

A LEGAL SURVEY OF THE REGULATORY AND BIOETHICAL ISSUES ASSOCIATED WITH THE USE OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE SERVICE DELIVERY IN NIGERIA ***

Abstract

Artificial Intelligence (AI) can be contextually explained as machines that mimic human or animal cognitive capacity cum activities. Artificial Intelligence applications have progressed from the experimental phase to the implementation phase in daily life activities, and various fields of human endeavour, including research and healthcare service delivery. This Paper interrogates, in the main, the application of Artificial Intelligence in healthcare service delivery, especially in medically assisted human reproduction, the benefits it provides, the challenges associated with its use, and the bioethical issues associated with its application in patient care; the main focus of the Paper is Nigeria. The paper adopted a doctrinal research method. The study finds inter alia that there is a dearth of materials on the regulatory framework for the use of Artificial Intelligence in healthcare practice, despite the obvious bioethical concerns associated therewith. It is concluded that there is a need for the application of Artificial Intelligence in healthcare delivery to be within the bounds of law and ethical practice. Accordingly, the Paper recommends that various countries and jurisdictions should endeavour to intentionally establish adequate legal, regulatory, and national digital policy frameworks for regulating the implementation and monitoring of the use of digital health strategies for improved care and access, reduced cost, and protection of patients' rights.

Keywords: Artificial Intelligence, Regulatory, Bioethical, Healthcare, Service Delivery.

1. Introduction

Artificial Intelligence (AI) can be defined as the ability of machines to learn and demonstrate intellectual ability and/or engage in certain cognitive activities. It is defined as the automation of cognitive activities associated with human thinking such as decision-making, problem-solving, and learning.¹ Artificial Intelligence is defined as the ability of machines to learn and display intelligence, which is in stark contrast to the natural intelligence demonstrated by humans and animals. Artificial Intelligence applications have progressed from the experimental phase to the implementation phase in daily life activities, and various fields of human endeavour, including research and healthcare service delivery.² For instance, Android phones have speech-to-text software applications (speech recognition applications) that assist in efficient communication. Also, the security interface of face and eye recognition software applications is built into most Android phones and serves as an effective security check for theft and unauthorized access. On the other hand, a large volume of information obtained from successful clinical trials and patient management can be analyzed and stored in a medium to

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¹SJ Russell and P Norvig, *Artificial Intelligence: A Modern Approach* (3rd edn., New Jersey: Pearson Education, Inc, 2010) p.1 <https://people.engr.tamu.edu/guni/csce421/files/AI_Russell_Norvig.pdf> accessed on 20 July 2024.

²R Wang et al, 'Artificial Intelligence in Reproductive Medicine' *Reproduction* (2019)158(4) R139 – 154 at 139 <<https://rep.bioscientifica.com/downloadpdf/view/journals/rep/158/4/REP-18-0523.pdf>> accessed on 20 July 2024.

improve accuracy in healthcare service delivery and reduce the inevitable errors in medical diagnosis and treatment.³ These capabilities certainly surpass the natural intelligence in humans and would obviate the need for some medical resources, thereby reducing the cost of healthcare services. For instance, Robotic assistants are being used during surgical procedures, for monitoring hospitalized patients, and in geriatric medical management to assist aged patients with their routine activities such as medication and so on.⁴ The functionality is that, while the Robotic structure houses the AI, the AI comprising the algorithms or computer programming, provides intellectual capacity to the robots. But, despite the lure to replace most factors in healthcare delivery with AI applications, it cannot effectively and completely replace the human factor in patient care because the patient-caregiver relationship, interaction, and decision-making require human intellect.

In Medically Assisted Human Reproduction, the quality of the embryo(s) for transfer is one of the important factors affecting the success rate of IVF cycles. This is however determined by the quality of spermatozoa and ova fertilized and developed as embryo(s). Presently, there is no naturally devised parameter by medical practitioners to accurately ascertain the quality of these human gametes or embryo(s). Hence, the successful outcome of clinical pregnancy after an IVF cycle can neither be predicted with utmost certainty, nor the cause of a failure explainable.⁵ To improve treatment outcomes, fertility experts have introduced individualized ovarian stimulation, extended embryo culture duration, painstakingly studied the embryonic development to select the best for transfer. Nevertheless, the expected upsurge in the incidence of resulting pregnancies is yet to be seen. This dilemma is what AI presumably will resolve through: reducing the incidence of failed egg retrievals, facilitate the selection and transfer of at least single, euploid embryo that will result in a healthy, live-birth.⁶ It is believed that these measures will shorten the waiting time for couples to achieve conception.

Okonofua & Odunsi stated that treatment of infertility using any of the assisted reproductive technologies such as IVF, ICSI, IUI and so on, should be individualized, based on the causative factor.⁷ Similarly, it is believed that the best individualised treatment for infertile couples can be determined using AI, particularly the machine learning (ML) and deep learning (DL) forms.⁸ ML is a scientific computer program focused on how computers learn from data, using algorithms. In the healthcare sector, machine learning assist healthcare practitioners by differentiating between learning the tasks those practitioners are proficient in from learning those tasks wherein the practitioners have recorded minimal achievement and predict outcomes for tasks that are too tasking for humans.⁹ Deep learning however, is a further subset of machine learning which operates on artificial neural networks,

³VL Patel et al, 'The Coming of Age of Artificial Intelligence in Medicine' *Artif Intell Med.* (2009) 46(1) 5–17 at p. 4 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2752210/pdf/nihms116162.pdf>> accessed on 20 July 2024.

⁴E Topol, 'The Patient Will See You Now: The Future of Medicine is in Your Hands', *Journal of Clinical Sleep Medicine*, 11(6) (2015) p. 689 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4442231/pdf/jcsm.11.6.689.pdf> accessed on 20 July 2024.

⁵R Wang et al, (n 2) p. 140.

⁶C Calhaz-Jorge et al, 'Assisted Reproductive Technology in Europe: Results generated from European registers by ESHRE in 2012' *Human Reproduction*, Vol.31, No.8 (2016) pp. 1638–1652 at 1638. <<https://academic.oup.com/humrep/article/31/8/1638/2379971>> accessed on 23 July 2024.

⁷F Okonofua and F Odunsi (eds.) *Contemporary Obstetrics and Gynecology for Developing Countries* (Benin: Women's Health and Action Research Centre. 2003) 158.

⁸C Siristatidis et al, 'Predicting IVF Outcome: A Proposed Web-based System Using Artificial Intelligence', *InVivo* (2016) 507 - 512 at 507 <<https://iv.iijournals.org/content/invivo/30/4/507.full.pdf>> accessed on 23 July 2024.

⁹M Fralicket I, 'Machine Learning in Medicine,' (2019) 380 (26) *N. Engl. J. Med.* 2588 <<https://www.nejm.org/doi/pdf/10.1056/NEJMc1906060>> accessed on 23 July 2024.

mimicking the pattern of neurons in the brain. With many layers of neurons any conceivable task can be done if the neurons are stimulated by training.¹⁰

2. Regulation of Artificial Intelligence

AI combines learning, reasoning and ability to act autonomously, making it a desirable asset in various fields of patient care. In most countries, including Nigeria, there are no statutory enactments specifying when, how and where AI should be applicable, the nature of data to be captured for AI to avoid breach of right to privacy, who bears liability for defects or malfunction of the machine, who monitors the implementation of the regulatory framework and how, the penalty for contravening the law or violation of rights, remedy for the victims, who bears the liability for misuse, negligence or adverse outcomes resulting from the use of Artificial Intelligence. In *Mracek v. Bryn Mawr Hospital*¹¹ the court held the practitioners operating the robot liable, as the intervening cause of injury the plaintiff suffered. For patients' safety, the court held in *Taylor v. Intuitive Surgical Inc.*¹² that manufacturers have a duty to warn hospitals about the dangers in the products they purchase.

The vast field of Artificial Intelligence applicability in healthcare service delivery makes it essential to specify modalities for scientific machine programmers to obtain, classify and publish as established algorithms, information from patient records, to maintain sanctity and dignity of persons,¹³ and comply with the ethical principle of nonmaleficence.

In Nigeria, the Federal Ministry of Communication developed National Digital Economy Policy and Strategy 2020-2030 for establishing digital Economy in the country and designated the National Digital Economy Council to monitor its implementation.¹⁴ The first pillar of this document is Developmental Regulation, which is aimed at reviewing existing legislation for enhancing the development of digital technology, facilitating the enactment of appropriate legislation to protect digital technological infrastructure to enhance national growth and security. The researchers believe that a healthy population is a positive sign of growth and national strength and as such, the intended statutory enactments should specifically streamline the application of digital technologies such as Artificial Intelligence in healthcare service delivery. The National Health Act, 2014 is the principal legislation regulating healthcare services in Nigeria. It streamlines the rights and obligation of healthcare users and providers, and aims to provide best possible healthcare service to persons in Nigeria within the limits of available resources.¹⁵ The National Council on Health being the highest policy making body in health matters, is mandated by Section 5(1)(c)-(d) of the Act to ensure delivery of basic health services and prioritize other health services to be provided considering available resources and. It therefore follows that since

¹⁰DJX Chowet al, 'Does Artificial Intelligence Have a Role in the IVF Clinic' *Reproduction & Fertility* (2021) Vol. 2(3)C29 <<https://raf.bioscientifica.com/view/journals/raf/2/3/RAF-21-0043.xml?main%20body=pdf-62708>> accessed on 23 July 2024.

¹¹ 363 Fed. Appx. 925, 926 (3d Cir. 2010) <<https://casetext.com/pdf-email?slug=mracek-v-bryn-mawr-hosp-2>> accessed on 23 July 2024. Healthcare practitioners have a duty to make sure that the AI data relied on for patient management is appropriately evaluated. Liability enures when practitioners breach their legal duties - failure to meet the standard of care assessed according to the standard of learning and skill expected from or exhibited by other practitioners of same level and under similar circumstances.

¹² 187 Wash.2d 743, 389 P.3d 517 with docket number: No. 92210-1, 92210 (decided by Washington Supreme Court on February 9, 2017) <<https://case-law.vlex.com/vid/taylor-v-intuitive-surgical-888916722>> accessed on 23 July 2024.

¹³ Constitution of Federal Republic of Nigeria 1999, ss 17(2)(b), 17(3)(d), 34 and 37.

¹⁴ National Digital Economy Policy and Strategy 2020-2030 for a Digital Nigeria <https://ndpc.gov.ng/Files/Policy-National_Digital_Economy_Policy_and_Strategy.pdf> accessed on 23 July 2024.

¹⁵ National Health Act, 2014, s 1 <<https://scorecard.prb.org/wp-content/uploads/2019/06/Nigeria-National-Health-Act-2014.pdf>> accessed on 23 July 2024.

AI improves healthcare service, the National Council are obligated to advise the federal government accordingly to wit: statutorily incorporating AI into the healthcare system; bearing in mind the available national resources, to ensure equitable distribution and protect people's right to access healthcare service. Section 50(1)(a), (b) of the Act prohibits the application of any medical technology for the purpose of human cloning and specifies the penalty in its subsection 2.

The Minister for Health is also empowered to make regulations on matters necessary to expedite the provisions of the Act. Hence, he can make a regulation to guide the application of Artificial Intelligence in healthcare service delivery.¹⁶By the Code of Medical Ethics in Nigeria 2004,¹⁷all communications between the patient and the practitioner made in the course of treatment shall be treated in strict confidence by the practitioner and shall not be divulged unless compelled by law or overriding common good or with the consent of the patient.¹⁸Section 21 of the Code provides that:

It is mandatory for registered practitioners to be aware of new frontiers in the advancement of medically related scientific knowledge and actions. In view of the potential significance of these high-tech based advances, registered practitioners are advised to be cautiously involved in such new fields as cloning, genetic engineering, genomics etc. Certainly, specific guidelines on such and similar terrain of knowledge and practice will have to be made available in due course by the Council

Thus, practitioners are mandated to be abreast with advancements in medical practice; AI is an example of such advancement. In other words, medical practitioners and indeed healthcare workers should be up to date with technological modifications and advancements in medical devices and equipments that will improve healthcare service delivery and better patient care.

3. Examining the related Bioethical Issues

Application of Artificial Intelligence in healthcare service delivery, particularly in Assisted Human Reproduction, throws up some bioethical issues which are discussed hereunder.

3.1 Undermined Patient/Clinician Relationship

The duty of utmost care that healthcare providers owe the patients are somewhat undermined by Artificial Intelligence application. Interaction between healthcare providers and the patients is encumbered due to their inability to understand the Artificial Intelligence model's decision.¹⁹ For instance, in assisted reproduction, the fertility care provider usually explains the procedure from hormone stimulation, embryo selection and transfer, the basis of this decision taken with respect to number of embryos to be transferred, to the possible reasons for an implantation failure. After such ethical counseling, the care giver elicits feedback from the patients which may be questions that require further clarification(s).Consequently; patients are involved in their treatment and are better psychologically prepared for the outcome of the procedure. The healthcare provider is also careful to act according to accepted standard to avoid incurring liability. However, where the healthcare giver is made to rely on the assessment and decision of the Artificial Intelligence, interaction between the human parties is minimized as each depends and strains to understand the AI's activity. Such that information

¹⁶National Health Act, 2014, s 59<<https://scorecard.prb.org/wp-content/uploads/2019/06/Nigeria-National-Health-Act-2014.pdf>> accessed on 23 July 2024.

¹⁷ Code of Medical Ethics in Nigeria 2004 <<https://www.mdcnigeria.org/downloads/code-of-conducts.pdf>> accessed on 23 July 2024.

¹⁸Code of Medical Ethics in Nigeria 2004, s 9 (F)<<https://www.mdcnigeria.org/downloads/code-of-conducts.pdf>> accessed on 23 July 2024.

¹⁹ J Bjerring, and J Busch, 'Artificial Intelligence and Patient-Centered Decision-Making', *Philos. Technol.* 34, 349–371 (2021) <<https://doi.org/10.1007/s13347-019-00391-6>> accessed on 23 July 2024.

that ought to flow from the healthcare giver to the patient is truncated by the Artificial Intelligence that decides why a particular embryo is selected, the number of cells present in the embryo and cellular fragmentation, the probability of a successful implantation and why implantation may fail.

3.2 Patient Autonomy

Artificial Intelligence application may undermine patient autonomy by compromising the decision-making process in healthcare service delivery, almost retrogressing to the previously accepted paternalistic decision-making model in clinical practice, where the clinician or healthcare provider's opinion and recommendation is simply imposed on the patient who must accept same, except that in this case, it would be the AI's paternalistic decision. This is contrary to the joint decision-making model where the patient is given adequate information and counseling by the healthcare provider but allowed to take a decision. This is called respect for patient's autonomy.²⁰

3.3 Compromised Consent

Consent means permission granted in full knowledge of the possible consequences. Consent in healthcare service delivery must be informed.²¹ If information that is usually conveyed to the patient by the healthcare giver to facilitate an autonomous decision making is no longer accessible to the patient, because it is reposed in the Artificial Intelligence model to enable it perform some functions, without necessarily explaining same to the patient receiving the healthcare service, an informed consent cannot be said or seen to proceed from such a patient, whether or not the patient verbalises or endorses a written consent form as a prerequisite for a medical or surgical procedure. Therefore, where Artificial Intelligence is to be used in patient care for any procedure, it is necessary that informed consent to be signed by the patient should encompass an acknowledgement of the knowledge of data usage, the functions of the Artificial Intelligence, its limitations, merits and demerits. The patients should also be free to decline Artificial Intelligence access or services.

3.4 Unsatisfactory and mismanaged Patient Care

Distorted or misinterpreted information by the Artificial Intelligence can grossly affect patient management regimen and clinical outcome. In reproductive medicine for instance, there are reported differences between the profiles of male and female embryos in early *morph kinetics*.²² If the AI model understands and associates any of these profiles with high implantation success rate, it may systematically select embryos correlated with this success for implantation, irrespective of the gender. Assuming the embryos correlated with high success rate are females but the patient's choice is a male baby and this distorted preferential selection is not detected, the embryologist and the fertility expert will be misled into transferring such embryo as the desired one into the patient's uterus albeit successfully. The patient receiving the service becomes dissatisfied upon finding out the sex of her baby in-utero through an ultrasonography because the desired sex of baby remains unmet. The mismanaged care becomes grossly glaring if the sex preference is based on the child's well-being such as avoiding a sex-linked disease or genetic trait for which a costly procedure of pre implantation genetic diagnosis is necessarily done before transferring the embryo to the uterus for implantation.²³

²⁰C Charleset al, 'Shared Decision-making in the Medical Encounter: What Does it Mean?' (1997) 44(5) Social Science & Medicine 681 <<https://www.sciencedirect.com/science/article/abs/pii/S0277953699001458?via%3Dihub#preview-section-references>> accessed on 23 July 2024.

²¹Code of Medical Ethics 2004, s 19.

²² Wang et al, 2018 (n 2).

Morphokinetics: time-specific morphological changes during embryo development providing dynamic information on a fertilized egg.

²³D Gardner, M Meseguer, C Rubio and N Treff, 'Diagnosis of Human Preimplantation Embryo Viability' (2015) 21 Human Reproduction Update 727.

3.5 Beneficence and Nonmaleficence

The principle of beneficence is the obligation of physician to act for the benefit of the patient and supports a number of moral rules to protect and defend the right of others, prevent harm, remove conditions that will cause harm, help persons with disabilities, and rescue persons in danger.²⁴

On the other hand, Nonmaleficence is the obligation of a physician not to harm the patient. This simply stated principle supports several moral rules – do not kill, do not cause pain or suffering, do not incapacitate, do not cause offense, and do not deprive others of the goods of life. The practical application of nonmaleficence is for the physician to weigh the benefits against burdens of all interventions and treatments, to eschew those that are inappropriately burdensome, and to choose the best course of action for the patient.²⁵ The question now is: “Bearing in mind that the basis of bioethics in healthcare service delivery should be beneficence for the patient, is it justified to use Artificial Intelligence without being certain that it won’t cause more harm or offend bioethical principles in healthcare practice?”

Health facilities providing fertility services are keen to adopt new strategies for embryo selection to improve the success rates of their treatment cycles, which is a benefit derivable by applying Artificial Intelligence to fertility care. Thus, the probability of achieving clinical pregnancies and live births at initial rather than repeated cycles is maximized. In addition, successful embryo selection process reduces cost of the procedure and less waiting time for conception and parturition.²⁶ Couples can also store the excess selected embryo for future transfer, such that they can have their baby when desired-family planning. However, Peter should not be robbed to pay Paul in such application of Artificial Intelligence.

3.6 Confidentiality and Privacy

The issue of patients’ privacy inures from the fact that the information with which the Artificial Intelligence operates is usually generated from patients’ personal records, which are analysed and classified as algorithms to elicit the required response with the Artificial Intelligence. The queries raised on here include: were such patients informed prior to computation of their records for such scientific projects? If yes, did they give an informed consent for the use and sharing of all or some part of their clinical data collected? Were their data anonymised prior to usage? The Artificial Intelligence appears to mechanize healthcare service which not only interferes with the duty of confidentiality existing between the patient and the physician, but also undermines the privacy of the patient who may not be willing to divulge some personal information despite being in a vulnerable situation, due to anxiety and lack of confidence on the Artificial Intelligence application.

3.7 Best Interest of the Child

The selection model of embryos by the AI may not always be in the best interest of the child born through assisted reproduction. For instance, if the selection model based on the embryo with high implantation success rate ends up selecting embryos that will develop into children that have traits for developing a particular disease condition (maybe not genetically) such as polycystic ovarian syndrome or cancer. The embryos without such traits may have been denied the opportunity to become human

²⁴ B Varkey, ‘Principles of Clinical Ethics and Their Application to Practice’, *Med Princ Pract.* (2021) 30(1): 17–28 <<https://doi.org/10.1159%2F000509119>> accessed on 23 July 2024.

²⁵Ibid.

²⁶SK Sunkara et al, ‘Time as an Outcome Measure in Fertility-Related Clinical Studies: Long-Awaited’(2020) 35Human Reproduction1732<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7398622/pdf/deaa138.pdf>> accessed on 23 July 2024.

beings due to the embryo selection model applied by the AI that made them alternatives forgone in the opportunity cost of embryo transfer and human development. This is not to say that such innocent erroneous selection is not obtainable in human controlled embryo selection, but the precision expected of the AI may not exclude such unforeseen medical condition.

4. Challenges to the Use of Artificial Intelligence in Nigeria

A major factor that will constrain the application of Artificial Intelligence in Nigeria is inadequate infrastructural development. This includes poor road network and maintenance making rural –urban movement difficult and discourages investments in projects that would fast track development in the rural areas. In most African countries, Nigeria inclusive, there is wide spread lack or poor access to networks for communication and internet facilities in most communities due to insufficient network coverage in those areas.

The challenge of inefficient and epileptic electricity/power supply, restricting accessibility of electricity supply to few populations in the urban area, while majority depend on alternative means of electric power generation such as solar energy or power generating plants that operate on diesel or petrol. Considering the quantum of infrastructural decadence in the country and the socio-economic implication associated therewith, it would appear a herculean task advising or convincing the government of Nigeria to undertake installing Artificial Intelligence application in Nigerian healthcare service delivery. This is because the cost implication of procuring data, computer hardware and software for establishing and maintaining the Artificial Intelligence application is a huge deterrent to sourcing AI and subsequent use in public healthcare facilities. However, few private healthcare facilities may be able to do so or at least outsource the use of Artificial Intelligence applications. For instance, sperm sorting; a procedure done to identify and isolate male sex cells for ovum fertilization and subsequent transfer into the uterus, guarantees conception of male babies. But in Nigeria, the procedure is outsourced to a health facility in Philadelphia, USA because of the cost implication.

5. Conclusion and Recommendation(s)

From the foregoing, the researchers conclude that the application of Artificial Intelligence in healthcare delivery ought to be within the bounds of law and ethical practice. Accordingly, it is recommended that there is need for various countries and jurisdictions to intentionally set up (establish) adequate legal, institutional, and national digital policy frameworks for regulating the implementation and monitoring of digital health strategies to ensure efficient and seamless application of Artificial Intelligence within the bounds of law and ethical practice, and most importantly, promote better access to quality healthcare service at a reduced cost to the healthcare service consumers.