

Navigating the Legal and Ethical Terrain of Artificial Intelligence in Enhancing Patient Safety in Nigeria

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ABSTRACT

The emergence of Artificial Intelligence (AI) significantly impacts the understanding of medical errors, minimizes their occurrence, and provides contextual solutions for patient safety in Nigeria. Given the country's expanding population and constrained healthcare resources, the potential significance of AI in enhancing patient safety in Nigeria cannot be overstated. There is a rapid trend to integrate AI into Nigeria's healthcare system, however, this raises concerns about algorithm bias and privacy. This study explores the ethical and legal implications of deploying AI for patient safety in Nigeria and assesses how the existing Nigerian legal frameworks address these concerns. This research shows that although bias and discrimination are generally prohibited by the Constitution of the Federal Republic of Nigeria and other legal instruments, algorithmic bias which arises from the use of AI is not catered for by these laws. In addition, despite current privacy and confidentiality safeguards, AI in healthcare presents unique and novel challenges that the legislation does not yet address. Therefore, developing a new legal and governance structure to address both present and prospective challenges of AI in the health sector is extremely useful.

Keywords: Algorithm Bias, Artificial Intelligence, Legal and Ethical Ramifications, Medical Errors, Patient Safety

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I. INTRODUCTION

There is a global consensus among authors that Artificial Intelligence (AI) technologies hold immense potential for the healthcare sector, specifically in advancing patient safety (Clas-sen, Longhurst & Thomas, 2023, p. 1; Bates, Syrowatka & Jack-son, 2021; Choudhury & Asan, 2020). These technologies are be-coming more widespread in Nigeria as more healthcare facilities adopt and implement AI-based solutions to enhance healthcare delivery in the country. For instance, the Aajoh application em-ploys AI to diagnose patients' medical conditions (Igbadoo, 2020). Also, the Lagos State University Teaching Hospital (LASUTH) developed an AI-powered breast cancer detection system. The technology uses machine learning algorithms to examine mam-mograms in order to detect early indicators of breast cancer (Up-adhyay, 2023).

On the one hand, AI refers to systems that exhibit intelli-gent behavior by analyzing their surroundings and acting au-tonomously to attain certain goals (Sheikh, Prins & Schrijvers, 2023, p. 16). On the other hand, patient safety refers to the ab-sence of preventable harm to patients during medical care and aims to reduce the likelihood of healthcare-related injuries to a tolerable level (WHO, 2019). It is also the absence of unpleasant events that arise during the healthcare process and may result in long-term injury, an extended hospital stay, or even death (Nwosu, Onyekwulu & Aniwada, 2019, p. 1).

AI presents several advantages in the health sector, ranging from its ability to collect, share, and analyze data, to enhanc-ing collaboration, integration, and teamwork among healthcare practitioners and other stakeholders (Bates, Syrowatka & Jack-son, 2021; Secinaro et al., 2021, pp. 1-2; Collins et al., 2021, p. 3). Through a collaborative approach to collecting and sharing information, AI decreases duplication and fragmentation of care which is a traditional nature of healthcare delivery (Troseth, 2017, p. 16; Rosen et al., 2018, p. 434). This way, AI can break

down healthcare silos while fostering a sense of connection, teamwork and collaboration. This increases the possibility of improving clinical risk predictions and diagnosis (Bates, Syrowatka & Jackson, 2021; Choudhury & Asan, 2020).

Moreover, AI technologies facilitate improved involvement of patients in their healthcare. It also aids healthcare practitioners in maintaining a united front when it comes to patient history and treatment. This helps in putting AI's application into proper institutional context and enhances organizational learning which will translate to the advancement of patient safety. Thus, AI possesses great, varied, and multifaceted potentials, some are already applicable while others are yet to be explored (Secinaro et al., 2021, pp. 2, 16, 19). Thus, implementing AI-powered healthcare solutions in Nigeria such as the LASUTH's breast cancer diagnostic tool will promote patient safety by reducing errors and improving care quality. Part II of this paper presents more case studies on similar innovations in Nigeria. Also, the degree to which AI systems comply with ethical standards such as data protection and privacy will impact patient trust and safety outcomes.

Despite these capabilities, AI has legal and ethical implications that threaten the protection and enhancement of patient safety, and these implications are also present in Nigeria. These concerns range from the accentuation of bias and discrimination; the undermining of anonymity, privacy, and confidentiality; risks of hacking and breach of data, onerousness of assigning responsibilities and liabilities as well as inadequate understanding of the safety boundaries of its deployment (Dada, 2023).

For a nation like Nigeria, which faces complex challenges of limited healthcare resources, fast expanding population, and rising demands for high-quality medical care, these concerns must be taken into account if AI is to be used responsibly and safely in the health sector in order not to compound and exacerbate the existing challenges (Abubakar et al., 2022, pp. 1155-1158, 1177)

This research utilized academic and legal analyses of both primary and secondary sources to identify the legal and ethical issues in the use of AI for the enhancement of patient safety in Nigeria.

This paper is organized into six sections. The first part serves as the introduction. Following this opening section is Part II, which explores AI's potential in advancing patient safety. Additionally, the paper delves into the specific applications of AI within the healthcare industry in Nigeria. Part III addresses the ethical considerations associated with healthcare AI, specifically analyzing the implications of bias, discrimination, confidentiality, privacy, and data security for the promotion of patient safety. In Part IV, the paper examines the existing legal and ethical framework governing the use of AI in enhancing patient safety in Nigeria. Part V provides recommendations, and finally, Part VI concludes the paper.

II. THE ROLE OF ARTIFICIAL INTELLIGENCE IN PROMOTING PATIENT SAFETY

In this section, the authors thematically analyze the findings from both the qualitative and doctrinal approaches in line with the identified legal and ethical concerns. Consistent throughout the literature review is the diverse and multifaceted potential of AI in enhancing patient safety (Sokol, 2019; Bajwa et al., 2021, p. e191). For instance, there is widespread consensus that data holds a lot of potential for healthcare and patient safety. Data, in itself, is useless unless and until it is analyzed. It is the analysis that puts data in the proper institutional context and enhances organizational learning which will translate to the advancement of patient safety. AI is effectively employed to analyze health data and other critical information for this purpose (Bates et. al., 2021, p. 2).

Also, evidence indicates that the advancement of patient safety requires dependable teamwork and partnership both

within and across all boundaries whether organizational, departmental, technical, or cultural (Bates et al., 2021, p. 2). AI has been found to help improve collaboration, integration, and teamwork. For instance, with the LASUTH AI-powered breast cancer *diagnostic* tool, radiologists, oncologists, and other relevant professionals can easily collaborate to improve diagnosis accuracy and speed.

In addition, research indicates that one of the things that makes healthcare practitioners more prone to making mistakes is stress and this is a special concern in a densely populated country like Nigeria (Nwosu *et al.*, 2020, p. 5). With the ability of AI technologies and automation to effectively carry out duties previously done by people e.g. the use of infusion pump technology, unnecessary stress will be reduced, and patient safety will improve (Thimbleby, 2013). Furthermore, AI applications can be used to minimize the incidence of harm in a variety of domains, including infections linked to healthcare, adverse reactions to drugs, deep vein thrombosis, pressure sores, falls, diagnostic errors, and complications from surgery (Bates *et al.*, 2021, p. 1).

It is for the above benefits that AI-powered services are proliferating in the Nigerian health sector. Some of these services are featured below.

A. Overview of AI in the Nigerian healthcare industry

AI technology has found application in the healthcare sector in Nigeria. Aajoh, a Nigerian company established in March 2016, operates within the health industry in Nigeria. The company created the Aajoh application which employs AI to diagnose patients' medical conditions. The software was created utilizing patient-generated data, with a model based on users' health symptoms. Aajoh has been trained to recognize signs of various health-related conditions and diseases. Consequently, it may accurately anticipate an illness when presented with a new list of symptoms from new patients (Igbadoo, 2020). As of November 2016, Aajoh had established relationships with two hospitals in

Nigeria, totaling over thirty-two thousand data entries (Jackson, 2016).

Ubenwa is another AI system developed in Nigeria in 2017 that uses cry sounds to detect neurological and respiratory problems early in infants. To determine and forecast if a newborn baby's cry contains signs of asphyxia, Ubenwa analyzes the frequency and amplitude patterns in the cry (Ladipo, 2022; Onu et al., 2017). Baby asphyxia is the third leading cause of infant death, particularly during birth. It usually happens when a newborn does not get enough oxygen before, during, or after birth. Newborns are offered hope through Ubenwa. More trials on the use of Ubenwa are being done in Nigeria at the University of Port Harcourt Teaching Hospital (Igbadoo, 2020). In trials with approximately one thousand four hundred pre-recorded baby cries, Ubenwa's AI system achieved over ninety-five percent prediction accuracy (Adepoju, 2017). Ubenwa collaborates with pediatricians in Brazil, Canada, and Nigeria to collect substantial, distinctive clinical data and build novel AI algorithms (Onu, 2023).

A Nigerian health tech startup called Helium Health manages electronic health data, streamlines clinical processes, and offers telemedicine services using AI. Helium acts as the operating system for the delivery of care, streamlining daily tasks and facilitating seamless provider-patient interaction. Clinicians, governments, and public health stakeholders rely on Helium Health's technology and data to raise standards along the continuum of healthcare delivery, enabling African families to live longer, healthier lives. The platform's interoperability enables hospitals in the network to make paperless referrals (Chukwuma, 2021; Jackson, 2021). As a result, if hospitals A, B, and C are a part of the Helium network, patient records can be effortlessly transferred between them. This will be applicable if a patient relocates or needs to be transferred to another hospital because of complications (Uba, 2023). Also importantly, Helium Health pioneered a healthcare financing platform powered by AI and

distributed two-point-five million US dollars in non-collateral loans to one hundred and fifty-five facilities (Velebny, 2023).

Smaart Health is also breaking ground in Nigeria's health-care sector by providing universal access to primary healthcare. Smaart Health is a smartphone app driven by AI that allows individuals to conduct on-demand medical consultations on their smartphones. In less than two minutes, a precise medical diagnosis and instructions for the next step are received. Users can also interact with foreign-based doctors directly and receive high-quality medical advice and prescriptions from the comfort of their homes. Smaart Health's AI-powered smartphone app can aid in eliminating mistakes relating to human fatigue and relieve doctors of some monotonous tasks (Ojewale, 2018; Smaart Health, 2017).

III. ETHICAL CONSIDERATIONS IN HEALTHCARE AI

There are ethical and legal ramifications of employing AI to advance the safety of patients. Employing AI to advance the safety of patients leads to a reconfiguration of legal and ethical boundaries leading to several concerns including but not limited to discrimination, confidentiality, data privacy and security, autonomy and informed consent, assignment of responsibility and liability as well as raises fundamental questions about how to organize existing legal framework to ensure patient safety. This section discusses the bias and discrimination implications as well as the implications on privacy, confidentiality, and data security vis-à-vis the provisions of relevant laws.

A. Bias and discrimination implications of AI in the Nigerian health sector

While it is true that the rapid growth of AI technologies has opened up a new option in the field of medicine that promises better patient outcomes, improved diagnostic accuracy, and a more effective way to offer care, several AI technologies depend

on machine learning, which is a process in which the system is trained to make predictions through datasets (Sokol, 2019). AI uses algorithms to discover or learn associations of predictive power from data. This is accomplished by gathering data, making a representation of that data, and drawing conclusions from the information. In other words, an algorithm scrutinizes an enormous quantity of data to identify patterns and generate an outcome, for instance, a diagnosis (Bajwa, 2021, p. e189; Secinaro et al., 2021, p. 19). As a result of this capability, which may also be used to handle administrative tasks, healthcare practitioners are disposed to make better decisions, prevent mistakes, and ultimately improve patient safety (Igoe, 2021). The greater the robustness and diversity of the data input, the more accurate the output. The quality of data input determines the trustworthiness of the information output. Incorrect outputs can result from false, misleading, or biased datasets. Thus, the prediction, strength, and dependability of AI tools are premised on the robustness and quality of input data.

However, because AI algorithms rely on previously inputted data for training, there is a risk that biases and discrimination in the data may be perpetuated (Sokol, 2019). If the training data used to construct AI models are biased, the resulting algorithms may unintentionally duplicate and amplify these biases, resulting in discriminatory consequences (Ferryman, Mackintosh & Ghassemi, 2023, p. 834). Algorithmic bias in healthcare is the use of an algorithm that amplifies already-existing inequities in socioeconomic level, ethnicity, religion, gender, disability, or sexual orientation, thereby magnifying inequities in health systems (Panch, Mattie & Atun, 2019, p.1). That is to say, algorithms primarily reflect biases in the world on a potentially large scale and without adequate control, thereby worsening the biases and impeding the provision of accurate, safe, and evenly distributed healthcare ((Panch et al., 2019, pp. 1-2; Igoe, 2021).

Because bias exists in the real world, its appearance in data may be unavoidable. Bias can creep into the process from the

start, during research design and data collection, data entry and cleaning, algorithm and model selection, and implementation and distribution of the results. Machine learning algorithms will eventually pick it up in some form. For instance, several AI tools are based on homogeneous data and these AI systems might not be able to accurately diagnose or give treatment recommendations for heterogeneous populations making their results inapplicable to them and aggravating the already extant healthcare inequities (Panch, Mattie & Atun, 2019, p. 2). In other words, minority communities usually have low data representation, which increases the chance that they will be over or under-diagnosed when AI techniques are employed to guide decision-making (Sokol, 2019).

This paper considers this a case of discrimination and bias against vulnerable populations, technically. This implies that although AI has the potential to improve diagnosis, it also has the unintended consequences of discriminating against vulnerable populations (Castets-Renard & Fournier-Tombs, 2020). In addition, AI may make predictions about future events based on the huge amount of data fed into it. Disclosure of AI predictions about an individual, particularly to third parties, can lead to discrimination against that person (Price II, 2019).

The enjoyment of the right to health must be without bias and discrimination; taking no regard to race, age, ethnicity, or other characteristics. Several national and international legal instruments are averse to discrimination. Section 15(2) of the 1999 Constitution of the Federal Republic of Nigeria (“CFRN” or “the Constitution”) prohibits discrimination on any ground be it sex, religion, origin, status, linguistic association, or ethnic ties. The Constitution rather advocates for national integration and social cohesion. Article 26 of the International Covenant on Civil and Political Rights (ICCPR), Articles 2 and 10 of the International Convention on Economic, Social and Cultural Rights (ICESCR), the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD), the Convention on

the Elimination of All Forms of Discrimination Against Women (CEDAW), and Articles 7 and 23 of the Universal Declaration of Human Rights (UDHR) all prohibit discrimination in one form or the other.

These anti-discrimination laws, however, were not enacted to address medical accuracy or algorithmic bias. The ICCPR guarantees the right to equal legal protection against discrimination on any basis. The ICESCR encourages State Parties to guarantee that all of the Covenant's rights are practiced without discrimination, including the right to health enshrined in Article 12. The Covenant also requires that particular measures of protection and support be implemented on behalf of all children and young people, without regard to parentage or other circumstances. In Article 5, the ICERD, which forbids all forms of racial discrimination, prohibits racial discrimination in the exercise and enjoyment of the right to public health and medical treatment. Furthermore, the Preamble, as well as Articles 12 and 14 of the CEDAW, guarantee women's right to healthcare free of discrimination. The combined reading of Articles 7 and 25 of the UDHR indicates that discrimination in health care is prohibited. Since these laws were not created to address these emerging needs or innovative types of unintentional or indirect discrimination, none of them take algorithmic bias or medical accuracy into account. They are rather aiming to achieve equality and national cohesion.

At the regional level, the African Charter on Human and Peoples Rights (ACHPR) in its Article 16 provides that every individual shall have the right to enjoy the best attainable state of physical and mental health while its preamble discourages all forms of discrimination. The African Charter on the Rights and Welfare of the Child also provides for the right of the child to health and health services in its Article 14 while Article 3 provides that every child shall be entitled to the enjoyment of the rights and freedoms recognized and guaranteed in the Charter irrespective of the child's or his/her parents' or legal guardians' race, ethnic group, color, sex, language, religion, political or oth-

er opinion, national and social origin, fortune, birth or other status. This implies that the right to health as recognized in both Charters must be enjoyed without discrimination. Nevertheless, algorithmic prejudice is not considered a form of discrimination under these criteria. The provisions may only be stretched to accommodate this if need be.

On the other hand, the CFRN in its section 17(3)(d) provides that the country shall direct its policy towards ensuring that there are adequate medical and health facilities for all persons. Article 5(e)(iv) of the ICERD states that racial discrimination in all its forms as it pertains to the right to health and medical care should be eliminated. Also, article 25 of the UDHR provides for the right to health. Being a party to these Conventions, Nigeria as a country is mandated to respect, protect, and promote the right to health. Noteworthy, by virtue of section 12 of the Constitution, no treaty or other legal instruments shall have the force of law except such has been enacted into law by the National Assembly. With the domestication of the ACHPR, the provision of Section 17(3)(d) of the CFRN and the provisions of the ACHPR can be construed to imply that the deployment of AI in healthcare for the promotion of patient safety should be for the enjoyment of all and not some privileged individuals. This is not always the case.

In Nigeria, there is a remarkable level of inequity in healthcare. The country's medical and health facilities are neither adequate nor equally accessible to all citizens. The average Nigerian cannot afford to receive safe and high-quality healthcare (Abubakar et al., 2022, pp. 1156, 1174; Lawanson & Opeloyeru, 2016, p. 229). . Using AI technologies exacerbates this inequity. AI technologies frequently need a strong digital infrastructure and high-speed internet access (Attaran, 2023, p. 5977). Urban areas in Nigeria have better access to technology than rural ones, creating a digital gap. Access issues may result in unequal distribution of the benefits of AI developments (Okocha & Edafewotu, 2022, p. 45).

The Constitution's clause on equal chances and access to public resources might thus be considered as being violated and disregarded by this unequal access to technology. In addition, it should be noted that biases that mirror current societal biases may be inherited by AI systems from the dataset they rely on. Also, biased AI algorithms can reinforce discrimination and inequity in a diverse society like Nigeria, where religious, political, ethnic, cultural, and geographical variety is paramount. Thus, biased AI algorithms are a constitutional concern in Nigeria because the country's constitution forbids discrimination on the grounds of race, religion, or geography.

However, the Constitution does not seem to be equipped to address this bias and inequity because Section 17(3)(d) appears illusory and misleading. This provision is accommodated under Chapter Two, which covers socioeconomic rights that are just pious aspirations or wishes but are not justiciable or enforceable in accordance with the Constitution itself (the Constitution s6(6)(c)). Using AI technologies reinforces these inequities because an average Nigerian may not have access to AI-based healthcare. It should be noted that algorithmic bias is not just a technical issue because the data inequities that cause such bias also determine who gets sick, who seeks medical attention, who is represented in the datasets used by health systems, how they are treated, and who survives (Panch, Mattie & Atun, 2019, p.2).

Even when an average Nigerian has access to AI-based healthcare, algorithmic bias may still arise. This is due to the fact that health systems differ in design, objectives, and the range of people they serve from various cultures and environments, with varying socioeconomic profiles, lifestyles, preferences, and genetic endowments; most AI technologies are not created using data that reflects this broad diversity (Panch, Mattie & Atun, 2019, p.2). However, data are not evenly available for all socio-economic groups. The data of the underrepresented groups is usually not incorporated into the development of AI algorithms, rendering the system poorly suited to make predictions for the group

(Panch, Mattie & Atun, 2019, p.2). In Nigeria, data is not easily available, and AI requires a large amount of data to train the innovations. This lack of data may be attributed to Nigerians' declining trust in health research and associated activities (Ogueji et al., 2023). Despite the existence of a regulatory framework for the conduct of health research, many use Pfizer's experience as a reason for non-participation in health research and associated activities (Ojewale & Mukumbang, 2023, p.5; Archibong & Annan, 2021).

To be successful, any AI-driven clinical or policy intervention must gain the trust of individuals who provide their data and whose lives are touched, as well as physicians and policymakers who may use AI to influence their decisions (Asan, Bayrak & Choudhury, 2020, p. 2). As a result, it is critical to gain the trust of the Nigerian community to enable diverse and equal data representation, which would counter biased and erroneous outcomes.

AI is a potential game changer for improving data inference for treatment and population health and can be leveraged to promote patient safety while limiting the negative effects of bias and discrimination when more robust, diverse, and high-quality data is incorporated into the AI system translating into effectiveness and accuracy for a wide range of populations. This, however, has other implications including the risk of eroding confidentiality, violating privacy and data security, as well as disregarding autonomy.

B. Confidentiality, privacy, and data security implications of AI in the Nigerian health sector

Since AI relies on vast volumes of sensitive and personal health information, guaranteeing confidentiality, privacy, and data security is critical. AI can forecast patients' sensitive information even if the information was not obtained by the algorithm. This may constitute a breach of patients' privacy, particularly if third parties are granted access to the inference of

the AI system (Price II, 2019). In addition, the availability of data for AI makes it vulnerable to hacking and data breaches. Addressing privacy and data security concerns is critical. Strict oversight of data use and transfer will be essential in protecting patients' personal information and interests (Khalid et. al, 2023, p. 5; Crigger & Khoury, 2019, p. 189).

Confidentiality protects patient information by limiting access to authorized personnel and keeping it private and secure. With the advent of AI, there is a greater need to set up reliable safeguards for patient data (Tariq & Hackert, 2023). To safeguard data transmission and storage, healthcare organizations must use strict protocols and encryption techniques, reducing the possibility of hacking or unauthorized access (Zarour et al., 2021). With the reliance of AI systems on massive data collection and processing, privacy concerns arise necessitating the need to handle patients' health information, such as medical records, diagnostic findings, and genomic data, with extreme caution and care on the one hand. On the other hand, data security is critical to preserving the integrity and confidentiality of healthcare data. This implies that AI systems should be built with strong security procedures, such as encrypted data transmission, secure networks, and authentication procedures (Khalid et. al, 2023, p. 5; Crigger & Khoury, 2019, p. 189).

Section 37 of the CFRN, which is the foundation of data privacy rights, guarantees and protects the privacy of citizens (patients inclusive), their homes, correspondence, telephone conversations, and telegraphic communications. In some cases, Nigerian courts have given a comprehensive and wide-ranging interpretation to this section of the Constitution by ruling that it is against a person's right to privacy to disclose their personal information without getting their permission.

In *MTN Nigeria Communications Ltd v. Barr. Godfrey Nya Eneye (MTN v. Eneye, 2013)*, the Nigeria Court of Appeal decided that the defendant's unauthorized disclosure of the claimant's mobile phone number breached his basic right to privacy.

Additionally, in *Ezugwu Emmanuel Anene v. Airtel Nigeria Ltd. (Anene v. Airtel, 2015)*, the plaintiff sued Airtel, his service provider, in the FCT High Court in 2015. Among other things, the plaintiff claimed that his right to privacy was violated by numerous unsolicited calls and texts from Airtel and other parties to which it had provided access to his number. The trial court awarded him damages of five million naira (₦5,000,000.00) for the invasion of his privacy. These are some of the cases showing the general stance of the Nigerian authorities in protecting privacy. However, the authors are not aware of any established cases involving AI and healthcare.

All information pertaining to a healthcare user, including information referring to their health state, treatment, or stay in a health establishment, is confidential, under the Nigeria Data Protection Regulation (NDPR) 2019. Although not updated, the Regulation stands in tandem with the Nigeria Data Protection Act 2023 (NDPA) as it concerns the confidentiality of information. Hospitals and other healthcare facilities are governed by this law because it supports the provisions of the National Health Act (NHA) 2014 regarding confidentiality. Section 26 of the NHA states that patient information should be kept confidential unless disclosure is in the best interests of the patient. The Patients' Bill of Rights (PBoR) 2018 also states that privacy and confidentiality of all information and medical records is vital unless disclosure is in the interest of public health and in accordance with prevailing law. Section 39(2) of the NDPA listed measures that data controllers and processors may take to ensure confidentiality to include, pseudonymization, or other methods of de-identification of personal data, and encryption, among others.

NDPA is the most relevant, current, and comprehensive law on data protection in Nigeria. It establishes a legal foundation for personal information protection and data protection practice in Nigeria. One of the major objectives of the NDPA, as stated by section 1(c), is to promote data processing practices that

safeguard the security of personal data and the privacy of data subjects. According to the explanatory memorandum and part IV of the NDPA, it intends to protect personal information and prevent unauthorized access or exploitation. It sets safeguards to ensure that personal information is well-secured and not divulged to unauthorized parties. The NDPA establishes general principles and procedures for the processing of personal data. It specifies the circumstances under which personal information may be collected, utilized, kept, and shared. It covers permission, purpose limitation, data minimization, accuracy, and accountability. Also addressed in the NDPA is the processing of sensitive personal information such as biometric data, health records, religious opinions, and political affiliations. To promote increased privacy protection, it imposes additional rules for the management of sensitive data.

Section 24(2) of the NDPA states that a data controller and data processor shall use appropriate technical and organizational measures to ensure confidentiality, integrity, and availability of personal data while Section 29(1)(c) provides that where a data controller engages the services of a data processor, the data controller shall ensure that the engaged data processor implements appropriate technical and organizational measures to ensure the integrity and confidentiality of personal data. Section 30(1)(g) and Section 65 together, it becomes clear that the handling of sensitive data, which includes information like an individual's genetic and biometric data for unique identification, details about a person's race or ethnic origin, or data about an individual's health status, should only occur for medical care or community welfare purposes. Moreover, this processing should be conducted by or under the supervision of a professional or a similar service provider who is bound by confidentiality obligations, among other specified exceptions.

In addition, Section 39(1) of the NDPA provides that a data controller and data processor shall implement appropriate technical and organizational measures to ensure the security, integri-

ty, and confidentiality of personal data in its possession or under its control, including protections against accidental or unlawful destruction, loss, misuse, alteration, unauthorized disclosure, or access, taking into account the nature, degree, and likelihood of harm to a data subject that could result from the loss, disclosure, or other misuse of the personal data among others. This provision appears to permit the use of data for the development of AI algorithms if the data owner's consent is acquired. In this instance, appropriate and detailed safeguards of the fundamental rights, freedoms, and interests of the data subject must be provided for as stated by section 30(1)(h).

Although the NDPA in its section 39(2)(a) and (b) endorses pseudonymization and encryption of data, the possibility of re-identification despite data aggregation and removal of protected health information exists. There is also the likelihood that non-identifiable data elements will be combined to identify an individual. Pseudonymization is the process of substituting pseudonyms (artificial identities) for direct identifiers (such as names) in sensitive data. Personal identifiers are retained independently from the original data, which can still be connected back to individuals. This enables analysis and storage without jeopardizing privacy. In contrast, encryption changes plain text into a coded message, rendering data unreadable to unauthorized users. This prioritizes data security and safeguards against data breaches. (Kohlmayer et al., 2019, p. 2; Priyanka & Singh, 2023, p. 801). However, the level of awareness of the existence of these principles by AI creators and users in Nigeria is not ascertained.

Nonetheless, none of the laws seems explicit on what should be done precisely, or to what extent the rights and interests of data subjects should be protected. For instance, the Montreal Declaration for a Responsible Development of Artificial Intelligence (2018) establishes the principles that should govern the development of AI tools and defines specific terms used in the Declaration to ensure consistency in understanding. Although Nigerian laws also have interpretation sections where expres-

sions used in the laws were defined, the principles stated under the laws were general and may not adequately address privacy issues arising from the use of AI. The reason for this is not farfetched: the laws were not enacted with AI or patient safety in contemplation and inferences are being drawn only from the requirements of the laws for data privacy, confidentiality, and security. Thus, a legislation that is specifically tailored towards the use of AI in health will be more appropriate.

IV. THE IMPLICATIONS OF EXISTING FRAMEWORKS ON THE DEPLOYMENT OF AI

Although several laws impact patient safety, it is doubtful whether these laws are sufficient to effectively address issues concerning the use of AI technologies for the advancement of patient safety. This is because AI and its implications for patient safety were not taken into consideration when these laws were enacted. For instance, Section 5 of the National Agency for Food and Drug Administration and Control Act (NAFDAC Act) states that the Act was enacted to control and oversee, among other things, the production, sale, use, exportation, and importation, of medical equipment as well as ensure compliance with standard specifications, determine product suitability, make pronouncements regarding product quality, and seize or destroy unregistered and counterfeit products. Looking through the provisions of the Act, it is unclear whether the terms 'products' and 'medical devices' include AI devices.

Similarly, the Food, Drugs, and Related Products (Registration, Etc.) states that, on the one hand, before a medical device can be manufactured, advertised, imported, exported, distributed, or sold in the country, it must be registered in accordance with the Act's provisions. A permit, on the other hand, can be granted for the manufacture or importation of a drug, drug product, medical device, or cosmetic for the purpose of carrying out clinical trials or registration. Section 4 of the Act states that reg-

istration under this Act may be canceled or suspended if, among other things, the prescribed standard of efficacy, safety, or quality is not met. The suspension or cancellation of registration must be published in the Gazette, and the product must be removed from the market. In this case, it is also unclear whether AI devices are covered by the term ‘medical devices’.

According to Section 17 of the Federal Competition and Consumer Protection Act (FCCPA) of 2018, the FCCPA was enacted to make sure that fair, effective, and competitive markets are developed and promoted in the Nigerian economy. This will make it easier for everyone to get access to safe products and ensure that all consumers' rights are protected. While Sections 1 and 3 of the Standards Organisation of Nigeria Act (SON) states that the Act was passed to ensure high product standards, one of the main purposes of the Act according to section 5 and 17 is to protect and advance the interests of consumers by removing unsafe and subpar goods from the market and requiring offenders to replace such products with safer ones. Similar to the NAFDAC Act, it is uncertain if AI devices fall under the definition of ‘products’ under both Acts.

The challenge with this series of uncertainty is that it is not clear to what extent these laws apply to hold AI firms in the Nigerian health sector accountable in the instances of a breach. According to the U.S. Food and Drug Administration, AI software used for the treatment, diagnosis cure, mitigation, or prevention of disease or other conditions is considered to be a medical device classified as Software as a Medical Device (SaMD) (Pew, 2021, p. 5; FDA, 2019, p. 2). In addition, the UK Medicines & Healthcare Products Regulatory Agency also classifies AI technologies used in healthcare as medical devices (MHRA, 2023).

Section 31 of the NAFDAC Act defines ‘medical device’ as any instrument, apparatus, or contrivance (including components, parts, and accessories thereof) manufactured, sold, or advertised for internal or external use in the diagnosis, treatment, mitigation, or prevention of any disease, disorder, abnormal physical

state or the symptom thereof, in man or animal. Flowing from the position in the United Kingdom and the United States and from the wording of Section 31 of the NAFDAC Act, it should be safe to presume that AI technologies should be governed by the provisions of the NAFDAC law. However, it will be clear if this is specifically included in the laws so as not to give room for any ambiguity or vagueness.

PBoR (2018) which is a collection of patients' rights, goals, and expectations during treatments as well as the Nigerian Code of Medical Ethics (2004) also have implications for the deployment of AI to advance patient safety. The PBoR (2018) provides for the rights of patients to access information and the right to fully participate in implementing the treatment plan and making decisions. The PBoR also provides that privacy and confidentiality of all information and medical records is vital unless disclosure is in the interest of public health and in accordance with prevailing law.

The Nigerian Code of Medical Ethics also provides in Rule 9(i) that practitioners should always strive to improve their medical knowledge and skill, and practice according to accepted scientific principles in rendering care to patients. In addition, Rule 28 of the Code provides that physicians should upgrade their skills as best as possible in the light of advancing knowledge in the profession because medicine must be practiced with acceptable standards, decorum, and methods; Rule 32 states that physicians should know their limitations in terms of skills and facilities while Rule 41(a) provides that physicians should be willing to refer patients to better skilled or equipped colleagues or hospitals.

While it appears that the above-mentioned laws do not cover the use of AI to promote patient safety and healthcare quality, the nation has taken steps towards the development of a governance framework for the proper and effective operation of AI technologies in the country. The National Centre for Artificial Intelligence and Robotics was established to foster research and

development on emerging technologies, as well as their practical application in areas of national relevance to Nigeria, including healthcare (Obianyo & Ater, 2022, pp. 59-60). In addition, the National Information Technology Development Agency (NITDA) is currently developing a National Artificial Intelligence Policy (NAIP) to maximize the benefits, mitigate potential risks, and address some of the complexities associated with using AI in daily activities (Isaac, 2022). Hopefully, the policy will take into account the ramifications of AI-powered healthcare (Obianyo & Ater, 2022, pp. 59-60). It is essential to strike a balance between the advantages of AI-driven advancements in patient safety and the protection of confidentiality, privacy, data security, and patient autonomy, and doing so will be made possible by a robust legal and governance framework.

An analysis of Nigerian health laws in light of the legal and ethical issues involved in deploying AI for the advancement of patient safety in the country reveals that the laws are insufficient to effectively address issues concerning the use of AI in healthcare, particularly for the advancement of patient safety. This is because AI and its implications for patient safety were not taken into account when these laws were enacted.

V. RECOMMENDATIONS

Considering the identified legal and ethical ramifications of the use of AI in promoting patient safety, it is important to ensure that there is inclusion and adequate representation of data in developing AI algorithms so that data will be representative, transparent, and equitable. This will address the issue of bias and discrimination that is likely to arise from underrepresentation of data. Hence, developers should ensure the principles of diversity and inclusion are taken into consideration when AI algorithms are being developed.

To effectively address the critical concern of data disparity which may influence or lead to algorithmic bias, close monitoring

and oversight of the development and application of AI systems in the Nigerian healthcare sector is imperative. When collecting and labeling training datasets, healthcare organizations, and policymakers must prioritize diversity and inclusivity. It is important to frequently keep the disadvantaged populations in mind and seek to protect them so they can receive better care. This should be done by establishing a standard in the algorithm that favors the underprivileged. To that purpose, developers or teams building AI algorithms should be clearly aware of the unique characteristics of the health system and environment for which they are creating algorithms, taking into account the varying demands of various populations. They must make sure that the data used to train AI algorithms is inclusive and reflective of the population in terms of gender, socioeconomic status, location, and ethnicity. This will aid in the reduction of bias in AI systems. In addition, rigorous data preprocessing techniques should be used to identify and correct biases in training data. This may entail cleaning data, quantifying the bias, and removing any discriminating qualities.

Furthermore, regulators must continually monitor, evaluate, and audit AI algorithms in order to detect and correct any biases that may occur during their deployment. All stakeholders, including clinicians, must also acquire the necessary AI skills. Clinicians' comprehensive knowledge of the clinical setting will be very beneficial when they are part of the team that creates, oversees, and assesses AI algorithms. Although it may be challenging to find AI experts in Nigeria, groups like Data Science Nigeria, Datalab Nigeria, Robotics and Artificial Intelligence in Nigeria (R.A.I.N), etc. are already providing opportunities for training to Nigerians interested in learning AI capabilities.

The government should invest as well as encourage organizations to invest in enhancing digital infrastructure and internet access, particularly in rural and remote areas. This is because the development of affordable and accessible telehealth services to extend healthcare delivery to remote regions, and support for

initiatives to improve digital literacy and skills among underserved populations are all crucial to reducing the risk of widening disparities, especially in Nigeria's underserved regions. Due to the continuous difficulty in reducing bias in AI systems, future research on bias detection and correction methods tailored to the Nigerian healthcare context should be prioritized. The government, in its capacity as regulator, should ensure that routine checks of AI systems for fairness and transparency are carried out. The government should also ensure that mechanisms for corrective action are put in place. Institutions such as NITDA are best placed to assist with this routine check. Engagement with international organizations and experts to share knowledge on bias mitigation should also be taken into account.

Establishing an equilibrium between protecting the privacy and security of patient information while still advancing patient safety research is vital. This issue cannot be ignored because privacy is a constitutional right that must be safeguarded, and the advancement of patient safety is likewise a worthy goal. This aligns with Rigby's position that the advantages and disadvantages of AI technology must be addressed and balanced before AI devices are put to use (Rigby, 2019, p. 122). While employing AI tools for the promotion of patient safety is in the patients' best interest, healthcare practitioners should ensure that a fair and appropriate balance is struck between safeguarding patient privacy and data security on one hand and ensuring patient safety on the other since technology is developing more rapidly than the law.

It is important to note that AI can be used to influence patient safety positively if it is integrated into healthcare processes and its use is implemented and interpreted by healthcare practitioners. Bearing in mind that AI is still in its infancy and some of its long-term implications are unknown (Spatharou et al., 2020). AI should be a complementary tool and never a replacement for professional clinical judgment. AI tools should also be used as a complementary tool to avoid bias because it is usually unable to

capture some contextual information such as patients' nonverbal gestures and this is a great limitation that could lead to the occurrence of error.

To effectively address the legal and ethical implications of deploying AI to promote patient safety and improve healthcare, a legal and governance framework is required. Without an accurate governance framework, AI in healthcare will not be what it is hoped to be. Instead of advancing patient safety, it will further threaten it. Unfortunately, Section 3(2)(b), the Nigeria Data Protection Act which is the most current, relevant, crucial, and comprehensive single legislative instrument on data protection in the country, tows the path of the National Data Protection Regulation and expressly exclude the use of personal data in furtherance of public health from its coverage. The law should be amended to include the use of personal data in furtherance of public health. Alternatively, a law should be enacted to specifically cater to the use of AI in healthcare. There is therefore a need for a governance framework that adequately addresses evolving legal and ethical challenges. The framework should include novel and improved data laws that address the gaps in the current laws in an innovative and multidisciplinary manner.

VI. CONCLUSION

Leveraging AI in healthcare has great potential for advancing patient safety. AI has the ability to enhance collaboration, analyze huge amounts of data seamlessly, and help patients to be better looped into their care. Specifically, AI applications can be used to minimize the incidence of harm. However, AI also has the potential to promote bias and discrimination, as well as undermine privacy and confidentiality.

As analyzed above, Nigerians experience inequities as far as healthcare is concerned. These inequities are already complicated by several complex challenges including limited healthcare

resources. In addition to this, algorithmic bias perpetuates the biases and discrimination existing in the data used for training the AI. Although the Constitution and other applicable laws prohibit discrimination, the laws seem ill-equipped to address bias and inequity arising from the use of AI in healthcare.

The Constitution protects privacy in its section 37 and the courts, have in some cases, interpreted the right to privacy in an inclusive manner. However, the Nigeria Data Protection Act, the overarching statute on data protection in the country excludes the use of personal data in furtherance of public health from its coverage. This contradicts the comprehensive interpretation given by the courts. To avoid contradictions, vagueness, and ambiguity, it is important to have specific legislation to cater to the inadequacies inherent in the existing laws.

Therefore, in order to address the difficulties peculiar to AI and make sure they are in line with societal norms, the authors recommend that healthcare regulations be routinely reviewed and updated. Additionally, precise guidelines and principles for the use of AI in healthcare should be created, along with strict data protection and security laws. These guidelines should include the principles of fairness, transparency, and accountability. Also, interdisciplinary collaboration between ethicists, data scientists, and healthcare professionals should be promoted as this will enhance the development of comprehensive ethical guidelines.

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