

## ORIGINAL RESEARCH ARTICLE

# Regulating assisted reproductive technologies (ART) in Nigeria: lessons from Australia and the United Kingdom

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Chinelo A Ekechi-Agwu<sup>1</sup> and Anthony O Nwafor<sup>2\*</sup>

University of Nigeria, Nsukka<sup>1</sup>; School of Law, University of Venda, South Africa<sup>2</sup>

\*For Correspondence: Email: [Anthony.Nwafor@univen.ac.za](mailto:Anthony.Nwafor@univen.ac.za)

## Abstract

Assisted reproductive technologies (ART), are innovative, non-coital medical procreative procedures, that have brought respite to a number of childless persons and couples, just as it also raises a number of ethical and medico-legal issues. A number of countries including Nigeria, are still struggling to find the appropriate legal framework to provide guidelines for this reproductive process to curtail inherent unethical practices associated with that development. The paper explores the available regulatory instruments in Nigeria and in cognate jurisdictions such as Australia and the United Kingdom, through a comparative study to ascertain the efficacy of the existing instruments in ensuring that unethical practices and abuses associated with ART are eradicated. The findings indicate that the regulatory instrument in Nigeria requires significant improvement in line with the legal frameworks in operation in the cognate jurisdictions to effectively guard against potential unethical practices and abuses associated with the application of ART. (*Afr J Reprod Health* 2020; 24[4]: 82-93).

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**Keywords:** Assisted reproduction, law, ethics, Nigeria, Australia, United Kingdom

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## Résumé

Les technologies de procréation assistée (TAR) sont des procédures médicales de procréation innovantes et non coïtales, qui ont apporté un répit à un certain nombre de personnes sans enfants et de couples, tout comme elles soulèvent un certain nombre de problèmes éthiques et médico-légaux. Un certain nombre de pays, dont le Nigéria, ont encore du mal à trouver le cadre juridique approprié pour fournir des directives pour ce processus de reproduction afin de réduire les pratiques contraires à l'éthique inhérentes à ce développement. Le document explore les instruments réglementaires disponibles au Nigéria et dans des juridictions apparentées telles que l'Australie et le Royaume-Uni, à travers une étude comparative pour vérifier l'efficacité des instruments existants pour garantir que les pratiques contraires à l'éthique et les abus associés aux TAR sont éradiqués. Les résultats indiquent que l'instrument réglementaire au Nigéria nécessite une amélioration significative conformément aux cadres juridiques en vigueur dans les juridictions apparentées pour se prémunir efficacement contre d'éventuelles pratiques contraires à l'éthique et les abus associés à l'application de l'ART. (*Afr J Reprod Health* 2020; 24[4]:82-93).

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**Mots-clés:** Procréation assistée, droit, éthique, Nigéria, Australie, Royaume-Uni

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## Introduction

Assisted reproduction technologies (ART) involves all the non-coital techniques used to achieve pregnancy among persons and couples who experienced problems with conception and child birth. Some of the techniques which have been tested and approved by medical science include Intra Uterine Insemination (IUI)/Artificial Insemination (AI), *In vitro* Fertilisation (IVF), and Intracytoplasmic Sperm Injection (ICSI)<sup>1</sup>. A recourse to ART is prevalent among persons with fertility or coitus challenges but with the desire to have their own child. The preference for, and the

desirable benefit of, ART over child adoption is that it affords a woman the opportunity to experience the biological, psychological and physical aspects of pregnancy, labour and parturition<sup>2</sup>. The South Africa Constitutional Court in *AB and Another v Minister of Social Development*<sup>3</sup> spared no words in describing the burden of infertility and the reliefs brought to humans by the evolution of the assisted reproductive technologies as follows:

*We are not in any way short of words when it comes to describing the effects of experiencing infertility: grief; sadness; despair; panic; helplessness; and isolation are but a few of the*

*feelings that often ensue. For a large number of people, infertility has been “the most upsetting experience of their lives”. For others, infertility is rated as comparably stressful to the loss of a partner or a child. The likelihood of depression has been shown to double for women who are infertile. Disturbingly, infertility levels are on the rise globally, with one in every ten people facing infertility problems. We are fortunate, however, to live in an era where the effects of infertility can be ameliorated to a large extent through assistive reproductive technologies. The technological advances seen over the last half century have greatly expanded the reproductive avenues available to the infertile. These reproductive avenues should be celebrated as they allow our society to flourish in ways previously impossible.*

The rapid advancement in this medical science, in spite of cultural and religious constraints<sup>4</sup>, does not seem to have been matched by a commensurate development in the legal framework in some jurisdictions to regulate the practice. This could create room for unethical practices and abuses which an appropriate regulatory instrument and agency of government could have prevented. In Nigeria, the first incidence of ART birth occurred about thirty years ago<sup>5</sup>. That length of time is considered more than adequate for the country to have put in place an effective regulatory instrument and organ of government to ensure efficacy in the application of this novelty in medical science and technology.

A law as a systematic set of rules, is established by the government to direct the conduct of persons, and to maintain order in the society<sup>6</sup>. The law sets out policies which determine rights and obligations of persons and organizations in the society. It also stipulates offences and penalties for a breach of the law. Persons involved in conducts that are regulated by law bear both a legal and moral duty to ensure compliance with the prescripts of the law. In some cases, the fear of

sanction, in whichever manner prescribed, compels adherence to statutory regulations.

This makes a statutory instrument an effective tool for regulating human conducts. The ART as a conduct involving a creation of life deserves a close scrutiny through the eyes of the law.

Ethics on the other hand, is derived from the Greek word; ‘ethos’ which refers to customs and habits<sup>7</sup>. Ethics also refers to a code of conducts established and adopted by a group of persons (a professional body), to guide or regulate the conducts of the members of that profession in the practice of their profession. Medicine is a highly regulated profession practiced by men and women of untrammelled intellectual esteem who enjoy the unequivocal confidence of their patients. The quest to curtail abuses of such confidence and to ensure optimal exercise of dexterity by the physician in the care for his or her patient necessitated the formulation of some moral codes of conduct, some of which have over the years metamorphosed into rules of law, to serve as guides in directing the services of the physician to his or her patient. These bodies of moral rules are simply referred to as the ethics of the profession or rules of professional conduct<sup>8</sup>. For instance, the Code of Medical & Dental Practice, 2004, established the acceptable standard of practice guiding medical and dental practitioners in Nigeria. In Australia, the National Health and Medical Research Council Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2004 (revised 2007) (NHMRC Guidelines) was established by the professional body in that country to regulate the practice of ART.<sup>9</sup> Sanctions contained in such guidelines, except when enacted as law, are generally not enforceable by the state, though there may be other professional repercussions which a member may suffer. The non-coercive nature of guidelines makes compliance persuasive and not compulsive.

The four fundamental principles of ethics are autonomy, beneficence, non-maleficence and justice<sup>10</sup>. Importing these principles into the practices of ART would demand that a practitioner should clinically assess the patient to determine the method of reproductive treatment that best suits the patient. A practitioner should consider the risks and benefits of the procedure to the patient before

making recommendations with the patient's health prognosis as a critical factor. A practitioner should also take the necessary steps to obtain informed consent of the patient through proper counselling. The patient exercises the right of autonomy to decide on whether to accept a medical procedure. Informed consent is pivotal in the administration of every radical medical procedure.

The judicial attitude is that the obligation to treat on the part of a physician must yield to the patient's autonomy as embedded in the right of self-determination, and that any treatment of an adult person of sound mind against the person's wish may result in a civil wrong. A physician's duty of care stops where the patient has expressed a contrary desire. It will amount to an erosion of a patient's autonomy and an undue exhibition of medical paternalism to continue to administer treatment against the wishes of a patient<sup>8</sup>. In *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo*<sup>11,12</sup> Ayoola, JSC, while delivering the Nigerian Supreme Court judgment, gave vent to a patient's autonomy founded on the constitutionally guaranteed right to liberty, privacy and freedom of thought, conscience and religion which can only be eroded:

*Where they impinge on the right of others or where they put the welfare of society or public health in jeopardy. The sum total of the rights of privacy and of freedom of thought, conscience or religion which an individual has... is that an individual should be left alone to choose a course for his life, unless a clear and compelling overriding state interest justifies the contrary.*

His Lordship emphasized the helpless position of a physician whose patient has refused a particular treatment where he observed that: "Since the patient's relationship with the practitioner is based on consensus, it follows that the choice of an adult patient with a sound mind to refuse informed consent to medical treatment...leaves the practitioner helpless to impose a treatment on the patient"<sup>11</sup>. Uwaifo, JSC in a concurring decision held as follows:

*I am completely satisfied that under normal circumstances no medical doctor can forcibly proceed to apply treatment to a patient of full and sane faculty without the patient's consent, particularly if the treatment is of a radical nature such as surgery or blood transfusion. So, the doctor must ensure that there is a valid consent and that he does nothing that will amount to a trespass to the patient. Secondly, he must exercise a duty of care to advise and inform the patient of the risk involved in the contemplated treatment and the consequence of his refusal to give consent<sup>12</sup>.*

A patient's autonomy is a matter of ethics as well as law. Law and ethics being systems of rule-making sometimes overlap or conflict. Where there is a conflict, the law usually prevails as a coercive instrument of state to compel compliance with the prescribed conduct. In the practice of ART, the relationship between law and ethics plays out where a state legislation is complemented by professional guidelines<sup>13,11</sup>. Guidelines inculcate in the practitioners some level of consciousness for the observance of the law and not necessarily compelled by the coercive arm of the law. This conforms with the opinion expressed by Hart that there is a relationship between moral rules (ethics) and legal rules (law) in every society's legal system. Without the flavor of morality, law will become very rigid, working hardship on its subjects who may seek ways of circumventing the law without overtly infringing on the provisions, thereby defeating the aim of the law<sup>6</sup>. Hart's position is evident in the practice of inter-country (cross border) ART, whereby individuals migrate from states where ART is strictly regulated, (for instance, the UK where Human Fertility and Embryology Act 1990 regulates the practice), to states with more liberal regulatory regime or favorable disposition to persons or couples desire for reproductive care<sup>12</sup>.

### ***Assisted reproductive technologies (ART) in retrospect***

The first successful birth through the ART mechanism was a baby girl called Louise Brown. She was born on 25 July 1978 at 11.47pm in the

United Kingdom<sup>13</sup>, while baby Durga was born on the 3rd day of October 1978 in India as the world's second baby conceived through the reproductive medical technology<sup>14,15</sup>. Incidentally, the medical process leading to the birth of both babies were commenced at the same time by Dr Mukhopadhyay of India and British scientists Robert G Edwards and Patrick Steptoe respectively<sup>14</sup>. Similar births have been recorded in other countries including Australia on June 30, 1980<sup>15</sup>, Canada on December 25, 1983<sup>16</sup>, South Africa in 1983<sup>17</sup> and Nigeria on March 17, 1989<sup>18</sup>. Reports show that there are more than eight million babies born in the world through ART as of July 3, 2018<sup>19</sup>.

Although the ART is a medically acceptable panacea for persons and couples with a reproductive history of infertility, the method to be used, it has been suggested, depends on the cause of the infertility as ascertained through medical diagnosis. The essence of this reproductive intervention is basically to allow a medically scientific combination of sperm and ovum, for the purpose of fertilization and procreation. This is achieved by by-passing both male and female pathological factors inhibiting natural conception such as condition of the gametes, hormonal balance, semen conduction and deposition<sup>20</sup>. It is largely agreed in the medical circle that for the desired result to be achieved, the sperm produced by the male must be of sufficient number, have normal structure and motility. On the other hand, the female should also be able to produce normal matured ovum during ovulation. The hormones produced by the glands must be sufficient and suitable to maintain the required chemical balance in the body and support a fertilized ovum<sup>21</sup>. There are however chances that despite the micromanipulation to fertilize gametes by a certified practitioner in a licensed facility, conception may not be achieved, and even when it is achieved, pregnancy may not result in a live birth<sup>22,24</sup>. This may either be because, a part of the procedure is faulty or any of those biological impediments mentioned above could militate against the implantation and nourishment of the embryo. The age of the woman is also a vital contributory factor<sup>23</sup>. When any of these

supervening factors is present and defies artificial circumvention, conception is said to fail<sup>22</sup>. On the other hand, where circumvention is successful, the implanted embryo is sustained in the uterus.

The medical assistance in artificial reproduction seemingly ends at implantation, in that regard suggesting that both the embryo conceived through medical technology and by natural means have equal chance of survival. In essence, ART as an innovation in the field of reproductive medicine, merely provides a solution; an alternative and artificial means of procreation, for couples or individuals who could not conceive naturally, but not a cure for infertility.

### ***Regulation of assisted reproductive technologies (ART)***

When advancements in the field of medically assisted reproductive technologies (ART) appeared to be facing abuses, governments in some countries have responded by enacting legislation and/or allowing the professional associations in those countries to establish guidelines regulating the practice of assisted reproductive technologies. Nigeria does not feature on the table 2.1 of the world record which reflects the status of each country in relation to the regulatory mechanisms adopted by the country<sup>24</sup>. This should however not be understood as suggesting that there is no legislation or professional guidelines, which either expressly or implicitly regulate assisted reproductive techniques in Nigeria. Legislation and policies regulating assisted reproductive techniques vary among states and between jurisdictions. A glimpse of what is presently obtainable in Nigeria can be examined through the mirror of legislation and guidelines existing in those countries that have specific regulations on assisted reproductive technique.

### ***Regulation of ART in Australia***

The state of Victoria in Australia is recorded as the first to enact a legislation to regulate assisted reproductive treatment. The legislation which was enacted in 1984<sup>25</sup>, was then restricted to the regulation of *in vitro* fertilization (IVF) which witnessed the first pregnancy in Victoria in 1973<sup>26</sup>.

A more comprehensive legislation covering the various aspects of assisted reproduction was enacted by the state in 2008<sup>27,29-30</sup> and is complemented by a regulation made in 2009<sup>28,32</sup> which sets the parameters for the implementation of the statutory provisions. The guidelines that should inform every assisted reproductive technologies (ART) are set out in section 5 of the Act as being: (a) the welfare and interests of persons born or to be born as a result of treatment procedures are paramount; (b) at no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise— (i) the reproductive capabilities of men and women; or (ii) children born as a result of treatment procedures; (c) children born as the result of the use of donated gametes have a right to information about their genetic parents; (d) the health and wellbeing of persons undergoing treatment procedures must be protected at all times; (e) persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion. Qualification to carry out this exercise is provided in section 7 which requires that the person must be a doctor who is carrying out the treatment on behalf of a registered ART provider or a person under the supervision and direction of such doctor. A woman can only undergo this medical procedure based on medical diagnosis and with informed consent given after full counselling on the need and risks involved in the procedure<sup>29</sup>. Counselling is also required before the donation of gametes, and the consent of the donors is a prerequisite for using such gametes for a particular treatment<sup>30</sup>. Gametes could also be used posthumously where the treatment procedure is carried out—(i) on the deceased person's partner; or (ii) in the case of a deceased woman, by the woman's male partner commissioning a surrogacy arrangement in accordance with Part 4; and (b) the deceased person provided written consent for the deceased person's gametes or an embryo created from the deceased person's gametes to be used in a treatment procedure of that kind; and (c) the Patient Review Panel has approved the use of the gametes or embryo; and (d) the person who is to undergo the treatment procedure has received counselling<sup>31</sup>.

Part 6 of the Act contains comprehensive provisions on the keeping of register and access to information. The register records information about the donor, the child born through the donor-gamete and the parent(s) of the child<sup>32</sup>. The keeping of the register, as observed by Johnson, enables donor-conceived adults, parents and donors to apply for information about each other. If a match occurs through use of the same donor code, donor-conceived half-siblings, recipient parents, donors or relatives can exchange information or choose to meet<sup>26</sup>. Safeguards are however contained in the provisions to ensure that a person's confidentiality is not eroded requiring consent where necessary. Section 68 of the Act generally exempts from the disclosure requirements, documents, if—(a) it contains information (whether or not that information is kept in a register under this Part) about or provided by a person as— (i) a donor; or (ii) a woman on whom a treatment procedure is being or has been carried out or on whom a treatment procedure may be carried out; or (iii) a person who is or has been the partner of a woman referred to in paragraph (ii); or (iv) a person who was born as a result of a treatment procedure; or (b) it is the Central Register or part of the Central Register. Such restriction in the disclosure of information is necessary to protect the privacy of the concerned persons, while on the other hand ensuring, where consent is given, the prevention of incestuous marriages and relationships which are part of the ethical challenges of assisted reproduction.

It needs to be emphasized that under the Australian law, a woman need not be married or co-habit with a partner to undergo the ART procedure. Section 10(1) of the Act, for instance, provides that a woman may undergo a treatment procedure only if— (a) the woman and her partner, if any, have consented, in the prescribed form, to the carrying out of a procedure of that kind. This was purposely made to ensure compliance with the judicial decision in *Pearce v South Australian Health Commission*<sup>33</sup> where the Supreme Court declared that insofar as section 13 of the Reproductive Technology Act of South Australia restricts the application of artificial fertilization procedures under license except for the benefit of "married

couples" the same is inconsistent with the provisions of the Sex Discrimination Act of the Commonwealth and to such extent is invalid by virtue of the operation of section 109 of the Australian Constitution. However, in *EHT18 v Melbourne IVF*<sup>34</sup> it was held by the Federal Court of Australia that the requirement of the consent of a 'partner' as in section 10(1)(a) of the Victorian Act only applies where the person lives with another person as a couple on a genuine domestic basis (irrespective of their gender). It would be discriminatory to require a woman to obtain the consent of an estranged husband, notwithstanding that they are living separately and apart and have done so for almost a year though not divorced. Whereas, if instead of being married, the applicant had been in a de facto relationship with the same man who is now her spouse but she then separated from him for such a period that it could no longer be said that she was living with him as a couple on a genuine domestic basis, she would not be required to obtain his consent under s 10(1)(a). The decision strengthens the position of women who would want to be the sole parent to the child, as the court observed "if her estranged husband gives his consent, he will be deemed to be the father of the child which will deny the applicant the status in law of being a sole parent with sole responsibility for raising the child, which is what she wants to do"<sup>34</sup>.

### **Regulation of ART in the United Kingdom**

The United Kingdom has also enacted a comprehensive legislation to regulate the application of assisted reproductive treatment. The Human Fertilization and Embryology Act of 1990 which is the principal legislation, has been amended by Human Fertilization and Embryology Act of 2008 (HFEA). In *Quintavalle, R (on the application of) v Human Fertilization & Embryology Authority*<sup>35</sup> Kay J observed that the legislation has been tightly drawn so as to ensure that the ground rules within which the HFEA operates restrict the potential for misuse of science and technology. The Act established an Authority called Human Fertility Embryology Authority (HFEA), to monitor and license both facilities and practitioners in the field of assisted human reproduction. Section 3 of the

HFE Act 1990 prohibits the use of gametes and embryos which have not been certified or licensed by the HFEA. In other words, only permitted embryos can be implanted into a uterus, using any technique in assisted reproductive technologies. The range of prohibited activities in section 3 was held by the court in *Quintavalle, R (on the application of) v Human Fertilization & Embryology Authority*<sup>35</sup> as including tissue typing in conjunction with pre-implantation genetic diagnosis or PGD which was described by the court as involving three stages: (1) an *in vitro* embryo is permitted to develop to the 6-8 cell stage which occurs three days after fertilization; (2) one or two cells are removed from it by the process of embryo biopsy; (3) genetic material from the extracted cells is then taken and analyzed. In this way, it is possible to see whether the original embryo will develop into a child with matching tissue.

Section 4A of the 2008 Act prohibits human cloning by providing that no person shall place in a woman— (a) a human admixed embryo, (b) any other embryo that is not a human embryo, or (c) any gametes other than human gametes. (2) No person shall—(a) mix human gametes with animal gametes, (b) bring about the creation of a human admixed embryo, or (c) keep or use a human admixed embryo, except in pursuance of a license. Section 14 of the 2008 Act provides for counseling of all parties involved in the medical procedure before any fertility service is offered to anyone. Consent of the donor and the person receiving treatment in relation to the gamete or embryo after effective counseling is emphasized by the Act<sup>36</sup>. The keeping of register and controlled access to the information are provided for in the Act. Section 24 of the 2008 Act provides for information that shall be recorded in the register by the Authority as those relating to- (a) the provision for any identifiable individual of treatment services other than basic partner treatment services, (b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual, (c) the keeping of the gametes of any identifiable individual or of an embryo taken from any

identifiable woman, (d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or (e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a 'relevant individual'<sup>37</sup>. A relevant individual is an individual who was or may have been born in consequence of—(a) treatment services, other than basic partner treatment services, or (b) the procurement or distribution of any sperm (other than partner-donated sperm which has not been stored) in the course of providing non-medical fertility services<sup>38</sup>. A child born of the medical procedure and who is of age may request information about his/her parent, an intending spouse may request for information about the partner, and a donor may request for information about the resultant child. Such information enables donor conceived children to have access to information with a view to identifying their genetic parents, including their half siblings and to prevent sexual and marital relationships within the societal and culturally prohibited levels of consanguinity. The disclosure of information contained in the register in other cases is generally restricted by section 25 of the Act and is to be dealt with on case by case basis.

Section 27 of the 2008 Act recognizes the mother of a child as the woman carrying or who carried the pregnancy to term. Section 39 of the Act provides for posthumous reproduction using both cryopreserved gamete and embryo, while section 47 is geared at resolving issues of disputed parenthood of a child by declaring that a woman is not to be treated as the parent of a child whom she is not carrying and has not carried, except where she is so treated—(a) by virtue of section 42 or 43, or (b) by virtue of section 46 (for the purpose mentioned in subsection (4) of that section), or (c) by virtue of adoption. The referred provisions relate to situations where persons are married or are in civil partnership and one consents to the placing of the embryo in the womb of the other woman. The party whose consent is required and has given the consent will be regarded as the other parent even when such a person, if a woman, did not carry the baby in her womb. Such a dispute, as observed by Sir James

Munby, President of the Family Division *In re A and others (Legal Parenthood: Written Consents)*<sup>39</sup> "is, as a moment's reflection will make obvious, a question of the most fundamental gravity and importance. What, after all, to any child, to any parent, never mind to future generations and indeed to society at large, can be more important, emotionally, psychologically, socially and legally, than the answer to the question: Who is my parent? Is this my child?" Similarly, in *Rose & Anor v Secretary of State for Health Human Fertilization and Embryology Authority*<sup>40</sup> Baker J said:

*It is to my mind entirely understandable that A.I.D. [artificial insemination by donor] children should wish to know about their origins and in particular to learn what they can about their biological father or, in the case of egg donation, their biological mother. The extent to which these matters will vary from individual to individual. In some instances, as in the case of the Claimant Joanna Rose, the information will be of massive importance. I do not find this at all surprising bearing in mind the lessons that have been learnt from adoption. A human being is a human being whatever the circumstances of his conception and an A.I.D. child is entitled to establish a picture of his identity as much as anyone else. We live in a much more open society than even 20 years ago. Secrecy nowadays has to be justified where previously it did not.*

The keeping of the register certainly ensures the availability of such information and preventing dispute through legislation as the parliament seeks to do in the UK which is worth emulating by cognate jurisdictions.

### **Regulation of ART in Nigeria**

After about thirty years of the birth of the first baby through the assisted reproductive technologies (ART) in Nigeria, parliament is yet to enact any specific legislation that will specifically address issues of ethical challenges and abuses associated with that practice as in other jurisdictions under consideration. The principal legislation regulating

healthcare delivery in Nigeria is the National Health Act of 2014. The Act provides a framework for regulating, developing and managing the national health system, and sets standards for rendering healthcare services in the federation and for related matters. The provisions in the Act are complemented by the Code of Medical Ethics in Nigeria<sup>41</sup> which principally deals with ethical issues pertaining to medical practice. There are glimpses but very scanty provisions in both the legislation and the Code that could impact on assisted reproductive technologies in Nigeria.

Section 26 of the National Health Act protects a patient's confidentiality by declaring that:

- (1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential.
- (2) Subject to section 27, no person may disclose any information contemplated in subsection (1) unless-
  - (a) the user consents to that disclosure in writing;
  - (b) a court order or any law requires that disclosure; or
  - (i) in the case of a minor with the request of a parent or guardian; and
  - (ii) in the case of a person who is otherwise unable to grant consent upon the request of a guardian or representative.
- (c) non-disclosure of the information represents a serious threat to public health.

A 'user' is explicitly defined in section 64<sup>42</sup> as the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is-

- (a) below the majority age, "user" includes the person's parent or guardian or another person authorised by law to act on the first mentioned person's behalf; or incapable of taking decisions, "user" includes the person's spouse or, (b) in the absence of such spouse, the person's parent, grandparent, adult child, brother, sister, or another;
- (c) person authorised by law to act on the first mentioned person's behalf. The clarity embedded in the statutory definition of 'user' would ensure

optimal protection of patient's information even in those exceptional cases of a patient's physical or mental incapacity.

Similarly, regulation 44 of the Code of Medical Ethics provides that the profession takes very seriously the ethic of professional secrecy whereby any information about the patient that comes to the knowledge of the practitioner in the course of the patient-doctor relationship constitutes a secret and privileged information which must in no way be divulged by him to a third party except with an informed consent of a patient given preferably in writing. In *NM v Smith*<sup>43</sup> Madala J explained why the non-consensual disclosure of confidential medical information can be the basis of a claim for damages, as follows:

*Private and confidential medical information contains highly sensitive and personal information about individuals. The personal and intimate nature of an individual's health information, unlike other forms of documentation, reflects delicate decisions and choices relating to issues pertaining to bodily and psychological integrity and personal autonomy.*

Respecting a patient's confidentiality and informed consent are cardinal rules of medical practice in Nigeria. Although there are exceptions to this general rule as provided in the Act, disclosure of health information cannot be made in Nigeria at the request of a donor-conceived child even when the child is of age as under section 24 of the UK Act. Such a child does not fall within the definition of 'user' under section 64 of the Nigerian Act which refers primarily to the person that received treatment and does not include the product of that treatment when such a person is of the requisite physical and mental capacity. The foreseeable negative consequence of the absence of legislation authorizing disclosure in Nigeria at the request of a donor conceived child is that babies born through assisted reproductive technologies could fall into such social and family relationships which the laws in the other jurisdictions have taken steps to prevent by authorizing a disclosure of information in a similar situation.

The restriction on disclosure in a less educationally developed country like Nigeria, with strong religious and cultural leaning on issues of procreation, may not be divorced from the perceived negative consequence such as stigmatization of the donor, the donee and the child. An instance of this was witnessed in the secrecy surrounding the first test tube baby in Nigeria who was born in 1989. While other countries were publicly celebrating such a momentous milestone in the field of medical science and technology, it was reported by the media in Nigeria that:

*The joint pioneer of first test-tube baby or rather In-Vitro Fertilization (IVF) baby in Nigeria, Prof. Oladapo Ashiru, has faulted reports about Nigeria's first test-tube baby....Ashiru, an embryologist and endocrinologist, told The Guardian that he, in collaboration with Prof. Osato Giwa-Osagie, performed the delivery of the first IVF baby at the College of Medicine University of Lagos (CMUL)/Lagos University Teaching Hospital (LUTH) in 1989. However, due to fear of stigmatization, the parents refused their consent for the child to be exposed to the media even up till now<sup>18</sup>.*

It would seem that the negative consequences of non-disclosure far out-weighs the issue of stigmatization. A child is entitled to know his or her true parentage. Such information gives the child an identity as emphasized by the English court in *Rose's case*. The none inclusion of a donor conceived child in section 26 of the Nigerian National Health Act, or in any other provision for that matter, can only be attributed to the fact that that piece of legislation does not have the interest of such child within its contemplation.

The requirement of informed consent is provided for in section 23. That provision requires that the health care provider should provide information to the user in a familiar language of the user's health status and necessary treatment relating thereto including: (a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the users health status would be contrary to the best interests of the

user; (b) the range of diagnostic procedures and treatment options generally available to the user; (c) the benefits, risks, costs and consequences generally associated with each option; and (d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal. This provision should ordinarily cover counselling as seem in the specific provisions in the other jurisdictions. Information in paragraph (c) cannot be effectively communicated to the patient without counselling and on the basis of which the patient should make a decision to give or deny consent to be treated.

The keeping of medical record is provided for in section 25. Such record is to be kept by the health establishment containing such information as may be prescribed and to be made available at that health establishment for every user of health service. Access to a healthcare record can only be granted by the user for the purposes of- (a) treatment with the authorization of the user; and (b) study, teaching or research with the authorization of the user, head of the health establishment concerned and the relevant health research ethics committee<sup>43,44</sup>. The keeping of medical record of 'user' falls short of the central register under the control of the regulatory authority as seen in other jurisdictions which contains details of all the processes in assisted reproductive technologies, including details of the donor, the donee and the child. The Nigerian health records is health institution based and relates only to the user which explains why only the user can grant consent for the disclosure of such information. The improper or the non- keeping of record was at the center of the controversy on when the first ART baby was born in Nigeria: was it the baby boy named Olushina Eghosa Oluwaremilekun, born in 1989 through the research endeavors of Professor Osato Giwa-Osagie an Obstetrician and Gynaecologist, and Professor Oladapo Ashiru an Endocrinologist, both of the Lagos University Teaching Hospital, or Miss Hannatu Kupchi, born on 11 February 1998 at Nisa Premier Hospital in Abuja, through the research effort of Dr Ibrahim Wada, the Medical Director of Nisa Premier Hospital<sup>18</sup>? Such a question has never arisen, and

may never arise, in those jurisdictions that have enacted legislation that provides for a systematic and comprehensive record keeping on ART births.

Specific provisions on human tissues<sup>42</sup> and gametes<sup>42</sup> are contained in Part VI of the Act. The provisions on the use of human gametes as relevant to this discussion is contained in section 50 of the Act as follows:

- (1) A person shall not: -
  - (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos; or
  - (b) engage in any activity including nuclear transfer or embryo splitting for the purpose of the cloning of human being.
  - (c) import or export human zygotes or embryos.
- (2) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to imprisonment for a minimum of five years with no option of fine.

Manipulation of gametes including embryo splitting and cloning of human being is prohibited in other jurisdictions as matters of ethics. Otherwise there could be the urge through medical science and technology to create human beings from animal gametes and vice versa. In *R (Quintavalle) v. Secretary of State for Health*<sup>45</sup> Lord Phillips of Worth Matravers MR had described the parliamentary policy on the UK Act that seeks to bring the creation and use of embryos under strict regulatory control as being for ethical reasons. "To the question of whether it is necessary to bring embryos created by cell nuclear replacement within the regulatory regime created by the Act in order to give effect to the intention of Parliament, there can only be one answer. It is essential. There is no factor that takes embryos created by cell nuclear replacement outside the need, recognized by Parliament, to control the creation and use of human organisms".

The regulatory regime referred to by the court in the UK has not been provided for in Nigeria. In the UK, the HFEA is vested with the responsibility to license and monitor all issues

relating to ART. The Nigerian law has not created a similar body although there is the National Council on Health mentioned in section 4 of the Act, but the functions of the Council are merely advisory. The only deterrence for a person engaging in such an unethical conduct would be the fear of five years imprisonment as provided in subsection (2) of section 50.

Section 50(1)(c) as shown in the provision set down above prohibits the import and export of human zygotes or embryos. The reason for this prohibition is not clear especially as the Act respects the right of any Nigerian to seek medical check-up, investigation or treatment anywhere within and outside Nigeria<sup>46</sup>. Treatment obviously includes assisted reproductive treatment. Where a Nigerian in Nigeria requires such treatment, which involves the use of donor gamete or embryo that is outside Nigeria, would it not be more convenient and less expensive to import such gamete or embryo to Nigeria for the purpose of the treatment?

The Australian law provides a good example of how a matter of this nature is addressed. Section 36 of the Assisted Reproductive Treatment Act of 2008 provides that a person must not bring donor gametes, or an embryo produced from donor gametes, into Victoria; or take donor gametes, or an embryo produced from donor gametes, from Victoria unless with the written approval of the regulatory Authority. The Act proceeds to set the considerations which should guide the Authority in granting the approval as follows: (a) whether the purpose for which the gametes or embryo will be used outside Victoria is consistent with a purpose for which it could be used in Victoria; and (b) whether the way in which the gametes or embryo will be used outside Victoria is consistent with the way in which it could be used in Victoria<sup>47</sup>. A regulation of this nature is what is needed in Nigeria and not a prophylactic ban on donor gamete or embryo being imported into Nigeria or exported from the country. The provision of section 50(1)(c) of the Nigerian Act cannot withstand the constitutional threshold of right to healthcare which is what section 46 of the Act seeks to uphold.

## Conclusion

Infertility and the inability of a couple to conceive and bear a child have so many negative consequences on the affected persons ranging from depression to suicide even when the causes are not of their own making. The innovations in medical science and technology in the past century has continued to bring enormous relief to the affected individuals and couples through assisted reproductive technologies.

There are challenges inherent in ART which range from social, religious, cultural, and ethical issues. The role of the state is centered on the ethical question relating to the eradication of abuses and manipulations associated with the applications of this medical technology. A number of countries in the world have enacted legislation and established regulations and institutions to monitor and exercise some level of control on the activities of persons involved in the administration of the ART. Australia is one of such countries and the United Kingdom is another. Both countries or states within such countries (such as the State of Victoria in Australia) now have comprehensive legislation and regulations on ART. Nigeria happens to be among the countries that is yet to enact specific statutory instrument on ART in spite of having witnessed the first ART baby about thirty years ago. Although there are glimpses of legal provisions in the National Health Act of 2014, those provisions are grossly inadequate to address the challenges associated with the ART. Nigeria should emulate the examples of Australia and the United Kingdom in regulating ART in the interests of the practitioners, the beneficiaries and the society.

## Contribution of Authors

The first author initiated the writing of the manuscript. Both authors contributed equally in the research. The second author handled the structuring of the manuscript and all the editorial stages up to the final approval.

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