cells, provided informed consent has been obtained. It further permits research on primordial germ cells obtained from aborted foetuses, with appropriate consent. The regulations also permit the use, for stem cell research, of cells derived from species other than humans, provided the cells' clinical validity and utility have been demonstrated and approved by the National Health Research Ethics Council. Donors of biological materials may receive reasonable reimbursement for expenses incurred for donation purposes.

A distinct feature of these regulations is the absence of any requirement for ministerial authorisation for the removal of biological material from living persons, unlike the National Health Act which does require such approval.

Table I. Salient points in regulatory frameworks of United Kingdom and South Africa

	United Kingdom	***South Africa***
Authorisation for stem cell research	The Human Fertilisation and Embryology Authority is responsible for licensing and monitoring stem cell research	The Minister of Health has wide-ranging authority to approve/reject issues relating to stem cell research
Therapeutic cloning of stem cells	Permitted in the UK	Permitted in South Africa, but reproductive human cloning is banned
Research on human stem cells	Tissues and cells for research are not to be transplanted into humans; leftover IVF embryos can be used for stem cell research	Research using adult stem cells is permitted subject to donor consent
Permissible limits for stem cell research	Research on embryos can be conducted within the first 14 days of their formation	Research must be carried out within the first 14 days, subject to ministerial approval, documentation and informed consent
Nature of legal framework	Strict but permissive legal framework; requires that the embryo be given some respect	Framework not fully implemented; the embryo has legal object status
Commercialisation of research	Framework balances the need for governance and for commercial development	Commercial regenerative medicine can be registered in South Africa through recognition procedures
Professional regulation	A number of organisations promote stem cell research but none provide professional regulation	The South African Stem Cell Transplantation Society provides professional regulation
Source of embryos for research	Embryos can be created specifically for research purposes or donated by patients undergoing fertility treatments	Surplus embryos from IVF procedures may be used to derive embryonic stem cell lines for research purposes

Source: Author

RESULTS AND DISCUSSION

Summary of findings from the literature review

Stem cell research in the United Kingdom has been enhanced by active public debate and a robust regulatory environment [33]. At the onset of human embryo research, Baroness Warnock's Committee proposed a regulatory system constrained by law as opposed to one based entirely on legal prohibition. The preferred approach emphasised flexibility, which the Committee believed was essential in a field characterised by changing and diverse public opinions. While the UK's regulatory approach to stem cell research is permissive, every act carried out on embryos is done with the approval and subsequent licensing by the Human Fertilisation and Embryology Authority (HFEA).

The rapid milestones achieved in stem cell research in the UK have been associated with its permissive regulatory system. According to Levine (2008), the UK has performed better than many other countries including the United States due to its strong research, and there exists a direct link between the country's regulations and its achievements to date. UK regulations permit the derivation of new human embryonic stem cell lines from surplus embryos from fertility treatments, and through the use of somatic cell nuclear transfer [34].

Another profound finding on stem cell research regulation in the UK relates to the permissive time limits for embryo stem cell research. A congressional argument ensued during the passage of the Human Fertilisation and Embryology (Research Purposes) Regulation in 2001, which governs the use of embryos in research. Members of Parliament held conflicting views on the permissibility of embryo research, due to differing opinions on when life begins. These included the view that life begins upon fertilisation of the egg, or that it begins after a 14-day period, when cell differentiation commences and after which the embryo can no longer be divided to create twins [35]. The Warnock Committee had, many years earlier, adopted a stance between these opposing positions, ultimately concluding that although the early embryo possesses exceptional status, such status does not justify its unqualified protection. This was the stance adopted in the 1990 HFE Act [36]. The Warnock Committee believed that if the contemplation given to an embryo were to progress with its growth, the requisite determination of when it transitions from one stage of growth to another might be impracticable. This would also make it difficult to ascertain the point at which protection increased from one level to the next. The 14-day limit for early embryo research was thus adopted as being objective, and representing the stage at which the primitive streak—precursor to the nervous system—starts to appear. Thus, research on human embryos may only be conducted within the first 14 days after fertilisation.

In conclusion, the UK's regulatory regime promotes a liberal approach which has as its overall objective the advancement of scientific progress whilst taking into consideration public concerns [37].

Although South Africa has regulations guiding the conduct of stem cell research, they have not been strictly followed, resulting in abuses and malpractice by medical practitioners chasing the potential gains of stem cell tourism [38].

Findings from key informant and in-depth interviews

The main thrust of the interviews conducted for this research was to document the opinions of relevant stakeholders on the subject of stem cell research in Nigeria. To this end, the participants were asked specific questions relating to the creation of embryos for stem cell research, destruction of embryos in the process of stem cell research, regulation of stem cell research in Nigeria, as well as cultural and religious perspectives on stem cell research. As stem cell research in Nigeria is relatively new, it is important to gain an understanding of such opinions, and especially those of women who attend fertility clinics, since the principal source of embryos for stem cell research is undoubtedly those left over or unused after fertility treatments.

On the issue of creating embryos specifically for research purposes

The question of creating embryos for research purposes, and of using those left over from IVF processes, revealed divergent views on the subject. The majority of participants held the opinion that using embryos for research purposes would be beneficial to the medical world, while a few held contrary views. One participant, a fertility doctor based in Ibadan, explained that the use of embryos for research purposes would enable a 'breakthrough towards more successful IVF'. He explained that medicine deals more with clinical trials and is not just about theories, and that such trials 'have to be conducted on living beings in order to be more practical and scientific'. He concluded that creating embryos for scientific

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purposes is a positive thing, as it will lead to many medical discoveries.

In support of this view, another male medical fertility doctor said, ‘I don’t think research on embryos should be banned because, if we do so, we are actually shooting ourselves in the foot.’ In the same vein, an embryologist at an IVF clinic also agreed with the use of embryos for research, stating emphatically that, ‘It should, it should, it should; in fact, there should be a lot of research on that. They should encourage people to do their research in that line, and it should be encouraged.’

However, one participant, a Lagos-based fertility doctor, had a contrary view, stating that human embryo research ‘should not be done because the human embryo is a person; using it for research should not be allowed.’ Other findings from the interviews suggest that the use of embryos for research is considered permissible subject to control by regulations and policies.

Contrary to the opinion of most of the fertility doctors and IVF experts, a majority of the female IVF patients disagreed with the use of leftover embryos for research. One woman who opposed the idea gave her reasons as follows:

‘That is not alright, because if you have been to a fertility centre before and you have seen an embryo, you will know that it is a human; it just remains the embryo to leave the bottle and transfer to the woman’s womb and start growing. So there is this attachment that you get by looking at the embryo at that point, so it is as good as saying that you are using a child for the purposes of research. The child is not a guinea pig; if you must conduct research, use a rat and not an embryo.’

Another woman could not give any reason for her stance, but it seemed that she felt uncomfortable about the use of embryos for research. Her assertion was supported by another IVF patient who asked, rhetorically, why she should use her created embryo for research when she is not a researcher. One of the women, however, was of the contrary opinion that IVF would not be available in the absence of such research. In her words, ‘If it is for research it is okay; that’s how it [ART/IVF] grows, and that’s how a human being comes to be.’

On the creation of embryos specifically for stem cell research

When asked whether embryos should be created specifically for research purposes, the respondents had differing opinions. Some felt that once life has been created in the form of a human embryo, that life cannot be destroyed or used for any purpose other than transferral to a woman’s uterus. Others believed that the end justifies the means, since embryo research results in technological advances for IVF. When asked to substantiate their answers, some opponents referred to the belief that a being comes into existence at the moment of fertilisation, with the potential to become a fully-fledged human being. Thus, creating embryos solely for research was, to them, wasting a potential human life. However, they were not averse to using their leftover embryos for research.

The IVF experts interviewed encouraged the creation of embryos for research purposes, because only when this is permitted can further discoveries be made in the field of IVF and treatments for other diseases. Specifically, a male respondent stated, ‘To me, this is good because in medicine, things are done mostly by clinical trials and not by theories alone. Embryo research enables better and more successful IVF outcomes.’

Religious perspectives on embryo stem cell research in Nigeria

When asked about the permissibility of embryo stem cell research according to the Islamic faith, the respondent stated that Islamic teachings attribute technological advancements to the greatness of Allah. Such advances are not mere coincidence, but follow a precise order and specific control found in Allah. Islam encourages scientific research, especially that which pursues cures for human diseases. Fadel [39], affirmed that Islam teaches that, before performing any act, a Muslim should seek to know whether or not it is

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permissible. He said that, while the Quran summarises Islam's fundamental ideologies and rubrics, the hadith specifies comprehensive regulations.

IVF and other new technologies have no specific reference in the Quran, and are governed by a process known as *Ijithad*, overseen by Islamic legal scholars. Some Islamic intellectuals view medical enquiry involving new technologies as a shared spiritual responsibility [40]. An Islamic verse credited to Prophet Mohammed (SAW), which enjoins Muslims to seek treatment and cure for all diseases, states that God did not create any disease without creating a cure for it, except death. Concerning stem cell research in particular, there are no established precedents; scholars fall back on *Ijithad*, which applies the wide-ranging principles of Islamic law as follows:

'All actions are permissible so long as they are not categorically prohibited'; and 'The welfare of the people resides in the statute of Allah [41]'.

In other instances where the Islamic texts remain silent, *Maslaha* (interpreted as 'public interest') becomes applicable.

Though a number of Islamic scholars endorse embryo stem cell research, all have agreed that creating embryos solely for research should be discouraged [42]. Likewise, a respondent Christian leader strongly disagreed with the creation of embryos for research purposes, hinging his opinion on the fact that, once an embryo is regarded as a human being, then it has life, and such life should be cherished and not terminated for research purpose. The Ifa priest, meanwhile, was of the opinion that an embryo is bound to be wasted if not utilised, so there is no reason it should not be used for research. He further opined that embryo creation for research does not matter because not every sperm gets fertilised; therefore, any sperm that does not get fertilised during normal intercourse and the process of childbearing is also bound to be wasted.

Islamic opinion regarding spare or leftover embryos

It should be noted that, for this category of research, stem cells must be removed from an embryo on about the fifth day of its development, and this procedure essentially terminates the potential for the embryo's further development. This introduces the question of whether this procedure terminates life, albeit potential life, which is linked to the determination of when, according to Islamic dictates, ensoulment occurs. In answer to this question, Contijoch [43] distinguishes three different schools of thought: The first, credited to Ibn Mas'ud, believes that the spirit is breathed into the embryo after 120 days of its formation. The opinion of Hanbali and Maliki is that a foetus attains human status earlier than 120 days post-conception; this school also believes that abortion is permissible within the first 40 days, because the embryo is nothing at this stage. The third, Shaffi'l, school of thought believes that it is not permissible to expel semen at any point in time once it has been implanted in the womb. It can be deduced from these various beliefs that the Ibn Mas'ud and Hanbali schools would not deem it unethical to use human embryos in stem cell research, because the procedure is carried out within the first five days of development. This is in contrast to the Shaffi'l school which believes that life begins upon fertilisation.

In summary, the stakeholders interviewed for this researched held the view that, since its potential benefits outweigh any disadvantages, stem cell research should be permitted in Nigeria, subject to robust regulation with necessary policies and guidelines.

Quest for reforms in Nigerian stem cell research regime: A liberal, permissive, or restrictive framework?

Several essential pillars have been identified to ensure ethical and effective practices surrounding stem cell research. These include a robust regulatory environment and appropriate processes for informed consent, quality assurance, and accreditation [44]. In the absence of these pillars, unproven or fraudulent stem cell treatments may thrive. Conversely, a robust regulatory framework for stem cell research and therapy would facilitate innovation by providing a means of control over the behaviour of all relevant actors in a way that aligns with the state's policy objectives. A number of legal and ethical issues arise from the continued use of stem cell therapy, and these can only be resolved through proper regulation. For instance, unfounded claims, based on unapproved clinical trials, have misled patients into false hopes regarding treatments for various ailments [45]. Three possible regulatory approaches to stem cell research have been identified; these are restrictive, permissive, and liberal. While these approaches reflect the various degrees to which the idea of stem cell research is deemed morally acceptable by different jurisdictions, and are shaped by varying historical and social contexts, they are also influenced by specific local factors such as available resources and funding, the state of the science base, and systems of healthcare provision. Jurisdictions that adopt a permissive approach allow a measure of flexibility and typically permit a range of activities, subject to specific regulatory checks and balances. These countries attempt to reach a regulatory compromise between conflicting or diverse interests. Some permit research using surplus or leftover IVF embryos under specific conditions. Permissive use of such embryos is subject to stipulated conditions, including informed consent from embryo donors [46].

RECOMMENDATIONS

The broad practice of assisted reproductive technology (ART) has progressed without much regulation in Nigeria, despite calls for such on numerous occasions. Nigeria has no doubt seen its share of unethical practices arising from a weak ART regulatory system, despite its well regulated medical and dental fields [47]. While it is difficult to ascertain whether Nigeria's regulatory approach falls into the restrictive, permissive, or liberal category, information obtained from the stakeholders in this study suggests that stem cell research is a welcome development in the country and holds great promise, particularly as Nigeria has witnessed a surge in diseases potentially treatable with regenerative medicine.

A restrictive policy regime for Nigeria would hinder achievements in the field of regenerative medicine due to the need to defend and uphold the rights of embryos that are the source of the cells required for research. On the other hand, a too-liberal approach may also be a dangerous path to tread: unproven stem cell therapies have thrived in jurisdictions where stem cell tourism is encouraged by the availability of providers operating for profit [48]. The approach adopted in Malaysia was to identify the particular health challenges faced by the country's aging population and channel the available funding into stem cell therapy research to meet those particular needs. The Malaysian Task Force's Advisory Report on Stem Cells identified the top four chronic diseases among the older population—dementia, musculoskeletal diseases, visual impairments, and cardiovascular diseases—and noted the potential of stem cell therapy to address these challenges in line with the country's Vision 2020 development goals.

Based on the foregoing, this article recommends that:

Detailed guidelines should be put in place for stem cell research in Nigeria, given the increase in uptake of assisted conception treatments in the country, and the availability of surplus embryos from fertility treatments.

The permissible uses of an embryo in Nigeria should be clearly and adequately spelled out. The use of embryos for cloning should be outlawed, and instances where they may be used for stem cell research should be clearly detailed. Statutory limits within which an embryo must be implanted or hatched should also be outlined.

A permissive but detailed regulatory regime is recommended for stem cell research in Nigeria. As the country is in its teething period regarding stem cell research and treatments, a rigid regulatory regime might stifle the activities of researchers whose work should be encouraged for the benefits that could accrue. Based on the comparative analysis undertaken for this research, the experience of the UK reveals that it is possible to have permissive laws while also achieving a broad oversight of all aspects of research activities. The South African experience has demonstrated that, where there are legislative gaps in stem cell research, the situation can be abused by unscrupulous individuals to cheat weak and unsuspecting persons desperate for treatment.

This study has some limitations that should be acknowledged. Given the ethical, religious, and cultural sensitivity surrounding stem cell research and IVF in Nigeria, participants' responses may have been influenced by social desirability, with some moderating their views to align with perceived moral or professional expectations. In addition, the findings rely on self-reported experiences and recollections, which may be subject to recall bias. Finally, the study did not include policymakers or regulatory authorities, and this may limit the extent to which the findings fully reflect future governance and regulatory dimensions of stem cell research in Nigeria.

CONCLUSION

Although guidelines, recommendations, and standard operating procedures have been published by international bodies such as the International Consortium of Stem Cell Networks, the International Stem Cell Forum, and the International Society for Stem Cell Research, stem cell research remains a matter that ought to reside strictly within the regulatory domain of national policy- and lawmakers. It is generally believed that stem cell therapies are developing very rapidly; thus, regulatory frameworks need to be sufficiently flexible to accommodate their pace of progress. It has been suggested that, in developing laws and policies, objectives should be pragmatic and every effort should be made to guarantee simplicity and precision. In the context of the regulation of stem cell research, while legislation should be enabling and not unduly restrictive so as to avoid stifling basic clinical research and biotechnological innovation, it should also include sanctions that are unambiguous and legally justified. Those affected by any legislative restrictions or penalties should be aware of the limitations and the consequences of any transgressions [49].

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ATTACHMENT A

In-Depth Interview Guide

1. What is your understanding of stem cell research?
2. Can you describe your experience with IVF and any information you received about embryos created during the process?
3. How do you feel about the use of surplus embryos for research or medical treatment?
4. What benefits, if any, do you think stem cell research could bring to individuals, families, or society?
5. Do you have any ethical, religious, or personal concerns about stem cell research? Please explain.
6. Would you support stem cell research being conducted in Nigeria? Why or why not?
7. How important is government regulation to you in deciding whether stem cell research should be allowed?
8. What fears or risks do you associate with stem cell research in Nigeria?
9. How should consent be obtained from patients whose embryos or biological materials may be used for research?
10. What conditions or safeguards would make you comfortable with stem cell research being practised in Nigeria?

ATTACHMENT B

Key Informant Interview Guide

1. How would you describe your understanding of stem cell research and its current status in Nigeria?
2. Are you aware of any stem cell research or related practices currently taking place in Nigeria? If yes, can you describe them?
3. In your view, what are the potential benefits of stem cell research for healthcare delivery in Nigeria?
4. What ethical concerns, if any, arise in relation to stem cell research, and particularly the use of embryos?
5. Do you feel embryos should be created specifically for advanced scientific research?
6. What is your view on stem cell regulation in Nigeria?
7. What is your assessment of Nigeria's current legal and regulatory framework for stem cell research?
8. What risks do you foresee in conducting stem cell research in Nigeria in the absence of clear regulation?
9. Drawing from international examples (such as the UK or South Africa), what regulatory approach do you think Nigeria should adopt?
10. What role should government agencies, professional bodies, and ethics committees play in regulating stem cell research?
11. What safeguards would you recommend to ensure ethical and responsible stem cell research in Nigeria?

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