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UTILIZING LEGISLATIVE INTERVENTION TO PROMOTE ASSISTED REPRODUCTIVE TECHNOLOGY IN NIGERIA

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Abstract

Assisted Reprodoductive Technologies is a process aimed at facilitating procreation devoid of physical sexual intercourse between the male and female partners. The procedure is medically designed to assist infertile couples to achieve conception and bear children, notwithstanding the probem of infertility. There are diffenrent methods of ART. However, each depends on the causes of the infertility as determined through clinical diagnosis. Generally, ART involves the manipulation of human sperm and ovum outside the woman's body to facilitate fertilitization and conception. It is against this background that the authors canvassed for a specific legislative intervention in the application of Assisted Reproductive Technology (ART) in Nigeria. The authors further argued for the use of assisted reproductive technology to achieve conception in the face of condition of subsisting infertility which has introduced several emerging issues that require legislative intervention. The paper noted that while several countries have taken deliberate actions to establish legal and ethical guidelines to regulate ART, Nigeria has failed to do so despite the relatively long duration of the practice in the country. The paper maintained that the development of binding and enforceable legal norms is fundamental to entrenching transparency, accountability, and quality assurance in ART practices. The authors adopted the doctrinal research approach and thereafter recommended the establishment of flexible and decentralized legal and institutional regulatory mechanisms that would create a minimum standard of practice and define the rights and obligations of individuals who are involved in the utilization of ART techniques in the country.

Keywords: Assisted reproductive technology, fertile and infertile couples, genetic disorders, pre-implantation diagnosis, medical regulation

1. Introduction

The rapid advancement of assisted reproductive technologies (ARTs) since the birth of Louise Brown, the world's first test-tube baby in 1978 has continued to challenge policymakers and stakeholders across the world.[1] ART procedures such as In Vitro Fertilization, preimplantation genetic testing, surrogacy, gamete intra-fallopian transfer, and embryonic sex selection which were previously regarded as a no-go area, have now become a reality and are constantly being utilized by many people the world over.[2] While these procedures continue to create more opportunities for infertile couples, they have also introduced several concerns relating to abuse of women, commercialization of gametes donations, unethical handling of embryos and gametes, and commercial surrogacy.[3] These challenges have forced many jurisdictions to ponder whether or not to regulate ART, the extent of regulation required, and the kind of ART practices to be abolished or allowed[4] In the United Kingdom, the answer to these questions is relatively simple because of their centralized governance system, unlike federal jurisdictions where the constitutional division of powers exist between the federal and state governments concerning powers to regulate ART.[5] However, most of the questions surrounding the practice of ART are yet to be properly addressed in Nigeria due to the absence of regulatory framework that would define and establish a minimum standard of ART treatment, entrench high-quality care, protest the interests of children born through ART, define the rights of ART participants, minimize risk, and promote public confidence in the application of the technology.

The paper strives to examine how legislative intervention can be used to address the peculiar challenges associated with the application of ART in Nigeria, against the premise that while some form of professional regulations are readily available, these regulations are largely unenforceable and as such incapable of entrenching minimum standard of practice for ART treatments.

[1] D. Adamson, 'Regulation of Assisted Reproductive Technology in the United States' *Family Law Quarterly* (2005) 39 (3) 727-744.
[2] F. Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (New York: Farrar, Straus, and Giroux, (2002), 5.
[3] R. Stenger, 'The Law and Assisted Reproduction in the United Kingdom and United States' *Journal of Law and Health* (1994) 9 (133) 135-153.
[4] D. Snow and R. Knopff 'Assisted Reproductive Policy in the Federal States: What Canada Should Learn from Australia' *School of Public Policy Calvary University: SSP Research Paper* (2012) 5 (12) 1-24.
[5] ibid.

Furthermore, the authors will establish the need for the Nigerian government to harvest comprehensive legal mechanisms and arm's length regulatory structures to regulate ART and ensure that the interests of those who utilize the technology are adequately protected under an enforceable legal and regulatory regime capable of establishing a minimum standard of ART practices and defining permissible and impermissible reproductive procedures in the country.

2 Nature and scope of ART

Assisted Reprodoductive Technologies connotes the process to facilitate procreation without the occurrence of sexual intercourse between the partied involved.[6] This procedure is medically designed to assist infertile couples to achieve conception and bear children because of the probem of infertility.[7] The method of ART to be used depends on the causes of the infertility as determined throught clinical diagnosis. Generally, ART involves the manipulation of human sperm and ovum outside the woman's body to facilitate fertilitization and conception. ART first occur as far back as 1960 in the United States of America,[8] United kingdom and Australia.[9] The historic first world's first test-baby Louise Brown was born through 'In Vitro Fertilization' (IVF) procedure on 25 July 1978.[10] Significantly, ART has expanded in scope and application assisting millions of infertile couples across the globe to overcome their reproductive challenge. It is estimated that more than 8 million children have been born worldwide as a result ART procedure.[11] Apart from procreation, ART may assist both fertile and infertile couples to determine the sex of the unborn offppring. The technology can also be ultilized to prevent the transmission of genetic disorders in an unborn offspring through pre-implantation diagnostic testing.[12] Thereby minimizing the transmission transmission of genetic diseases from genetic parents to their offspring. Over the years, ART procedure have developed from less sophisticated procedure of artificial insemination to more complex procedures such as in vitro fertilization,

[6] O. Ojilere and M. Agagua ' Assisted Reproductive Techologies and the Menace of Baby Factories in Nigeria' *Journal of Commerical and Comtemporary Law* (2019) 9, 24-35
[7] Okafor, N.I., et al, 'Perceptions of Infertility and In Vitro Fertilization Treatment among Married Couples in Anambra State Nigeria'*African Journal of Reproductive Health* (2017) 21 (4) 55-66.
[8] M.S. Frankel ' Role of Semen Cryobanking in America Medicine' *Br Medical Journal* (1974) 3 (5931) 619-621.
[9] D.F. De Stoop ' Human Artifical Insemination and the Law in Australia' *Australia Law Journal* (1976) 50 (6) 298.
[10] P.C. Steptoe and R.G. Edwards ' Birth After Re-Implantation of a Human Embryo' *The Lancet* (1978) 8085, 36.
[11] U.B. Wennerholm and C. Bergh, 'Perinatal Outcome in Children Born after Assisted Reproductive Technologies' *Upsala Journal of Medical Science* (2020) 125 (2) 158.
[12] E. Fragouli, 'Pre-implantation Genetic Diagnosis: Present and Future' *Journal of Assisted Reproduction and Genetic* (2007) 24 (6) 201-207

sperm and egg donation, zygote intrafallopian transfer, gamete intrafallopian transfer, intracytoplasmic sperm injection and gestational surrogacy. While ART continue to advance in leaps and bounds, it has also introduced myriad of ethical, social and legal challenges.

3. Subsisting Premise for the Regulation of ART

Several reasons have been highlighted for the regulation of ART. One of the reasons is that regulation is needed to secure the interest of all those who are directly implicated in the utilization of the technology.[13] These competing interests include those of the intending parents, gametes donors, ART-conceived children, and ART specialists.[14] Regulation is also required to abolish certain unethical and obnoxious practices such as human cloning, the designing of embryos, a mixture of human and animal gametes, the commercialization of human reproductive materials (embryos and gametes), and commercial surrogacy.[15] This practice tends to undermine the sanctity of human life and can only be abolished through legislative mechanisms. Arguments for regulation are also supported by certain constitutional restraints on reproductive liberty. For instance, section 45 (1) of the 1999 Constitution provides that "nothing in sections 37, 38, 39, 40 and 41 of this constitution shall invalidate any law that is reasonably justifiable in any democratic society (a) in the interest of defense, public safety, public order, public morality or public health, or (b) to protect the right and freedom of other persons."[16] The government could rely on this restriction to enact appropriate regulatory frameworks for ART and prohibit unethical practices of the technology capable of undermining public morality and public health. Regulatory intervention is also required to protect the interest of families by imposing certain mandatory obligations on ART providers to keep proper records, provide counseling for ART patients, and ensure that donated reproductive materials are properly handled.[17] Regulation could also assist in ensuring effective evaluation, supervision, and monitoring of ART service providers to protect the health and well-being of ART participants.[18] Specifically, precise and binding legal standards on ART are essential to ensuring that ART activities are conducted with due regard to the safety of

[13] J. .J. Morgan, State Regulation of Assisted Reproductive Technology, All Thesis and Dissertations, Brigham Young University, (2010) 2206.
[14] Ibid.
[15]Dame Mary Warnock, 'Report of the Committee of Inquiry into Human Fertilization and Embryonic (Department of Health and Social Security, 1984) 1-113
[16] 1999 Constitution, s. 45 (1) (a) and (b).
[17] C. Naomi, *The New Kingship: Constructing Donor Conceived Families* (New York University Press, 2013) 151.
[18] B.M. Lyria, 'Understanding Legal Responses to Technological Change of In Vitro Fertilization' *Minnesota Journal of Law, Science and Technology* (2006) 6 (2) 505-576.

individuals, communities, and society at large.[19] Furthermore, a legal framework on ART would assist in ensuring that ART participants can make informed decisions about whether or not to utilize ART procedures. The significance of regulatory measures on ART was also emphasized *in re Marriage of Buzzanca*[20] by Justice Robert Monarch thus:

> We join the chorus of judicial voices pleading for legislative attention to the increasing number of complex legal issues spawned by recent advances in the field of assisted reproduction. Whether merit there may be to a fact-driven case-by-case resolution of each new issue, some overall guidelines would allow the participants to make informed choices and the courts to strive for uniformity.

The development of a legal framework would also help to protect the interest of children conceived through ART including their paternity, right to inheritance, and welfare. The rights of donor-conceived children can also be guaranteed under an effective and efficient legal and institutional framework.

4. Philosophies on Assisted Reproductive Technology

There are subsisting philosophies as well as regulatory approaches to ART, and they include the following- free market, professional and legal regulations.

i. Free Market Regulation

One of the major concerns which may be introduced by emerging socially and medically relevant technology like ART procedures is whether or not, government can introduce steps to regulate their application or leave them to free market forces to determine development and availability. Free market regulation denotes some degree of industry self-regulation on the part of providers subject to competition including the forces of demand and supply. It allows consumers free choice, and to providers, to provide any procedure they could.[21] It promotes reproductive freedom by ensuring that consumers and providers have open access to the market.[22] Individuals who have money can purchase whatever goods and services they want by making their choices known through their purchasing power. A free market cannot

[19] D. Chalmers, 'Professional Self- Regulation and Guidelines in Assisted Reproduction' *Journal of Law and Medicine* (2002) 9, 414 -425.
[20] (1998) 61 Cal. App. 4th 1412.
[21] M. Schermer ' Reprogenetic Technologies Between Private Choice and Public Good' In E. Parens and J.Johnston, *Human Flourishing in An Age of Gene Editing* (Oxford University Press, 2019) 212, 210
[22] MA Ertman 'What's Wrong with A Parenthood Market? A New and Improved Theory of Commodification' *N.C.R. Review (*2003) 82, 1, 16.

operate without certain form of restrictions. With regard to adoption market, for instance, it has been argued that child abuse and neglect legislations should be enacted together with certain form of 'limited' background checks in order to prevent abuse, unethical practices and exploitations.[23] Other restrictions such as the prohibition of rejection by intended parents of babies 'not in conformity with their expectations' requiring certain specific performance by the biological mother have also been suggested.[24]

Translating this concept to ART presupposes that certain regulatory goals can be achieved by preventing market abuse via honest advertisement apart from controlling the application of the technology through the imposition of safety diagnosis, anti-discriminatory guidelines, and other measures.[25] Market can self-regulate itself by ensuring that responsible and effective application of ART is promoted and that introduction of extralegal market forces capable of promoting low quality at higher prices are prevented.[26] Hence, to market reliable services, ART providers must ensure that they provide standard services and as such price could be regulated by the market through forces of demand and supply. The high cost of ART services in Nigeria is governed by the forces of demand and supply. Only 76 ART clinics offer ART service in Nigeria with a population of over 200 million people with a higher rate of infertility. The continue rise in cases of infertility without a commensurate increase in the numbers of ART providers to meet the demand for ART services coupled with lack of active government intervention will definitely result in higher prices for ART services.

Free market regulation can prevent state-imposed discrimination among ART users on basis of marital status or sexual orientation by ensuring that every adult of reproductive age have access to the technology.[27] It allows consumers to choose ART services they desire without undue restrictions. Free market can be controlled through available law of torts, such as negligence rather than strict government regulation.[28]

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[23] E. Landes and R. Posner ' The Economics of the Baby Shortage' Journal of Legal Studies (1978) 7, 323; RA Posner, 'The Regulation of the Market of Adoption' *Boston University Law Review* (1987) 67 (59) 343, 344
[24] ibid, at P. 67.
[25] G. Cohen and E. Adashi, The FDA is Prohibited from Going Germline' *SCI* (2016) 353, 545, 546.
[26] Posner (note 22) at 62
[27] Ertman (note 21) 43
[28] D. Fox ' Birth Rights and Wrongs: How Medicine and Technology Are Remaking Reproduction and the Law' (Oxford University Press, 2019)

The main benefit of free market regulation of ART procedures is that it promotes reproductive freedom, efficiency, consumers' choice, and novelty. It allows participants to gather relevant date or information on the efficiency of the technologies and the perception about their application invariably displacing the pervasive process of general comments.[29] It can promote widespread awareness, availability and acceptability of ART procedures.[30]

However, it should be pointed out that free market regulation has its own drawbacks.[31] It can led to situations where many infertile couples and single women cannot afford the price of ART services even when competitive prices exist. This will promote economic inequalities in access to ART services. Furthermore, it may allow access to ART services to be restricted to individuals who pay for it, except where there is government intervention through actions such as insurance coverage.[32] The main goal of most fertility specialists in a free market setup is to maximize profit without due regard to the interest of intending parents and prospective children.[33] Free market can led to commodification, human reproduction, and family formation which are cardinal component of parentage.[34]

By diverse imagination, it is apparent that free market regulation is unsuitable for a developing state such as Nigeria, because it may operate to promote commodification of children, unethical practices and exploitation. Assisted reproductive technologies involve sensitive areas of medical procedures to be left to market mechanisms including the forces of demand and supply. Free market regulation may put families, children and donors at risk and subjects of exploitations in the hands of fertility specialists. ART industry in Nigeria requires some level of formal and professional regulation to achieve its desire objectives.

ii. Professional Self-Regulation

ART can also be regulated by informal and professional self-regulatory guidelines. These guidelines are usually established by medical professional bodies, who are traditionally saddled

[29] JD Mahoney and G. Siegal, 'Beyond Nature? Genomic Modification and the Future of Humanity' *Journal of Law and Contemporary Problems* (2018) 81, 197-210
[30] ibid
[31] DE Roberts 'Why Baby Market Aren't Free' *UC IRVINE Law Review* (2017) 7, 611-620
[32] Schermer (note 20) 11.
[33] JL Rosato, 'The Children of ART (Assisted Reproductive Technology): Should the Law Protect them from Harm' *Utah Law Review* (2004) 57, 60.
[34] S. Suter, 'Giving In to Baby Markets: Regulation without Prohibition' *Michigan Journal of Gender and Law* (2009) 16, 217-223.

with the responsibility of making rules and establishing acceptable standards of practice for the medical profession. Professional self-regulation can also be used to develop standards of application of emerging scientific devices, medical procedures, and diagnosis.[35] One of the characteristics of self-regulation is flexibility.[36] It can easily be altered to address new and emerging challenges relating to ART. For instance, the Reproductive Technology Accreditation Committee (RTAC) of Australia.[37] The RTAC has played a major role in the establishment of accreditation requirements for ART providers in Australia. It also ensures that ART providers have the necessary tools and equipment to carry out their operations before certification. The RTAC conducts regular supervision and monitoring of accredited ART facilities to ensure that they comply with established standards of practices These standards include the provision of quality services, and publication of objective, unbiased, and transparent treatment outcomes.[38] Apart from Australia, professional self-regulation is also deeply rooted in the United States of America where the activities of medical professional bodies such as the American Society for Reproductive Medicine (ASRM)[39] have assisted a great deal in advancing the course of reproductive medicine across the United States. The responsibility of ASRM is also complemented by the Society for Assisted Reproductive Technology[40] which was established in 1987 as an affiliate of ASRM, to provide professional services to ART specialists, ART patients, and public institutions in the US. The SART is also responsible for the publication of the facility clinic success rate report. Furthermore, the code of practice and laboratory guidelines established by both the SART and ASRM are now applicable in every part of the United States. Like the United States, certain forms of professional self-regulation have also been established in Nigeria, particularly, those relating to medical practice generally. The Nigerian Medical Association (NMA),[41] for instance, is vested with the responsibility of ensuring that medical and dental procedures are conducted professionally. The body has made significant contributions to the

[35] Mahmoud Fathalla, supra, 'Current Challenges in Assisted Reproductive Technology,' 4-12.
[36] ibid
[37] A good example of a self-regulatory body on ART is the Reproductive Technology Accreditation Committee (RTAC) in Australia. The activities of RTAC have shown that self-regulation measures are significant in addressing the issue of ART. See generally, the National Health and Medical Research Council (NHMRC) *Ethical Guidelines on the of Assisted Reproductive Technology in Clinical Practice and Research: Working to Build a Healthy Australia,* 2017.
[38] ibid.
[39] American Society for Reproductive Medicine < https://www.asrm.org> accessed 14 October 2023.
[40] [Hereafter, SART] Society for Assisted Reproductive Society < https://www.sart.org> accessed 14 October 2023.
[41] Nigerian Medical Association <https://nationalnma.org> accessed 14 October 2023.

formulation of health legislations and policies in the country. Apart from the NMA, the Association for Fertility and Reproductive Health[42] has also been established by fertility specialists in the country to provide the required training and up-to-date knowledge about issues relating to reproductive health. The association also creates awareness and enlightens members of the public about the problem of fertility and the options available for addressing it.

iii. Legal Regulation

Formal regulation often takes the form of legislation which is validated by parliament, the state, or judicial authorities. These institutions are constitutionally empowered to establish legal rules in their respective jurisdictions for the good of society. Historically, formal regulation of ART was incomprehensible because issues relating to the right to personal liberty including assisted reproductive procedures were considered as matters within the realm of private regulation.[43] This position is based on three factors; Firstly, marriage and family affairs were traditionally regulated by religious organizations. Secondly, the field of medicine has an extended history of professional self-regulation and the application of formal rules to medical practice was recently introduced. Thirdly, the socio-cultural and religious diversity of human society can make it very untidy for formal regulation to hold sway on matters that were more philosophically oriented.[44] This view began to fade away after some time and the need for state intervention emerged. This fundamental shift occurred 1980s when there was considerable public interest in the application of assisted reproductive technologies due to some fundamental reasons:

(a) the use of ART including the storage of human embryos may result in unethical experimentation of embryos.

(b) the development of ART is capable of resulting in the mixture of genetic testing with reproductive procedures.[45]

As a result, several commissions were set up by almost all Western European countries to look into those issues and propose suitable solutions. Reports of the commissions indicated that ART had introduced serious legal, social, and ethical issues of public concern that need to be addressed

[42] [Hereafter, The AFRH] Association for Fertility and Reproductive Health <https://afrhnigeria.org> accessed 14 October 2023.
[43] C. Byk, 'Public and Private Regulation of Reproductive technologies', *Medicine and Law* (1995) 14, 215-219.
[44] ibid.
[45] Ibid.

by the government.[46] These findings eventually led to the establishment of formal regulatory mechanisms for ART in many Western societies. In the United Kingdom, for example, the Human Fertilization and Embryology Act of 1990 was established to regulate the activities of ART service providers. The Act also regulates the licensing, inspection, and monitoring of ART services including the use and storage of embryos and gametes. It established the Human Fertilization and Embryology Authority (HFEA) to implement the provisions of the Act. Other jurisdictions like Canada, Sweden, France, Australia, and Germany have also established specific legislation on ART. Formal regulations have also been established in some Latin American countries,[47] except Costa Rica where the practice of ART has been prohibited through constitutional amendment.[48] While many Western societies continue to develop legislative measures to address the issue of ART, there is almost a lack of legislative intervention in Sub-Saharan Africa. As a result, ART service providers in the sub-region have continued to rely on formal and informal guidelines applicable in Western countries to guide their activities.[49] This is despite the relatively long duration of the practice of ART in the sub-region. This challenge affects the quality of ART services that are provided in the subregion resulting in abuse of women, unethical practices, and manipulations.

5. Framework on Assisted Reproductive Technology in Nigeria

There have been several efforts to regulate assisted reproductive technologies in Nigeria. One of these initiatives is the Assisted Reproduction Authority Bill 2012, which seeks to establish the Nigerian Assisted Reproduction Authority and regulate the practice of assisted reproductive technologies (ART) in the country. Unfortunately, the Bill has not yet been passed into law. Except for Lagos State, where ethical guidelines exist,[50] other states including the Federal Capital Territory have failed to develop specific legal

[46] Ibid.
[47] Florencia Luna 'Assisted Reproductive Technology in Latin America: Some Ethical and Sociocultural Issues' in Effy Vayena, et al (eds) *Current Practices and Controversies in Assisted Reproduction* (World Health Organization, 2002)32-40.
[48] ibid., 33. This prohibition has since been annulled by the Inter-American Court on Human Right in the case of *Artivia Murrilo and Orders v Costa Rica* (2012). But the government of Costa Rica is yet to comply with the judgement.
[49] Osato Giwa-Osagie 'ART in Developing Countries with Particular Reference to Sub-Saharan Africa' (note 24) 23
[50] The Nation 'Lagos Unveils New Guidelines on ART' (May 10, 2019) < https://thenationonlineng.net/lagos-unveils-new-art-guidelines> accessed March 5, 2024.The Lagos State Guidelines on Assisted Reproductive was established to among other things, address issues relating to registration, accreditation, renewal of clinics, monitoring, enforcement, and penalties in ART practice. Besides creating a regulatory body for ART, it also sets the

and ethical guidelines to regulate ART practices. Despite this, many Nigerians have continued to utilize the technology to address their reproductive challenges and bear children. The underlying challenge, however, is how the rights and responsibilities of the parties who are involved in ART arrangements can be established without a specific legal regime that would define permissible and impermissible rules of conduct regarding ART practices. Apart from this, the use of gamete donors has introduced third parties into the reproductive process whose interests need to be properly defined. Therefore, there is an urgent and compelling need for the Nigerian government to regulate ART. To achieve this objective, existing legislation that has some bearing on ART needs to be reviewed and evaluated.

To answer the question of whether or not ART should be regulated in Nigeria, there is the need to critically examine some legal provisions that directly or indirectly implicate ART to determine whether or not they have sufficiently addressed the challenges inherent in the application of reproductive technology in the country. These legislations include:

i. The National Health Act (NHA), 2014

The National Health Act was enacted in 2014 as the legal instrument for the regulation, growth, and management of the Nigerian health system including the establishment of minimum national standards for health care delivery across the country.[51] The objectives of the Act include the promotion of collaboration among every healthcare service provider, ensuring efficient and effective healthcare delivery, defining the rights and obligations of health institutions, health services providers, health personnel, and patients, and promoting access to healthcare services in the country.[52] The Act established the National Council of Health with the responsibility to promote and protect the health of every citizen of Nigeria, develop appropriate policies and guidelines on health care, facilitate the implementation of the National Health Policy, and establish health care priorities and targets for the government, etc.[53] The Act also contains several provisions on emergency treatment, the confidentiality of patient information, the patient's right to complain about treatment, the referral of a patient, the duty of health care providers to keep proper records of treatment, the prohibition of human cloning, and the removal and transplantation of human tissue. The Act mandates healthcare providers not to decline any

minimum standards for assisted reproductive treatment practices concerning clinical practice, facilities, personnel, and ethical issues.
[51] National Health Act 2014.
[52] National Health Act, s. 1 (a)-(e).
[53] ibid, s. 5.

emergency treatment to their patients.[54] A patient is entitled to know the risks, diagnostic techniques, costs, and prospects of treatment under the Act.[55] Healthcare providers also must protect the right of patients to information beneficial to patients' well-being unless such information is considered by the providers to be detrimental to their best interest.[56] Section 30 of the Act provides for the confidentiality of patent information. It states that information relating to a patient should be handled with utmost confidentiality and must not be disclosed to a third party except as permitted by the Act.[57] Furthermore, a patient has the right to complain to a healthcare provider over poor medical treatment or diagnoses.[58]

Section 50 of the Act specifically prohibits all practices relating to the cloning of human beings. It states that no person shall engage in the manipulation of reproductive and genetic materials (embryos and gametes, indulge in acts that involve the transfer or splitting of reproductive material to facilitate human cloning or engage in the importation and exportation of reproductive materials.[59] It also banned the removal and transplantation of human tissue from one person to another in places other than (a) a hospital that is specifically authorized to carry out such procedure, (b) or under the written authority of a physician in charge of clinical services or any other physician empowered by him, and (c) by a physician permitted by the person in charge of the hospital when the physician in-charge of clinical services is unavailable.[60] Section 53 banned people from donating their tissue, blood, and blood products for monetary gain except reimbursement for reasonable expenses which may have incurred during the process of the donation.[61] The sale or commercial dealings in human tissue, blood, and blood products are outlawed under the Act. However, health establishments are allowed to accept reasonable payment for the purchase of tissue, blood, and blood products.[62]

[54] ibid, s.20.
[55] ibid, s. 23.
[56] ibid, s..26.
[57] ibid, s. 26.
[58] ibid, s.30.
[59]ibid, s. 50.
[60] ibid., s.51
[61] ibid., s. 53 (1) (a)
[62] ibid., s. 53 (1) (b)

The Act also permits the donation of human bodies and tissue of dead people.[63] It states that individuals who are capable of making a will may donate their body or any particular tissue in their body to be used after their death or authorized post-mortem study of their body under the will.[64] However, the donated body or tissue can only be used for specific purposes which include the education of students in the field of health, conducting research in the health sector, development of health education, treatment for a living person, and the creation of therapeutic and diagnostic materials.[65] Any consent granted under this provision can only be revoked or withdrawn by the donor in the same way and manner it was made.[66] The Act also provides for penalties for breach of the provisions. For example, under section 50 (1) (2), any person who manipulates, sells, clones, imports, or exports human reproductive materials (embryos and gametes) is guilty of an offense and shall be liable on conviction to imprisonment for not less than 5 years without an option of fine. The Act defined health establishment as "including the whole or part of a public or private institution, facility, building, or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic intervention, nursing, rehabilitative, palliative, convalescent, preventative or other health services."[67] This provision can be interpreted to include public and private ART facilities. It is also defined user as any person who receives medical treatment or care at a health facility for blood or blood products, or other health services. Where the user is below the age of majority, it shall include parents, guardians, or any individual authorized by law to act on the person's behalf. Also, where the user is incapable of making informed decisions, the user shall include the person's wife or husband, and where the husband or wife is not available, it shall comprise the person's parent, grandmother, adult child, brother, sister or another person permitted by law to take decisions on the person behalf.[68] Although the Act contained several provisions which directly or indirectly implicate the application of ART in Nigeria, it was never established to regulate ART. Therefore, the failure of the Act to address issues relating to the right of gametes

[63] See specifically, Dr. DU Odigie, Prof A. K. Anya & Prof. Justus A. Sokefun , An Examination of the Nexus between Law and Medicine in the Procurement and Transplantation of Human Organs in Nigeria, International Journal of Research and Innovation in Social Science, IJRISS Vol. VI Issue V, May 2022
[64] ibid., 55 (1)
[65] ibid, s. 56.
[66] ibid, s.57.
[67] ibid, s. 60.
[68] ibid, s. 60.

donors, donor anonymity, use and storage of embryos and gametes, fertility treatments, and admixture of human and animal gametes for reproductive purposes is understandable.

ii. The Medical and Dental Practitioners Act, 2004

Another law that implicates the practice of ART in Nigeria is the Medical and Dental Practitioners Act 2004. The Act is the main regulatory framework for medical and dental practice in the country.[69] It provides for the registration and discipline of medical and dental surgeons. It established the Medical and Dental Council of Nigeria with the responsibility to determine the requirements and qualifications for becoming a medical and dental practitioner, establish a code of medical practice, and the maintenance of a register of medical and dental practitioners in the country.[70] The MDCN is an artificial legal entity with perpetual succession and a common seal. It can sue and be sued by its corporate name. The Act also established the Medical and Dental Practitioner Investigating Panel with the responsibility of investigating allegations of acts of infamous conduct, against medical practitioners.[71] Where an allegation is found to be true, the panel would refer the matter to the Medical and Dental Disciplinary Tribunal prosecution.[72] Section 17 of the Act established several offences concerning medical practice. This offence includes engaging with requisite qualification and skill, accepting any monetary payment or reward as a medical practitioner without acquiring the necessary qualification and experience, using the title of a doctor without any reasonable excuse, and deceiving members of the public.[73] The Act also makes it an offense for a medical practitioner or dentist to administer or recommend the application of a dangerous drug as defined by the law. Offenses established under section 17 attract summary conviction with a fine of N5,000.00.[74] Similarly, a person can be convicted or liable to a fine of not more than N10,000,00 or to a term of imprisonment not exceeding 5 years or both.[75] These provisions implicate the practice of assisted reproductive technology in the country. ART is just another branch of medical practice that deals with infertility and reproductive health. Thus, ART practitioners are required to comply with the provisions of the Act. However, there are certain inherent lacunas in the Act particularly those relating to licensing,

[69] Medical and Dental Practitioners Act Cap. 221 Laws of Federation of Nigeria, 2004[Hereafter, The MDCN]
[70] ibid, s. 1.
[71] ibid, s. 15,
[72] O.N., Irehobhue, *Remigius Comparative Health Law and Policy. Critical Perspectives on Nigeria and Global Health Law* (1st edn, Ashgate Publishing Limited, 2015) 95.
[73] Medical and Dental practitioners Act, s. 17 (1).
[74] ibid, s. 17 (5) (a).
[75] bid., s. 17 (5) (b).

registration, monitory, and supervision. ART is a specialized area of medical practice that needs proper regulation to protect the interests of all the participants who are involved in its utilization. Therefore, a special regulatory agency is required to ensure proper licensing and supervision of ART centers in the country. The supervision of ART practices cannot be done by the MDCN because of the complexity, dynamism, and peculiarity of ART services. Therefore, there is a need for the establishment of a specific regulatory authority that will handle the licensing, supervision, and monitoring of ART service providers in the country.

iii. Nigerian Code of Medical Ethics

This Code was established by the Medical and Dental Council (MDCN) under the powers vested in it under section 1 (2) (C) of the Medical and Dental Practitioners Act 2004. The Code contains several rules of professional conduct for medical and dental practitioners in the country.[76] It also established acceptable and minimum standards of medical practice. The Code identifies acts and omissions of medical practitioners that could be regarded as infamous conduct in professional respect.[77] These acts include the procurement or conspiracy to procure abortion, euthanasia, and performance of professional duty under the influence of alcohol and harmful substances. Infamous conduct also involves acts of adultery or improper relationship with patients. [78]The Code also emphasizes the need for hospitals or health facilities to maintain good etiquette. It states that hospitals are under obligation to protect the privacy of their patients, provide a proper explanation of fees, prohibit smoking within the clinic premises, and maintain proper courtesy with patients.[79] Rule 13 of the Code deals with the registration of specialists by the MDCN. It prohibits medical and dental practitioners from practicing as specialists or presenting himself/herself as such unless they are registered by the MDCN to do so.[80] The issue of informed consent of patients is addressed under the Code.[81] The Code also recognized the practice-assisted conception and other related technology thus:

> High technology based on human reproductive processes is 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

[76] Code of Medical Ethics 2008
[77] ibid, rule 26 -70.
[78] ibid, rule 40-41.
[79] ibid, rule 9.
[80] ibid, rule 13.
[81] ibid, rule 17

> statutes to govern these desirable practices in society are yet to be enshrined, ethical considerations show the essence of care and attention to the several needs of the donor, recipient, and offering at every step in these practices. Whilst the Council is devoting particular attention to the 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. Whilst both sperm and egg donations in vitro fertilization are accepted as ethically sound practices, in embryo donations, gestational surrogacy, or full surrogacy, the practitioner will need to resolve ethical matters in respect of the following: counseling and consent of donor, gamete, and embryo processing, monetary compensation for embryo donation for research.[82]

This provision recognized the need for specific legislative intervention to address the multi-faceted issues that are associated with the practice of assisted reproductive technology in the country. To achieve this objective, the Nigerian government must learn from the regulatory experience of other jurisdictions.

iv. Food and Drugs Act, 2004

The principal law regulating the manufacturing, sale, and advertisement of food, drugs, cosmetics, and devices in Nigeria is the Food and Drugs Act.[83] The Act prohibits the manufacturing, sale, import, or storing of any device that causes harm or injury to the user even when applied according to the instructions of the manufacturer and under normal circumstances, Section 21 of the Act defines a device thus:

> As any instrument, apparatus, or contrivance (including component, parts, and accessories thereof) manufactured, sold, or advertised for use in the diagnosis, treatment, mitigation, or prevention of any disease, disorder, abnormal physical state, or the symptoms thereof, in man or animals.

This definition can be expanded to include instruments used in the process of ART.[84] These instruments include syringes, IVF tissue culture plates, IVF tissue culture dishes, pipette tips, dishes, and single or double-lumen needles. Others are needle guides, anti-vibration table, Airstream laminar flow bench, Intrauterine insemination and Oocytepuncture, ART Media catheters, etc.[85] While these devices are significant to the practice of ART, they have also introduced certain risks that are capable of compromising the safety and standards of procedures regarding the production, application, or storage of reproductive materials. Therefore, there is a

[82] ibid., rule 23.
[83] Food and Drugs Act Cap F 32 Laws of Federation of Nigeria, 2004.
[84] European Commission, Guidelines for Conformity Assessment of In Vitro Fertilization and Assisted Reproductive Products MEDDEV 2.2/4 (2012).
[85] Assisted Reproductive Devices Market Size by Segments, Share, Regulatory and Reimbursement, Procedures and Forecast to 2033.

need for the development of a specific legal regime to properly define the way and manner some of these tools are handed during ART procedures.

6. Comparative analysis on the Regulation of ART in select jurisdictions

i. United Kingdom

The application of assisted reproductive technologies is deeply rooted in the United Kingdom following the birth of Louise Brown, the world's first test-tube baby, who was delivered through *in vitro* fertilization in 1978.[86] Since then, other forms of assisted reproductive technologies like Gamete Intra Fallopian Transfer (GIFT), Zygote Intrafallopian transfer (ZIFT), Artificial Insemination, and Preimplantation Genetic Testing (PGT) have been developed to address the challenges of infertility in the UK. As a result, the UK has become a pacesetter in the use and regulation of assisted reproductive technologies across the world. The first attempt at legislative intervention occurred in 1984 when the Warnock Committee was set up, to examine the legal, moral, and ethical issues associated with the new reproductive technologies[87]. The committee recommended, amongst others, a regulatory regime to regulate clinical and reproductive research relating to assisted reproductive technologies and the development of a regulatory body. This followed the establishment of the Voluntary Licensing Authority (VLA) by the Medical Research Council and the Royal College of Obstetricians and Gynecologists in 1985. Soon after the VLA became operational, the British government released a white paper and indicated its intentions to establish a regulatory framework on assisted reproductive technologies. This eventually paved the way for the Human Fertilization and Embryology Act (HFEA) of 1990.[88] The Act established the Human Fertilization and Embryology Authority (HFEA).[89] This Authority establishes the necessary regulatory mechanisms to guide and direct individuals who are involved in the utilization of ART in the UK. The Authority is required to submit an annual report regarding its statutory activities to the Secretary of Health who would thereafter present it to the House of

[86] P.C. Steptoe and R.G. Edward 'Birth after the Reimplantation of a Human Embryo' *Letter to the Editor* (1978) 312 Lancet 366.
[87] Warnock Report (note 9).
[88]Human Fertilization and Embryology Authority< https://www.hfea.gov.uk/ >accessed on 7 October 2023.
[89] Human Fertilization and Embryology Act 1990.

Parliament.[90] The Authority is also mandated to provide relevant information relating to embryos and ART services to the government, patients, and ART providers.[91] One of the major functions of the Authority is the granting of licenses to persons and bodies who are involved in the provision of ART services guaranteed under the Act. The categories of licenses that are recognized by the Act include a license for treatment, a licence for storage, and a licence for research.[92] The authority to consider and grant licence applications is vested in the Licence Committee which is created by the Authority. The Committee is mandated to consider the individual application and ensure that each applicant is a "suitable person to hold a license" and that such a person has the "character, qualifications and experience" to provide ART services by the provisions of the Act.[93] The Committee is required to conduct proper inspection and reinspection before granting a license to any person.[94] The Authority has the right to refuse or revoke a license[95]. It is also the responsibility of the Authority to establish a Code of Practice relating to the activities conducted under any particular license.[96]

The Act also contains provisions that seek to ensure transparency, accountability, public trust, and confidence by ensuring that the Parliament is updated with regular and current information about the activities of the Authority particularly regarding the activities carried out, those who are responsible,e and their outcomes. The Act also seeks to ensure that members of the public are adequately represented in the Authority. It states that more than half of the members of the Authority shall not be physicians, or individuals who use or store gamete including those directly or indirectly involved in any research relating to human gametes.[97] These categories of persons are also prohibited from occupying the position of Chairman or deputy chairman of the Authority under the Act.[98] When considering the treatment services and restrictions on the power of the Authority to issue licenses, regard must be had to the duty of parliament to impose social restrictions on contemporary actions relating to assisted reproductive technologies. Hence, apart from establishing the pattern of regulation, the Act also specified the content of what should be

[90] Ibid, s. 6-7
[91] Ibid, s. 8 (a)-(b).
[92] ibid, s. 11.
[93] ibid, s. 16.
[94] ibid, s. 9 (7) -(11).
[95] ibid, s. 18-19.
[96] ibid, 25.
[97] HFEA Sched. 1& 4 (2) – (4).
[98] ibid, Sched. 1 & 4 (3)

regulated by defining the relevant activities that require a license, the formal status of the offspring that may result from those activities, and the limitations on the various treatments and research relating to assisted reproductive technologies. These boundaries include the definition of embryo under the Act. It states that 'embryo' implies a live human embryo where fertilization is complete' and reference to any embryo comprises 'an egg in the process of fertilization.'[99]

The Act allows only embryos that are developed, stored, and used outside the human body.[100] It prohibits the creation of hybrid gametes or trans-species reproductive procedure that involves the mixture of a human embryo with that of a non-human. To this end, the Act specifically forbids any fertilization process that involves inserting in a woman any live embryo other than a human embryo and depositing a human embryo in an animal.[101] It also prohibits human cloning in all its forms and ramifications. The effect of the Warnock Report could be seen in the provision of the Act that specifically prohibits the storage or usage of an embryo after the manifestation of primitive streak which is usually believed to always occur 'not later than the end of the period of 14 days beginning with the day the gametes are mixed, not counting time during which the embryo was stored.[102] Apart from defining the date of commencement of the human developmental process, the Act has also established certain forms of limitations on treatment procedures including the eligibility criteria for those treatments. It states that embryo creation shall be conducted outside the human body. This development may include the application of donated gametes to be conducted by a licensed ART provider.[103] The Act forbids women from using artificial insemination or attempting to achieve pregnancy with the assistance of a male who may be hired to facilitate such an objective. It also fails to provide for situations where a woman could achieve pregnancy through artificial insemination using the sperm of her husband or partner. Section 13 (5) of the Act restricts the number of persons who can receive ART treatment as part of the conditions for the issuance of the licence. It states that "a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of

[99] HFE Act s. 1
[100] ibid, 1 (2)-(3)
[101] ibid, s. 3 (2) (a)-(b), 3 (b).
[102] ibid, s. 3(3)(a), (4)
[103] HFEA s. 4(1) (a), (b)

any other child who may be affected by the birth."[104] This provision suggests a heterosexual relationship including the need for children conceived through ART to have their genetic father. The provision also seeks to ensure that adequate care is provided for children conceived via ART. This care is not only limited to the child but also other children who may be directly or indirectly affected by the birth of such a child. They may include the siblings or half-siblings of the ART-conceived offspring. Single women are also eligible to receive treatment provided a proper evaluation is conducted by the ART provider concerning the potential of a single parent to take care of the child. The Act also mandates ART providers to ensure that patients are properly counseled and their consent is obtained before treatment. It states that no woman shall be made to undergo any ART treatment involving the application of donated gametes unless the consent of the donor and that of the woman is obtained. It also stated that where a woman is treated alongside with man, the man must be given adequate counselling and relevant information about the nature of the treatment and the consequences of his decision.[105] Schedule 3 of the Act establishes detailed provisions regarding the condition for consent. This requirement includes the responsibility to ensure that no donated gametes are utilized for ART treatment without the consent first obtaining the consent of the donor.[106] The Act also prohibits the storage of donated gametes without the donor and this consent must include the procedure for usage and disposal after the death or incapacity of the donor.[107] The consent shall be in writing and can be withdrawn or modified before the application of the donated embryo for ART treatment and examination.[108] For consent to be valid, the Act requires that any person giving consent shall have a reasonable understanding (informed consent) of the nature, benefits, and harm that is involved in the treatment chosen by the patient.

In other to establish the legal status of a mother, the Act also attempts to clarify the legitimate status of a father as it relates to the parental status of children conceived through ART. It states that if a woman was married when the embryo or sperm and eggs were placed in her, or she was inseminated and the sperm was not that of her husband, then the husband is to be treated as the father unless it is shown that he did not consent to the placing in his wife of the embryo or

[104] ibid, s.13(5)
[105] ibid, 13 (16).
[106] HFEA Schedule 2 & 3.
[107] iIbid.
[108] sched. 3 para 1.

sperm and eggs on her artificial insemination with the donor's sperm.[109] However, where the ART services were given to a woman and a male simultaneously, then he would be regarded as the legitimate father of the resulting child.[110] The Act also recognizes the legal status of a male partner of a married couple. It states that a male partner to a legitimate couple will be regarded as the husband of a couple that is lawfully married when considering the paternity of the child delivered by the woman during the pendency of the marriage.[111] To indicate consent, the male partner must establish certain commitments that may include following his partner to treatment, and why the de facto husband stays away. To this end, the husband or partner would be treated as the child's genetic father once either of them gives consent. However, if the partner refuses to give consent, the husband would be assumed to be the father of the ART-conceived child under the common law. This presumption can be rebutted by the husband by proving that he did not consent to the donor insemination to his wife and as a result cannot be treated as the father of the child.[112] The paternity of ART conceived can also be established through blood or DNA tests. Section 28 (6) (b) of the Act states the circumstances under which sperm donors may be denied paternity of a donor-conceived child. It states that a sperm donor cannot be treated as the genetic father of the donor-conceived child if he consented to the usage of his sperm by another party. However, a donor-conceived child may become fatherless if it is established that neither his mother's husband nor the sperm donor is the genetic father.[113] A child may also lose paternity if the sperm of a man or any embryo resulting from his sperm is applied for treatment after the death of the man.[114] This provision specifically discourages the practice of posthumous parenting and childbearing using the gametes of individuals after their demise.

Additionally, the Act provides that any person who gives consent for the storage of a gamete or embryo must state clearly what would happen to the gamete or embryo after his death.[115] Hence, a husband can approve of his wife to use his frozen sperm to achieve pregnancy after his death, if she so complies, it means the deceased husband would not be regarded as the genetic

[109] ibid, s. 28 (2).
[110] ibid, s. 28 (3).
[111] ibid. s. 28 (4).
[112] ibid, s. 28(6(a), Sched.3, 5(1).
[113] ibid, s. 28 (6) (b) and sched. 3, para 5 & 1.
[114] bid, s. 28 (6) (b).
[115] HFEA Sched 3 para 2, s. 2 (b).

father of any child that results from such treatment.[116] It also provides for circumstances where the court can declare that a child conceived via assisted reproductive technologies which belonged to the de facto couples. These exceptional circumstances include (1) when the child is delivered by a woman who is not the wife of the husband provided the gametes of a donor or that of the husband or wife or both were used to achieve the conception, (2) if within six months after the birth of the child, the couples applied for the order (3) the children were staying with the couples or either of them in the UK at the time the application was made, (4) upon the couples attaining the age of 18, (5) the child's father, if he is not the husband, and the woman who delivers the children voluntarily agree to the court's order, (6) the court discovered that money was never applied to facilitate the taking of the child or getting the order.

These orders are significant to the extent that they allow couples to be recognized as parents of a child who was delivered and handed over to them by another woman simply because the child is genetically linked to any of the parents.[117] Several attempts have been by the UK Department of Health to give effect to this provision and ensure that the order of the court is implemented. A good example of such an attempt is the Draft Circular to Local Authorities of 1994 which stipulates the procedures for the appointment of guardian ad litem by the court for the child under the Family proceedings Court's rules. Under the rules, ART centers are empowered to disclose information regarding the manner of ART services adopted in the conception of the child. This formation is necessary to determine whether the gamete of a donor or that of the couples was used.[118] For more disclosure regarding this information, section 33 (6) of the Act has been amended by the Human Fertilization and Embryology (Disclosure of Information Act of 1992 to enable a guardian to file such information before the court under section 30 order. It is also the duty of the guardian under the rules to determine whether the granting section 30 order is in the interest of the ART-conceived child which the court would need to consider first including the welfare of the child before granting the order.[119]

It is interesting to note that many provisions of the 1990 Act have now been amended by the 2008 Human Fertilization and Embryology Act 2008 to reflect the complexities and nuances of

[116] HFEA 28 (6((b).
[117] ibid, s. 30 (1)-(7).
[118] ibid, 13 (5).
[119] Children Act 1989 s. 1(1).

the new reproductive technologies. Under the new Act, an embryo is defined as "a live human embryo and does not include a human admixed embryo and reference to an embryo "including an egg that is in the process of fertilization or is undergoing any other process capable of resulting in an embryo."[120] The has also amended the prohibitions relating to embryo include "an embryo other than a permitted embryo" as well as "any gametes other than permitted eggs or permitted sperm."[121] It also prohibits the placing in a woman any genetic material that does not emanates from a human being such as (a) a human admixed embryo, (b) any other embryo that is not a human embryo and (c) any other gametes other than human gametes.[122] It also forbids persons from engaging in the mixture of human gametes that of an animal, developing a human admixed embryo, and storing and applying human admixed embryo.[123] It further prohibits the licensing of ART treatment relating to human admixed embryos. Section 8ZA of the 2008 Act has expanded the functions of the Authority. It states the authority shall conduct its affairs effectively, efficiently, and economically and that in the exercise of its statutory obligations, the Authority shall be guided by best regulatory standards including the need to promote transparency, accountability, proportionality, and consistency relating to specific situations that required the attention of the Authority.[124] The Act also empowers the Authority to assist other public authorities or institutions in the United Kingdom. It states the Authority may assist any other public institution in the exercise of its statutory responsibility as it deems fit. However, this assistance may be rendered by the Authority upon such conditions that may include payment of a certain amount of money to the Authority.[125] The power of the Authority to delegate authority and establish committees has also been expanded under the Act. Section 9A states that the Authority could delegate some of its powers to a member or staff of the Authority, establish committees and sub-committees, and delegate some of its powers to it[126]. Membership of these committees or sub-committees might extend to individuals who are not members of the Authority.[127]

[120] Human Fertilization and Embryology Act 2008. S. 1 (a) & (b).
[121] ibid, 3ZA.
[122] ibid, 4A.
[123] ibid
[124] ibid 8ZA.
[125] ibid, 8E.
[126] ibid, 9A.
[127] ibid

The Act has also expanded the scope of counseling that is required for treatment. It states that no woman shall be provided ART treatment under the Act except she and any man or woman to be treated together are given adequate counseling about the consequences of the treatment on them.[128] This counseling must include the disclosure of all relevant information regarding the treatment services to be provided.[129] Any man who agrees to be the father of the ART-conceived child must be properly educated about the nature of treatment including its implication on the woman who will carry the child. The Act further provides for the categories of persons who can apply for the revocation of a licence as well as the circumstances under which such a licence may be revoked. It states that any person responsible or holder of a license can apply to the Authority to revoke a license granted under the Act. A licence could be revoked if the information provided to the Authority to obtain the licence is discovered to be false and misleading if the person responsible is incapable of discharging the responsibilities imposed by the licence if the person responsible fails to obey the directives of the Authority if the person responsible dies or convicted for a criminal offence under the Act if it is discovered that the holder of the licence is not a fit and proper person to operate the licence, and when there are fundamental changes of situations relating to the operation of the license.[130] The Act has redefined "mother" to mean "the woman who is carrying or has carried a child as a result of placing in her of an embryo or sperm and eggs, and no other woman is to be treated as the mother the child. This provision does not extend any child to the extent that the child is treated under adoption as the child of the woman. It is also immaterial if the woman resides in the United Kingdom or elsewhere at the time of treatment.[131]

The Act also mandates the development of a Code of Practice that would provide directions for its activities relating to a license under the Act. The Code of Practice must be approved by the Secretary and presented to the Parliament.[132] This Code of Practice has been amended severally to reflect the Authority's positions on issues relating to qualifications and duties of employees of licence centers, equipment and administrative processes of licensed centers, evaluation of the welfare of ART-conceived children as well as individuals who are looking for treatment,

[128]ibid, s. 14 (3).
[129] ibid.
[130] ibid 18.
[131] S. 33.
[132] ibid s. 26.

examination, and testing of gametes donors, disclosure of information to donors and intended parents, counseling, storage of gametes, consent, records, privacy, and confidentiality.

ii. Australia

Australia operates a federal system of government where power is shared between the federal government and state government.[133] The regulation of assisted reproductive technology in Australia is modeled along these entrenched constitutional structures and parameters.

a. Federal Regulatory Framework for ART in Australia

At the federal level, assisted reproductive technology is regulated by the National Health and Medical Research Council (NHMRC) Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research.[134] The guidelines initially came into force in 1996 but were later reviewed in 2004, 2007, and 2017 to address legislative lacunas on issues surrounding ART particularly those that arise from diverse and inconsistent legislations at the state level. Although every state and territory has made laws on issues regarding parentage, the majority are yet to legislate on surrogacy. Also, some states have failed to establish a comprehensive legal framework for ART. The NHMRC guidelines were primarily developed to address these loopholes. It is also a product of extensive engagement and consultations with relevant stakeholders who are knowledgeable in law, philosophy, medicine, and health care. The Guidelines established numerous ethical standards and rules for the various aspects of ART which include accreditation of ART facilities by the Reproductive Technology Accreditation Committee), prohibition of commercial surrogacy, gametes donation, and informed consent and counseling of patients and gamete donors. It is founded on certain ethical principles and values which include:

i. ART procedures are carried out in such a manner that respects the rights and interests of all participants.
ii. The health and interests of any children delivered through ART must be given utmost priority in the utilization of these technologies.
iii. These technologies should be applied in such a way as to minimize harm and maximize the potential of intended parents or couples who are involved.

[133] Commonwealth of Australia Constitutive Act 1901.
[134] National Health and Medical Research Council (NHMRC) *Ethical Guidelines on the of Assisted Reproductive Technology in Clinical Practice and Research: Working to Build a Healthy Australia,* 2017.

iv. The process of decision-making about ART must take into consideration the genetic linkage and social relationship that may result from their application.
v. The process of determining eligibility criteria for ART is just, transparent, and equitable and conforms with human rights standards including the right to freedom from discrimination.
vi. The application of ART must be based on an effective legal framework that tends to reduce interventions that are not premised on evidence and clinical results. [135]

Apart from these ethical principles, the guidelines also contained specific provisions about the use and storage of human reproductive materials. It mandates every ART center to ensure that valid consent of donors is obtained before the storage of their gametes and embryos. ART centers are also expected to: (i) ensure proper storage of human embryos and gametes; (ii) obtain and secure the personal information of the donors; (iii) examine the justification for continued storage of embryos and gametes; (iv) handle embryos and gametes that are longer required by donors and intended parents; (v) manage conflicts among couples on the use of stored embryos and gametes and (vi) handle the use or disposition of embryos owed by diseased persons.[136] The Guidelines also encourage the reallocation of embryos and gametes. It provides that any gametes that are no longer needed by couples or intended parents could be reallocated to another person. The Guideline also promotes the right to know one's biological origin. It mandates ART clinics to ensure that the biological origin of children born through gametes donation is ascertainable.[137] It also encourages ART facilities to ensure that gamete donor knows individuals born through their donation, particularly, the non-identifiable information relating to their number, age, and sex. Gamete donors are also expected to update ART facilities with any relevant changes about their health and contact information which may be useful to a child born through his/her donation[138]. The Guidelines also expressly prohibit ART specialists and clinics from engaging in acts that promote commercial surrogacy including inducing people into surrogacy contracts or arrangements[139]. It states that surrogacy arrangements are altruistic and must conducted without any financial compensation or inducement except credible and little reimbursements that are directly linked to the surrogacy

[135] ibid., para. 2.
[136] ibid., para. 7.
[137] ibid, para. 6 (1)
[138] ibid., para. 5.
[139] ibid., para. 8.

process, conception, and delivery.[140] These reimbursements may include the cost of clinic and counseling incurred before, during, and after conception and delivery, cost of travel and accommodation within Australia, loss of earnings, insurance, cost of child care, and legal consultation fees.[141]

Though the provisions of the guidelines are non-legally enforceable, they have continued to play a significant role in the advancement of ART regulation in Australia.[142] For instance, the Reproductive Technology Accreditation Committee (RTAC) of Australia,[143] has continued to rely on the provisions of the guidelines in conducting accreditation of ART facilities in Australia. Thus, any ART center could be denied certification based on non-compliance with the provisions of the guidelines. ART specialists, clinics, and the Ministry of Health both at the federal and state levels also have courses to rely on as a research guide on the use of ART and other clinical practices that are incidental to ART. The role of the Council of Australian Governments (COAG)[144] and the Standing Committee of the Attorneys General (SCAG)[145] in advancing recommendations for harmonizing ART policies have gone a long way in promoting the guideline as formalized standards for ART practice in Australia.[146] Another area where the federal government has also intervened in the practice of ART by way of legislation is the status of children born through ART. This intervention was achieved through several amendments to the Family Law Act of 1975. In 1983, the Act was amended by the Federal Government to the effect that any child born to a married woman using donated sperm would be regarded as the legitimate child of the woman and her husband provided the donation was done with the consent of the husband.[147] This particular clause was restricted initially to any child delivered by legitimate couples based on the marriage power under the Constitution. However, every child is regarded as the legitimate child of ART patients once the

[140] ibid., para. 8(1).
[141] ibid, para. 8 (9) (1).
[142] Dave Snow and Rainer Knopff, (note 104) p. 20
[143] RTAC is an organ of the Fertility Society of Australia that was unilaterally established by all the ART Specialists and centers in Australia.
[144] Council of Australian Governments (COAG) is a body of all the first or senior ministers of Austria
[145] Standing Committee of the Attorneys General (SCAG) is a body of all the Attorney Generals both the state and federal levels.
[146] Dave Snow and Rainer Knopff (note 104) p 20.
[147] Family Law At 1975 (Cth) s. 60 (H).

commonwealth and state rules so provided.[148] This provision can be interpreted to include ART children born by unmarried couples, single persons, and same-sex couples. Another significant effect of the provisions of section 60 (H) is that it has completely removed genetic relationships as the basis for deciding whether or not an individual is a parent of a child under the law. Therefore, the right to parentage can extended to persons other than married couples who in most cases are regarded as genetic parents of the child. This amendment to the Act has assisted a great deal in redefining the general perception about the nature of family, the right to establish a family without any restriction based on sex and marital status in Australia.[149]

b. States Regulatory Frameworks in Australia

In Australia, states have also established legal frameworks to regulate ART. These states include New South Wales,[150] South Australia,[151] Western Australia[152] and Victoria.[153] However, other Jurisdictions without specific legal regimes have adopted the NHMRC Ethical guidelines to regulate the practice of ART.[154] Apart from state regulatory frameworks, all ART facilities in the states are also expected to abide by the RTAC Code of Practice and the NHMRC ethical guidelines. These regulatory measures by the federal government have assisted a great deal in setting the basic standards for ART specialists and clinics, particularly in states that lacked a specific legal framework on ART. The Assisted Reproductive Technology Act 2007 of New South Wales governs ART practices commencing from the gathering of gametes to the fertilization and transmission of gametes for reproductive purposes. It also addresses issues relating to informed consent, disclosure of identifiable and non-identifiable information about donors, and the use and storage of donated gametes[155]. Other areas covered by the Act include artificial insemination, IVF, and cryopreservation. The NSW legal regime seeks to complement the various legislative measures by the federal

[148] See Part VII Para. D, s. 60(H) Family Law Act 1975 which deals with ART conceived children.
[149]Sex Discrimination Act 1984 (Cth), s. 6-6.
[150] Assisted Reproductive technology Act 2007 (NSW).
[151] Assisted Reproductive Treatment Act 1988 (SA).
[152] Assisted Reproductive Technology Act 1991 (WA).
[153] Assisted Reproductive Treatment Act 2008 (VIC).
[154] I. M., Kerridge et al, Ethics and Law for Health Professions (The Federation Press, 4th ed, 2013) 503
[155] Jenni Millbank et al, 'Towards Facilitative Regulation of Assisted Reproductive Treatment in Australia' *Guest Editorial* (2013) 701-709.

government particularly those contained in NHMRC Guidelines and RTAC accreditation manual. Section 3 states that the primary purposes of the Act shall include:

(a) the prevention of commercialization of human reproduction, and
(b) the prevention of the interests of the following persons: (i) a person born as a result of ART treatment, (ii) a person providing a gamete for use in ART treatment or for research in connection with ART treatment, (iii) a woman undergoing ART treatment.

The implementation of the Act is based on certain guiding principles which include the protection of the interests and health of individuals who utilize the technology. This includes children conceived through ART, embryo and gametes donors, and the woman who carries the pregnancy.[156] The Act also ensures that gametes donors voluntarily consent to the provision and use of their gametes. It further protects the rights of donor-conceived children access to their genetic parents. ART participants are also expected to have access to information about gametes and embryo donors including children born through such donation. The commercialization of gametes and embryo donation is prohibited under the Act.[157] Section 4 (1) provides an elastic and adaptable definition of ART. It states that "ART Treatment means assisted reproductive technology treatment being any medical treatment or procedure that procures or attempts to procure pregnancy in a woman by means other than sexual intercourse and includes artificial insemination, in vitro fertilization, gamete intrafallopian transfer and any related treatment or procedure that is prescribed by the regulations." This phrase "any related treatment or procedure that is prescribed by the regulations" implies that the state can always allow the introduction of new reproductive technologies through regulations. The term "ART services" is also defined by the Act to mean any one or more of the following services, treatments, or procedures that are provided for fee or reward or provided in the course of a business (whether or not for profit): (a) an ART treatment, (b) the storage of gametes and embryos for use in ART treatment, (a) the obtaining of a gamete provider for use in ART treatment or for research in connection with ART treatment.[158] Sections 6-9 of the Act mandates all ART service providers in NSW to undergo a form of registration before they can carry out their operations. Registered ART providers imply any person who is permitted by the Director-General to carry out ART services.[159] Under the Act, ART providers are expected to

[156] ART Act 2007 (NSW) s. 3 (b).
[157] Ibid, s. 3 (a).
[158] ibid., s. 4 (1).
[159] See Division 1 of Part 2 of the Act

engage in the supervision and counseling for ART participants particularly as it relates to ART services being provided. This supervisory responsibility must be conducted by certified medical personnel to enable ART participants to have essential knowledge and information relating to the nature and procedure of treatment to be provided.[160]

The Act provides for the process of collecting and using human embryos and gametes for treatment.[161] These sections mandate ART service providers always obtain the consent of participants before gametes can be applied for various approved purposes which may include the generation of human embryos for treatment, donation, medical research, and storage. Thus, embryos can only be stored with the consent of the donors in line with the provisions of the Act. The Act also requires ART service providers to maintain and keep proper records including central records where information about donors is kept for reference purposes. The information contained in such records may be useful to ART children in addressing issues relating to genetic disease and other health challenges. It has also formed the basis of the right to know one genetic origin and personal identity.

7. Prospects for ART in Nigeria

It is clear from the above that the Nigerian government has several lessons to learn from the regulatory regimes in the identified jurisdictions, particularly from the Australian experience. While the Australian experience may be beneficial to the Nigerian government in many respects, it is also important for the Nigerian government to recognize the differences between the two countries in terms of culture and tradition. Australia is chosen because of its federal system of governance which is similar to that of Nigeria. Some of the possible lessons include:

a. **Specific Regulatory Intervention by Federal and State Government**

Recall that Australia operates a federal system of government where governmental powers are divided between federal, state, and territorial governments. This decentralized constitutional structure is also reflected in the way and manner ART is regulated in Australia. Though the Australian federal government has no specific legal framework on ART, it has established several legislations that border on specific challenges that relate to ART. Particularly those involving the legal status of children born through ART including perverted use of the

[160] ART Act 2007 (NSW) s. 13-14.
[161] Ibid, s 16 -29

technology concerning embryo research[162] and outlawed practices like human cloning.[163] Apart from this intervention, the federal government has also utilized its constitutional power of interstate trade and commerce,[164] to develop a national minimum standard of practice on ART through the Reproductive Technology Accreditation Committee of the Fertility Society of Australia. The Australian regulatory model has also shown that state regulatory measures can exist along with federal regulation except that federal laws would always prevail over state laws whenever there is conflict between both laws.[165] This regulatory model is suitable for Nigeria having regard to the powers of the federal and state governments to make laws on health. It is recommended that the federal government develop national minimum standards and ethical guidelines for ART. This can be done by the Federal Ministry of Health in collaboration with the state Ministry of Health and other relevant stakeholders in the health sector in Nigeria.

b. Certification and Licensing of ART Service Providers

As already noted, the Australian government has put in place an effective mechanism for the certification and licensing of ART providers. This responsibility is usually performed by the Reproductive Technology Accreditation Committee of the Fertility Society for Australia. The Committee also establishes standards for ART service providers, establishes certification criteria, develops mechanisms for supervision and monitoring, and delists defaulting ART providers. While the RTAC concentrates on accreditation, the NHMRC guidelines are used to address medical and clinical issues particularly those relating to the number of embryos that can be transferred per IVF in one circle. The supervisory approach can be adopted by the Nigerian government through the establishment of a specific agency or institution that would be responsible for the licensing and certification of ART service providers at the federal and state levels. The government can also establish certain punitive measures against ART providers who fail to register their services and facilities.

i. Defining Eligibility Criteria for ART Services

Almost all categories of people can access ART in Australia except children. This class of people includes married couples, unmarried women, infertile single, and same-sex couples.

[162] Research Involving Human Embryos Act 2002 (Cth).
[163] Prohibition of Human Cloning for Reproduction Act 2002 (Cth).
[164] Australian Constitution, 1901, s. 52.
[165] Australian Constitution of 1901, s. 109.

The liberal approach to ART eligibility is founded on the non-discriminatory principle of Australian law which abhors all forms of discrimination on the grounds of gender, sexual orientation, or marital status.[166] This Australian experience cannot be completely adopted in Nigeria. While eligibility for access to ART can be extended to unmarried couples and single women based on the non-discriminatory provision in the constitution[167] but same cannot be said of same-sex couples or relationships which is completely outlawed in the country.[168] It is suggested that access to ART should be restricted to a married couple to protect the sanctity of marriage and ensure that embryo and gametes donation for reproduction is consistent with what family, parental rights, child maintenance and inheritance is all about. This process may however require an amendment to certain provisions which border on legal parentage, inheritance, status of children, and adoption.

ii. Cryopreservation

Cryopreservation is the procedure of storing or freezing reproductive materials (embryos and gametes) for future use.[169] In Australia, people are allowed to store their gametes and embryos between 10 to 15 years. The practice of cryopreservation should be regulated and accessible to married people who are desirous of preserving their unused gametes and embryos for future reproductive purposes. This practice should also be extended to single persons who are desirous of preserving their reproductive materials because of certain illnesses such as cancer which is capable of endangering fertility. These individuals can decide how long they want to store the gametes. However, gametes and embryos must be stored or frozen for a reasonable period which may not exceed 7 years. In addition to storage, the issues surrounding unused or unclaimed embryos and gametes can also be resolved through a specific legal framework on ART.

iii. Transparency and Disclosure in the Use of Donor Gametes

As earlier observed, donor anonymity has been abolished in Australia by the National Health and Medical Research Council (NHMRC) ethical guidelines established in 2005[170]. Since

[166] Family Law Act 1975, s. 60C (2) (a).
[167] 1999 Constitution, s. 42
[168] Same Sex Marriage (Prohibition) Act, 2013.
[169] Tae Hoon Jang *et al* 'Cryopreservation and its Clinical Applications', *Integrated Medical Research* (2017) 6 (1) 12-18.
[170] Donor anonymity was abolished in the Australian state of Victoria since 1998.

then, a donor-conceived child can request and access information about their donors after the age of 18 years. The Guidelines also require ART services to maintain donor registers where identifiable and non-information relating to donors are kept. Apart from Australia, donor anonymity has also been prohibited in many other jurisdictions such as Sweden, Portugal, Netherlands, United Kingdom[171]. Nigeria must follow this international trend geared towards the protection of the interest of donor-conceived children globally. Access to information about donors could assist donor-conceived children resolved certain medical issues and making future decisions by tracing their medical history to those whose gametes were used in conceiving them. [172]

iv. Protecting the Interest of ART-Conceived Children

The development of a regulatory framework for ART in Nigeria must be centered around the need to protect the best interest of ART-conceived children by establishing legal provisions relating to child rights in the country[173]. So, the interest of the child must be adequately protected and balanced against other competing interests in the application of ART. These interests must be stipulated within the context of a regulatory framework for implementation and enforcement.

v. Defining the Rights and Obligations of ART Participants.

The experience from the above jurisdictions has shown effective regulatory intervention on ART is capable of defining the rights and obligations of individuals who are involved in the utilization of ART procedures particularly those relating to ART specialists, gametes donors, donor-conceived children, and intending parents. The absence of a specific regulatory framework on ART creates a regulatory vacuum and uncertainty capable of undermining the adjudicatory powers of the courts to make decisions based on established legal rules.

8. Conclusion and Recommendations

[171] A. A. Obadan, 'Donor Anonymity and Right of Access to Personal Origins in Nigeria: A Critical Analysis' Heritage Bar Journal (2021) 1, 159 -180.

[172] V. Ravitsky, "Conceived and Deceived: The Medical Interests of Donor Conceived Individuals", Hastings Cen Rep (2012) 42 (2) Hastings Cen Rep, 17-22. Penning, G., "Genetic Databases and the Future of Donor Anonymity", Human Reproduction (2019) 34 (5),786-790; Pure Ovum, " DNA Testing Ending Donor Anonymity", <https://www.pureovum.com/intended-parent-resources/dna-testing-ending-donor-anonymity/> accessed 16 October 2023); Scheib J., and Ruby, A., "Impact of Sperm Donor Information on Parents and Children ", 2006, <https://www.researchgate.net/publication/222970002_Impact_of_sperm_donor_information_on_parents_and_children> accessed 16 October 2023.

[173] Child's Rights Act, 2003, s.1.

We have demonstrated the need for legislative intervention in the application of assisted reproductive technology in Nigeria. We noted that an effective and efficient regulatory regime is fundamental to promoting accountability, and transparency and to effectively balancing the rights and interests of individuals who are involved in the utilization of the emerging reproductive technologies. Therefore, the Nigerian government should as a matter of urgency develop a context-specific legal framework to address the peculiar challenges associated with assisted reproductive technology. To these ends, the paper recommends as follows:

A. That federal and state governments should be involved in the licensing, monitoring, and supervision of ART service providers in line with their constitutional mandate to legislate on health.

B. The adoption of formal and informal regulatory approaches in addressing the peculiar and emerging challenges associated with ART.

C. The protection of children conceived through donated gametes should take priority in all considerations regarding the use of ART in Nigeria.

D. Legislative intervention in ART should be sensitive to human rights norms and standards.

E. The prohibition of the use of anonymous gametes donors to promote transparency and disclosure in the utilization of human reproductive materials.

F. The Nigerian Government should establish a donor register where identifiable and non-identifiable information about gametes donors are recorded for future purposes and references.

There are challenges associated with ART and they include issues relating to legitimacy, succession, and citizenship of children born through the application of donated gametes from third parties. The application of the technolohgy also impact the religious and cultural beliefs of the people. While efforts are being made in some jurisdiction to develop legislative intervention to address these challenges, there is complete lack of regulatory intervention in Nigeria thereby making ART procedure to be applied under a legislative vacuum. However, attempts at introducing regulatory intervention has generated several contentions among ART providers, academics, and public commentators.


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