

The regulatory framework for assisted reproductive technology (ART) in Nigeria: Lessons from India

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Abstract

Infertility has been recognized by the World Health Organization (WHO) as a global public health concern, with both Nigeria in Africa and India in Asia significantly affected. According to WHO data, the prevalence of primary infertility in India is 3.9% (age-standardized to 25–49 years) and 16.8% (age-standardized to 15–49 years). In Nigeria, estimates from demographic health surveys indicate an 11% prevalence rate, while clinical studies report infertility rates ranging between 14.5% and 30%. Over the past fifteen years, the use of Assisted Reproductive Technology (ART) has become increasingly common in both Nigeria and India, growing at an annual rate of 5–10%. Although ART has provided hope to many individuals and couples facing infertility, it also raises significant legal, ethical, and social concerns, prompting the development of regulatory frameworks in several developed countries. India has enacted specific legislation regulating ART, whereas Nigeria remains largely unregulated in this area. This paper examines the regulatory frameworks governing ART in Nigeria and India. It finds that while Nigeria relies on a patchwork of general laws — including the Constitution of the Federal Republic of Nigeria 1999, the National Health Act 2014, the Child's Rights Act 2003, the Code of Medical Ethics in Nigeria, the Trafficking in Persons (Prohibition) Enforcement and Administration Act 2015, and the Lagos State ART Guidelines 2019 — India has established a dedicated law: The Assisted Reproductive Technology (Regulation) Act 2021. The study highlights the urgent need for Nigeria to develop a sector-specific regulatory framework for ART. It concludes that India is significantly ahead of Nigeria in ART regulation and suggests that Nigeria could draw lessons from India's approach by enacting comprehensive national legislation to govern ART practices.

Keywords: Words, assisted, reproductive, technology, legal, framework, Nigeria, India

Introduction

Human existence from one generation to another is strongly rooted in the concept of reproduction. Reproduction is a process by which living organisms produce offspring. In Africa and Asia, and the world over, children are the fabric of the society, without which no meaningful social and economic progress is considered worthwhile. This research work will focus on India in the Asian Continent and Nigeria in the African Continent. India and Nigeria share many commonalities as two large democracies that have emerged from similar historical pasts. Having attained independence before Nigeria, India provided a thrust and course of action for Nigeria's struggle for independence. Consequently, Nigerians pursued methods of non-violence in times that several other African countries employed violent, armed struggles to secure their independence ^[1]. -governing countries after a lengthy course of colonial rule. From leading anti-colonial and antiapartheid struggles to sharing common perspectives on contemporary social and political issues in the international sphere, India and Nigeria have developed deep-rooted ties. India, with a population of approximately 1.38 billion, is the second most populous country in the world, soon to be the most populous. Nigeria, with a population of just over 200 million, is the seventh most populous country in the world and Africa's most populous. Both countries are projected to be the two most populous democracies in the world by 2050 with India's population set at 1.67 billion and Nigeria's at 400 million.

India and Nigeria are both populous, multi-religious and multi-ethnic societies. Remarkably, the three major tribes and the many minority tribes in Nigeria are similar to the heterogeneous Indian society with 15 official languages and different ethnic backgrounds. Also, Indians and Nigerians today interact on various fronts due to colonial histories and a sense of camaraderie arising from common perspectives on contemporary issues, economic structures and cultures ^[2]. In addition, both Nations have had their fair share of grappling with the challenges relating to high rates of infertility and massive resort to ART, with lack of adequate regulation and its attendant challenges.

Nigeria and India have high rates of primary and secondary infertility, the results of the Demographic and Health Survey of Nigeria ^[3], indicate that approximately 4% of women aged 30 years and above have never given birth to a child. Nigerian Gynecologists frequently report that infertility cases constitute between 50% and 70% of their consultations in tertiary health institutions ^[4]. Infertility in Nigeria has been reported to be as high as twenty-five percent among couples, much higher than the global prevalence of eight to twelve percent. Globally, one in every six couples will experience a fertility problem during their reproductive age ^[5]. A general estimate is that between eight and 12 percent of couples experience some form of involuntary infertility during their reproductive lives. When extrapolated, to the global population, this means that 50 to

80 million people may be suffering from some infertility problem.

In India, the discussion of infertility (in both men and women) as a circumstance has just recently gained recognition. A double-digit increase in infertility has made it a personal and societal health concern in India. Infertility negatively affects couples socially, financially, and emotionally^[6]. The Indian Society of Assisted Reproduction reports that India has a population of 27.5 million infertile people. However, there is a little open discussion about the situation's mounting concerns and widespread ignorance of it. One in every fifteen Indian couples struggles with infertility. The issue is exacerbated by late marriages, demanding lifestyles, obesity, excessive consumption of fast food, smoking, drinking, and drug addiction.

Childlessness in India is estimated at approximately 2.5%. Among individuals aged 30–49 years, the rate is around 5.5%, while for the 45–49 age group, it stands at 5.2%. In absolute terms, this translates to about 4.9 million individuals. When cases of secondary infertility are included, the total number of infertile couples in India rises to approximately 17.9 million^[7]. Socially, infertility is considered an unacceptable condition, leading most infertile couples on a relentless quest for conception. In Nigeria, the social stigma of childlessness still leads to isolation and abandonment. There is an incurable and unbridled quest for fertility and procreation among Nigerian tribes. The socio-cultural milieu puts much stress on generation of children, family continuity and social immortality. In the wake of this social demand, baby factories exploit the situation to exist, thrive and proliferate. Barrenness or childlessness goes with social stigma and psychological trauma. As a consequence, a lot of barren couples patronize the baby farms in order to address these needs^[8].

In the same vein, studies from India suggest that Infertile couples are mostly stigmatized in society, leading to a sense of isolation and exclusion. The reproductive and child health programs do not adequately address the infertility issues in India. In Asia, Infertility is a serious and alarming health issue with ramifications for both social and physical well-being. Parenthood is a highly emphasized and nearly vital event for couples in every society.

Since the introduction of the assisted conception, In-Vitro Fertilization (IVF) by Professor Robert Edwards and the birth of the first baby, Louis Brown through IVF in Britain in 1978, the method has come to represent the best means of fertility treatment. Over the past one and half decades, the use of Assisted Reproduction Technology (ART) has become commonplace, increasing at a rate of five to ten percent annually. In spite of its having brought succour to many childless couples/individuals, the associated ethical, legal, and social challenges remain issues of great concern. This has led to the institution of regulatory guidelines in many developed countries.

Regulating Art in Nigeria

In Nigeria and other developing countries in sub-Saharan Africa, there is no state regulation of assisted reproductive technology (ART). Presently, there is no national regulatory framework on ART in Nigeria even though we have several centers in Nigeria. Some private clinics operate based on the Human Fertilization and Embryology Authority Guidelines. ART practitioners in Nigeria and other developing African countries have a voluntary adherence to guidelines set by

the American society of Reproductive Medicine, the British Human fertilization and Embryology Authority or the equivalent body in France or Germany^[9]. Although there have been attempts at the national level to regulate ART by the introduction of the In-vitro Fertilization Bill 2015 and the Assisted Reproductive Technology (Regulation) Bill 2016, Lagos state is the first to formally regulate this area of medicine. This bill was sponsored by Senator Lanre Tejuoso. Both the IVF and ART passed the second reading and were to be consolidated but died a natural death at the end of the 7th Session of the National Assembly.

In October 2024, A Bill for an Act to Establish Nigeria Surrogacy Regulatory Commission for Monitoring and Supervision of Surrogacy arrangements in Nigeria and to provide for the Registration, Regulation and Monitoring of Surrogacy Agencies in Nigeria and for Related Matters sponsored by Hon. Olamijuwonlo Alao Akala passed through Second Reading^[10]. The Bill, which seeks to establish the surrogacy regulatory commission and provide for allied matters, would provide the much-needed regulation for parties involved in surrogacy in Nigeria. While it is hoped that this Bill will eventually become a law in Nigeria, it should be noted that this Bill only covers one aspect of ART which is Surrogacy. It can be said that in Nigeria, there is presently no sector specific law on ART. This poses a problem as the absence of a legal framework has created a lacuna which has led to all manner of unethical practices and abuse. Some of the available laws that are related to ART in Nigeria will be examined in the foregoing section.

The Constitution of The Federal Republic of Nigeria 1999

The Constitution guarantees the Right to private and family life^[11]. This has been interpreted to include the right to procreate and have children. The Government is expected to do what it takes to encourage and promote family life. This includes providing and regulating medical facilities and providing access to ART for those who are having challenges with infertility. In addition, the Constitution also provides that the "State shall direct its policy towards ensuring that- there are adequate medical and health facilities for all persons; and the evolution and promotion of family life is encouraged^[12]". These provisions can be interpreted to support the recognition of ART, suggesting a potential entitlement to reasonable access to ART treatments. Although these constitutional provisions cannot compel the government to provide these services, they do not restrict individuals from seeking such treatments independently.

The national health act (nha) 2014.

The National Health Act (NHA)^[13]. provides a framework for the regulation, development and management of a health system and sets standards for rendering health services in Nigeria. The NHA established the National Health System^[14]. The National Health System defines and provides a framework for standards and regulation of health services in Nigeria. The NHA is not a penal legislation like the Criminal Code and the Penal Code. The NHA Act provides for the regulation, development and management of national health systems and sets standards for rendering health services in the federation; and for related matters^[15]. The Act provides that a person shall not remove tissue, blood or

blood product 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 granted in the prescribed manner; or that the consent clause may be waived for medical investigations and treatment in emergency cases; and in accordance with prescribed protocols by the appropriate authority ^[16]. The implication of this provision on ART is that no oocyte or gamete can be removed from any person without the person's consent.

The NHA also provides that a tissue, blood or a blood product shall not be removed from the body of another living person for purpose of merchandise, sale, or commercial purposes ^[17]. It prescribes the punishment for contravention of this provision as follows: "a person who contravenes or fails to comply with the provisions of this section commits an offence and is liable on conviction in the case of- (a) tissue, to a fine of N1,000,000 or imprisonment of not less than two years or both; and (b) blood or blood products, to a fine of N100,000 or imprisonment for a term not exceeding one year or both^[18]. This implies that no gamete or embryo shall be sold. This provision prohibits commodification of gametes or embryos. The National Health Act 2014 ^[19], in *et al* addition, prohibits reproductive therapeutic cloning of human beings and the importation and exportation of embryos and prescribes the punishment for contravention as imprisonment for a minimum of five years with no option of fine. It should be noted that these provisions, though germane, do not cover all the aspects of ART.

Childs Rights Act 2003

The Childs Rights Act prohibits the act of buying, selling, and dealing in children ^[20]. This provision criminalizes unregulated and underhanded ART practices that could degenerate into buying and selling of gametes and embryos. It also prohibits unscrupulous surrogacy arrangements and baby factories that involve buying and selling of babies.

Trafficking in Persons [Prohibition] Enforcement and Administration Act (TIPPEA Act) 2015

The Act criminalizes all types of human trafficking ^[21]. All acts of human trafficking are prohibited in Nigeria. According to the Act, "any person who recruits, transports, transfers, harbours or receives another person by means of threat or use of force or other forms of coercion; abduction, fraud, deception, abuse of power or position of vulnerability; or giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation of that person, commits an offence and is liable on conviction to imprisonment for a term of not less than 2 years and a fine of not less than N250,000.00." This provision prohibits all forms of human trafficking. This includes ART practices and arrangements that involve buying and selling of gametes, embryos and babies. It can be said that commodification, importation and exportation of gametes, embryos and babies are a form of human trafficking.

Code of Medical Ethics in Nigeria 2004

Part of the statutory duties of the Medical and Dental Council of Nigeria is the reviewing and preparing from time to time, a statement as to the code of conduct which the Council considers desirable for the practice of the professions in Nigeria supervising and controlling the

practice of homeopathy and other forms of alternative medicine ^[22]. In line with the above duties, the Council released the Code of Medical Ethics for Medical and Dental Practitioners in Nigeria also known as the Rules of Professional Conduct.

The Code provides for Informed consent in medical procedures. It states that Practitioners involved in procedures requiring the consent of the patient, his relation or appropriate public authority must ensure that the appropriate consent is obtained before such procedures, either for surgery or diagnostic purposes are done, be they invasive or noninvasive. Consent forms should be in printed or in written form either as a part of case notes or in separate sheets with the institution's name boldly indicated ^[23]. This provision covers all medical procedures, including ART services. The written consent of patients must be sought and obtained before procedures are carried out. This includes procedures like oocyte retrieval, egg or sperm donation, embryo transfer, surrogacy arrangements, among others.

The Code also provided for Assisted Conception and Related Practices ^[24]. The Code states that "High-technology based human reproductive processes are now being employed by registered practitioners in Nigeria. These techniques embrace wide professional practices that include in-vitro fertilization, sperm donor and egg donor techniques, embryo donation, gestational surrogacy, full surrogacy and other emerging procedures. Whilst the necessary statutes to govern these desirable practices in the society are yet to be enshrined, ethical considerations show the essence for care and attention to the several needs of donor, recipient, and offspring at every step in these practices. Whilst the Council is devoting particular attention to necessary and continuous development of the ethical guidelines in assisted conception and all its professional practice implications, practitioners are expected to resolve certain matters of ethical significance that may arise.

Interestingly, the code highlights gaps that the law should fill in the area of monetary compensation for embryo and embryo donation for research. The code notes that there are ethical considerations on monetary payments in view of connotations of selling and commercializing in the early form of human life. It has become necessary that the Laws of the country should make the provisions for resolving this. Meanwhile the Medical and Dental Council of Nigeria advises that gamete or embryo donation should be made as a voluntary service and not commercialized. In addition, there is the ethical risk of trading in embryos that are neither used to - initiate pregnancy nor discarded. Such issues as donor recruitment methods, monetary transactions, and types of researches to be applied to embryos certainly need statutory regulation. The Medical and Dental Council of Nigeria calls for appropriate legislation on the matter.

ART Practice in Lagos State (Regulations and Guidelines) 2019.

The Lagos State guidelines, the ART Practice in Lagos State: Regulations and Guidelines were unveiled in May 2019 by the Lagos state Ministry of Health in conjunction with Health Facilities Monitoring and Accreditation Agency (HEFAMAA) and Association for Fertility and Reproductive Health (AFRH) and other stakeholders. This was done in order to curb sharp practices. The document is known as 'ART Practice in Lagos State, Regulations and Guidelines'. It specifically addresses issues like registration,

accreditation, and renewal of clinics as well as the minimum standards for practices especially with regards to various ethical issues in assisted reproductive technology, monitoring, enforcement and penalties. The Lagos State guidelines deal with both clinical and ethical issues. It provides guidance on maximum number of embryos, cryopreservation, cross-border treatment, counseling, confidentiality for special cases, donation of gametes and embryo, posthumous use of gametes, surrogacy, pre-implantation genetic testing, record keeping, clinical best practices, research and even sanctions. It also delegates Health Facility Monitoring and Accreditation Agency (HEFAMAA) as the regulatory agency in charge of ART Practice in Lagos State ^[25].

The Commissioner for Health, Dr. Jide Idris said that the step is necessary in response to the growing need of Assisted Reproductive Technology, ART, interventions and emergence of other Advanced Medical Procedures and Research. By 2017, the number of documented ART practice outfit in Lagos had risen by leaps and bounds, from the very few in 1999 to over 20 clinics by December 2018, with many undocumented and not guided by clear cut and specific extant Laws and Regulations ^[26].

According to him, "The huge public outcry against unwholesome practices perpetrated majorly by uncertified and unaccredited specialists, was not a surprise. Reports of unethical practices of varied nature including paid advertisements and promos became rife; tales of extortion, unorthodox practices and even quackery reached totally unacceptable levels ^[27].

Some provisions of the Lagos state Guidelines on ART would be highlighted below.

a. Definitions of ART Procedures Were Provided as Follows

Assisted reproductive technology encompasses a variety of clinical treatments and laboratory procedures, which include the handling of human oocytes, ovarian tissue, sperm, testicular tissue, or embryos, with the intent of establishing a pregnancy. This includes but is not limited to *in vitro* fertilization (IVF), Gamete Intra-fallopian Transfer (GIFT), Zygote Intra-Fallopian Transfer (ZIFT), Embryo Biopsy, Pre-Implantation Genetic Testing (PGT), Embryo Cryopreservation, Oocyte or Embryo Donation, Gestational Surrogacy and Gamete and Embryo Cryopreservation.

b. Personnel

There should be a backup system in place for all personnel essential to a program. A single individual may fulfill the requirement for expertise in one or more areas. The guidelines provided for the medical personnel and their requisite qualification that should be present in an ART facility. These include: A designated overall Practice Director, Medical Director, Embryologist, Laboratory Technicians and Qualified Nurses.

c. Data Collection Management

The Embryology Laboratory must retain records of all its policies and procedures as well as personnel employment, training, evaluations and continuing education activities. In addition, documentation of the proper identification, outcome and disposition of all oocytes and embryos is important. The Laboratory must maintain these records for a period of time specified by Federal, State and Local Laws or for 10 years beyond the final disposition of all specimens

obtained during each patient's ART cycle, whichever is later. In the event that the laboratory ceases operation, provisions must be made for these records to be maintained according to the time frame required.

d. Informed Consent

According to the Guidelines, each prospective patient/couple must be provided with all relevant information necessary to make an informed decision regarding the proposed treatment and must be given the opportunity to ask questions in order to gain a better understanding. The communication process should be documented in the medical record and the patient must provide full written informed consent.

e. Regulating ART

According to the Guidelines, a Monitoring Committee will be set up to manage the practice of ART. The committee will comprise of HEFAMAA Officials and 3 nominees from the AFRH, which will include Clinicians and an Embryologist. The AFRH nominees shall have a tenure of 2 years renewable for a further 2 years.

f. Monitoring

All ART Clinics are mandated to keep proper records of patients treated in their facilities. Membership of AFRH ART Registry is advised for all clinics. Cycle data should be entered prospectively. The State Ministry of Health will have access to data submitted to the Registry and Clinics that fail to comply will be sanctioned.

g. Ethical Issues

The following ethical issues were outlined for consideration: No more than 3 Embryos should be transferred into any patient regardless of age. Clinics are encouraged to transfer a maximum of two embryos preferably. ART Centers are strongly advised not to guarantee outcomes of procedures. The Guidelines provide that Recipients should not be more than 55 years old ^[28], Egg Donors should be between 21-35 years and Sperm donors should be between 21-40 years. In addition, sperm Donors shall be anonymous ^[29]. The Lagos Guidelines further provide that only left over/excess embryos should be used for research purposes after obtaining consent from the Patients ^[30], and prohibits the transfer of human embryo into an animal or placing an animal embryo into a woman ^[31].

h. Surrogacy is not currently recognized in Nigerian law but is widely practiced

Clinics offering Surrogacy should have clearly spelt out consent forms and unambiguous agreements between all the parties involved. HEHAMA will conduct annual inspection of Clinic Facilities to ensure conformity with Quality Assurance guidelines.

i. Enforcement/Penalties

Infractions committed by Clinics will be penalized by warning with appropriate fines, suspension with appropriate fines and closure with appropriate fines.

Regulating Art in India

In 1982, the Indian Council of Medical Research (ICMR) a pioneering Indian organization in the field of Biomedical Sciences took initiative realizing the importance of treatment of infertility and initiated a project (led by T.C.

Anand Kumar and Indira Hinduja) at its Institute for Research in Reproduction (now ICMR-National Institute for Research in Reproductive Health) at Mumbai. As a result, India's first fully scientifically documented test tube baby, 'Harsha', was born on August 6, 1986^[32]. Due to ever increasing demand for management of infertility in the country led to the mushrooming of the IVF clinics in the country. ART in India is facing major safety concerns and risks that need to be evaluated at a large scale. In 2005, the Indian Council of Medical Research (ICMR) issued guidelines to regulate these clinics providing ART procedures (including surrogacy procedures)^[33]. The guidelines provide for registration of clinics offering ART services, permit single women and couples to access ART services, and allow ART banks to compensate donors. These guidelines also specify conditions for when surrogacy may be opted, and the compensation for surrogates. These guidelines were later translated into Assisted Reproductive Technology (Regulation) Bill, 2017 and Surrogacy (Regulation) Bill, 2016^[34].

In July 2019, the government introduced the Surrogacy (Regulation) Bill^[35]. The Bill provided for the registration of surrogacy clinics, defines the eligibility criteria of commissioning couples and surrogates, and provides for the establishment of boards to advise the government on surrogacy policies. The Bill was passed by Lok Sabha in August 2019. In Rajya Sabha, the Bill was referred to a Select Committee of the House^[36]. While examining the Bill, the Committee recommended introducing a comprehensive legislation to first regulate clinics and banks providing various fertility services, i.e., ART and surrogacy services.

The Assisted Reproductive Technology (Regulation) Bill, 2020 was introduced in the Lok Sabha in September 2021 and was referred to the Standing Committee on Health and Family Welfare in October 2020. In 2021, the Indian Parliament passed the Assisted Reproductive Technology (Regulation) Act (hereinafter referred to as the ART Act) to regulate ART clinics and banks. The Surrogacy (Regulation) Act 2021 was also passed by the Lok Sabha.

The ART Act aims to ensure that ART services are ethical, affordable, and socially acceptable. It also includes measures to protect children born through ART. The Act deals with proper supervision, regulation, licensing, and ensuring good ethical practices in the rapidly evolving field of assisted reproduction.

It can be said at this point that India has made more inroads in regulating ART than Nigeria and Nigeria can borrow a leaf from India in this regard. There is a national law regulating ART in India. The Assisted Reproductive Technology (Regulation) Act 2021 was enacted for the regulation and supervision of the assisted reproductive technology clinics and the assisted reproductive technology banks, prevention of misuse, safe and ethical practice of assisted reproductive technology services for addressing the issues of reproductive health where assisted reproductive technology is required for becoming a parent or for freezing gametes, embryos, embryonic tissues for further use due to infertility, disease or social or medical concerns and for regulation and supervision of research and development and for matters connected therewith or incidental thereto.

Some provisions of the ART Act would be highlighted below.

The Act is made up of 6 Chapters and 46 Sections. Chapter One contains preliminary provisions.

Chapter Two deals with the establishment of the National ART and Surrogacy Board and State ART and Surrogacy Boards and the National Registry. Chapter Three contains the Procedures for Registration assisted reproductive technology clinic or assisted reproductive technology bank. Chapter Four deals with duties of assisted reproductive technology clinic and assisted reproductive technology bank. Chapter Five contains the Offences and Penalties. Chapter Six contains the Miscellaneous provisions.

The Act established the National Assisted Reproductive Technology and Surrogacy Board^[37], and the State Assisted Reproductive Technology and Surrogacy Board^[38], as the Authorities to regulate assisted reproductive technology in India and implement the Act. The Act also established the National Assisted Reproductive Technology and Surrogacy Registry^[39]. Some of the functions of the Registry include^[40]:

(a) To act as a central database in the country through which the details of all the clinics and banks of the country including nature and types of services provided by them, outcome of the services and other relevant information shall be obtained on regular basis;

(b) To assist the National Board in its functioning by providing the data generated from the central database of the Registry.

The data generated from the National Registry shall be utilized by the National Board for making policies, guidelines and shall help in identifying new research areas and conducting research in the area of assisted reproduction and other related fields in the country.

The powers and functions entrusted to the national and the state ART and surrogacy boards will help in the implementation of the Act at the grassroots level. The process of the registration as mentioned in chapter III provides a period of 60 days from the establishment of a national registry. Establishment of a national ART registry will help in generating big data which can be subjected to analysis for research and for guiding policy matters and current clinical practice for good reproductive health of citizens. The Act contains an elaborate definition section^[41]. This would help clear ambiguities.

The Act makes provision for Written informed consent^[42]. The clinic shall not perform any treatment or procedure without— (a) the written informed consent of all the parties seeking assisted reproductive technology; (b) an insurance coverage of such amount as may be prescribed for a period of twelve months in favour of the oocyte donor by the commissioning couple or woman from an insurance company or an agent recognized by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, 1999 (41 of 1999). The clinics and banks shall not cryo-preserve any human embryos or gamete, without specific instructions and consent in writing from all the parties seeking assisted reproductive technology, in case of death or incapacity of any of the parties.

Pre-implantation Genetic Diagnosis^[43]. The Pre-implantation Genetic testing shall be used to screen the human embryo for known, pre-existing, heritable or genetic diseases only. The Act places restriction on sale of human gametes, zygotes and embryos^[44]. — The sale, transfer or

use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party within or outside India shall be prohibited except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board.

Research on human gametes and embryos is prohibited completely by the Act ^[45]. — (1) The use of any human gametes and embryos or their transfer to any country outside India for research shall be absolutely prohibited. (2) The research on human gamete or embryo within India shall be performed in such manner as may be prescribed.

Rights of a child born through assisted reproductive technology are guaranteed under the Act ^[46]. The child born through assisted reproductive technology shall be deemed to be a biological child of the commissioning couple and the said child shall be entitled to all the rights and privileges available to a natural child only from the commissioning couple under any law for the time being in force. The Act also provides that a donor shall relinquish all parental rights over the child or children which may be born from his or her gamete ^[47].

Provisions of the offences and penalties have been elaborated in chapter V in detail. If implemented in letter and spirit, it will ensure strict compliance by ART clinics and ART banks and award appropriate penalties in cases of offence committed as per the provisions of the Act.

Conclusion and Recommendations

This paper examined the available Regulatory Framework for ART in Nigeria and India and noted that India has enacted a sector specific law on ART which is the Assisted Reproductive Technology (Regulation) Act 2021. Some aspects of this Act were underscored. The paper observed that though Nigeria doesn't have a sector specific law on ART, there are some laws in Nigeria that relate to ART and regulate the practice of ART in Nigeria. Some of these laws were examined. It is concluded that there is the need for a sector specific law on ART in Nigeria. In addition, there should be constant and in-depth regulation of ART in Nigeria which must define and prescribe roles and status for the all the collaborators in the procreation effort ^[48]. The rights and duties of physicians in the exercise must be clearly defined. Categories of persons which shall be entitled to fertility must be unambiguously stated ^[49]. Flowing from the above, the following recommendations are suggested:

1. To start with, the Surrogacy Bill 2024 which is currently before the House should be passed into Law. The Nigerian Government should take the necessary step to enact a sector specific law on ART in Nigeria that would cover most types of ART procedures. This provision would also include penalties for offenders. In other words, the Nigerian Government should provide for a comprehensive legislation that will protect the health and safety of Nigerians using ART, prohibit unacceptable practices, and regulate ART activities and related research. The legislation should ensure strict control of ARTs practices and address issues such as informed consent, the legal status of the intended parents, legal status of children born through IVF, gamete donation, the fate of unused gametes, embryo research. Practices such as cloning, sale of gametes and embryos should be prohibited. The ART law should

also outline the legal status and rights of the intended parents and the children.

2. A Regulatory Body should be established to implement the provisions of the Act and supervise the ART Clinics in Nigeria. The Body should be empowered to grant, suspend and revoke licenses to ART Practitioners and Clinics, prescribe Minimum requirements for IVF infrastructure, equipment and personnel qualifications.
3. Additionally, the proposed ART legislation in Nigeria should include mechanisms for resolving disputes related to parental rights or status of children born through IVF or problems with IVF clinics, negligence on the part of the Practitioners, among others.

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