

Legal frameworks for the development of digital healthcare in Africa: current situation and future outlook

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ABSTRACT

There has been a recent push for digital health services among African health players. Because of this, we need to look at how legal processes play a part in the medical industry's digital revolution. In an effort to delve into this function, the paper employs an analytical technique to diagnose the African legal reality. The article also identifies Africa's digital capabilities using statistics from the International Telecommunication Union. The study's conclusions focused on the fact that Africa does not yet have a legislative framework in place to regulate blockchain and artificial intelligence, two key technologies necessary for the digitalisation of the health industry. It is possible for African states to clarify healthcare AI legislation and include new texts about smart contracts into civil law.

KEYWORDS: Digital transformation; legal mechanisms; healthcare; blockchain; electronic patients' data records; Africa

Introduction

The quality of health care has become the focus of public and private sectors, as digital transformation has become a tool to achieve that goal, especially since digitization contributes to reducing costs while doubling efficiency and productivity (Abdolkhani et al., 2022). One fact that can be stated is that technology creators are those who have integrated modern technologies, introducing them to healthcare users, resulting in amazing results for them. This is evident in the area of patient test results management, where the use of electronic records enables rapid and accurate diagnosis and treatment planning (Hoerbst & Ammenwerth, 2010). In addition, modern technology contributes to the provision of remote health services, including diagnosis and monitoring. This has made health services available to people located in remote and isolated areas, and also has made it easy for doctors and health care providers to exchange medical records (Craig & Patterson, 2005). The uses of artificial intelligence have also spread in the field of data analysis. This helps to identify trends and patterns by analyzing patient data, and contributes to determining effective treatment plans (Panch et al., 2019).

It is necessary to point out that the digital

transformation of health services in Africa has become inevitable, but this digital transformation must be accompanied by legal mechanisms, as they play a pivotal and indispensable role in protecting patients' rights. Thus, legal mechanisms ensure the digital transformation process in a responsible and secure manner (Sibuyi et al., 2022).

There are several important branches of law that apply to the digitization of the health sector (Mattsson, 2016). First, personal data protection laws play an important role (Ferraud-Ciandet, 2010; Sarabdeen & Mohamed Ishak, 2024). Moreover, intellectual property protection laws intervene to protect digital medical innovations, as do the provisions of the Civil Law that regulate the liability provisions of doctors. These laws determine the civil liability of the doctor and technology systems used in treatment in the event of harm to the patient (Andoulsi & Wilson, 2012). Last but not least, consumer protection laws protect patients as parties to a contractual relationship with health institutions (Herveg, 2006).

The article aims to discuss a scientific gap related to the role of legal mechanisms for digital transformation of digital services in Africa. It is noted that there is no research on the subject, and therefore it is necessary to clarify the legal aspects of digital transformation, as the legal framework determines the role of digital policies. This same framework also plays a role in protecting and encouraging innovation. In addition, the legal aspect represents an effective protection tool to ensure patients' rights and privacy in the digital transformations of the health sector. Such rights are threatened by the increasing use of electronic medical records and blockchain technologies, and the accompanying legal and ethical concerns. Regional international organizations have sought to modernize their laws, as we point out that at the European Union level (Farouk & Alsamara, 2023), there are very advanced texts in the field of digital services, and they apply to digital transformation in the health sector. An example of this is European Union Regulation 'No. (2022/2065)' issued by the European Parliament and the Council on 19 October 2022 regarding the single market for digital services, where it was amended. There is also Directive (2000/31/EC) which bears the name Digital

Services Regulation (Gillet, 2023). Our article aims to examine the efforts of the African Union in this field. In addition, the article aims to identify the obstacles facing the digital transformation of health services in Africa, which vary between technical, financial, and cultural difficulties. The article then attempts to identify legal methods to confront these obstacles.

Literature review

'To Wallet or Not to Wallet: The Debate over Digital Health Information Storage' (Karacic Zanetti & Nunes, 2023) by Karacic and Rui is worth reading because it stresses the significance of considering and solving the ethical problems that may arise from digital health technology. Among the possible advantages of health wallets are the following: the capacity to undertake research to enhance current treatments and interventions; the creation of personalised medicine via comprehensive data collection; and the elimination of medical mistakes through centralised information.

Townsend's thesis, which examines the regulatory frameworks governing privacy and data protection in the effective implementation of electronic health care in Africa, is a significant contribution to the field of eHealth in Africa. The study asks whether reform and greater regional collaboration in regulatory policy-making are necessary. After introducing medical service applications, the author discussed data privacy, outlined the relevant legal framework in South Africa and Africa, and concluded with a critical analysis of the Malabo Convention on the Protection of Personal Data. Ethical implementation of digital technologies, the author argues, necessitates not just user trust but also consideration of cultural variations. Ethical restraints, efficient legal laws and mechanisms, and operational imperatives are the three pillars upon which the author lays the responsibility for this technology's appropriate use.

The paper "Digital and Public Health in West Africa" by Diallo should also be consulted. (According to Diallo, 2021) In it, the author noted that the 2013–2016 Ebola epidemic helped bring attention to the significance of the health system, as several nations in the area stepped up to the plate to establish national plans for digital health, which included data regulation legislation. This research is important, but it can only include West African nations, therefore its applicability is restricted.

"How Can Digital Health Technologies Contribute to Sustainable Attainment of Universal Health Coverage in Africa?" is the title of the work by Olu et al. In 'A Perspective' (Olu et al., 2019), the authors highlight several challenges that African countries face when it comes to digital health. These include a lack of understanding and understanding of digital health, inadequate health

systems, unstable power supplies, slow internet connections, and an absence of internet interoperability.

Methods

In order to explain the relevant legal processes, the essay employs a scientific technique known as the descriptive approach. Additionally, it examines the legal texts pertaining to digital health in Africa, such as legislation safeguarding personal data and legal considerations pertaining to digital health records, using an analytical method. Furthermore, the essay delves into the status of ICT in Africa using statistics sourced from the International Telecommunication Union (ITU). When it comes to matters of information and communication technology, such as telephones and Internet connectivity, the United Nations specialised agency known as the International Telecommunication Union (ITU) is the place to go.

Results and discussion

The state of digital transformation in healthcare in Africa

The potential of Africa in the field of digital transformation in health

In recent years, signs of telehealth services have appeared in Africa. This shows that the continent of Africa has good potential in the field of digital transformation, such as the rapid expansion of the use of phones, which improves access to health services in rural areas (Aranda-Jan et al., 2014). Despite this, the continent still faces great challenges. The use of mobile phones (Betjeman et al., 2013), electronic health records, and blockchain technologies are a beginning, but much remains yet to be done (Adetoyi & Raji, 2020).

Obstacles to the digital transformation in healthcare in Africa

The digital transformation of health in Africa faces many obstacles, including:

Low penetration rate of information and communication technologies (ICT). For circumstances beyond their control, people in these places are often unable to participate in digital health services. Efforts to increase the number of people on the continent who have access to reliable energy and the internet are one practical response to this problem. Using solar panels and other renewable energy initiatives to power health clinics and rural communities is one such example. Additionally, plans are afoot to increase internet connectivity via the deployment of wireless and satellite technology. When it comes to bringing digital change to Africa's healthcare system, these projects are crucial.

Since 3 G mobile networks have substantially enhanced connection in several regions of Africa, they are now an essential component in the digital health revolution of the continent. Clarke and Mars (2015) found that more

individuals would be able to access health-related resources, information, and services online if network coverage was higher. Health care providers in Africa can now access even the most remote areas, thanks to the proliferation of mobile health service applications made possible by the country's third-generation internet infrastructure (Mwangama et al., 2020). The proliferation of mobile health services is also attributable, in part, to the rise of electronic financial payment applications; and since it is well-known that electronic payment does not necessitate substantial means, patients can reap the benefits of these apps with nothing more than an internet-connected phone (Anta et al., 2009).

Coverage of at least one 3G mobile network in Africa from 2015 to 2022 is shown in Figure 1. Mobile phones have facilitated the dissemination of health information to many individuals, which has contributed to the advancements achieved in the digital transformation of the continent (Kamsu-Foguem & Foguem, 2014).

Figure 1 illustrates the potential for 3 G mobile network connection to the E health system. From 2005 to 2022, the cumulative number of mobile-cellular telephone subscribers is shown in Figure 2. The number of people who stand to gain from health care digitisation is shown in the figure. Figure 3 displays the annual growth rate (in millions) of internet users in Africa from 2005 to 2022.

Missing pool of skilled workers. One of the biggest problems with digital health solutions in Africa is the absence of trained personnel to use them. This is in addition to the overall problem of a lack of healthcare professionals in the area. Digital health solution developers, implementers, and maintainers are an even more scarce breed. Numerous programs in Africa are aiming to create and educate a competent digital health workforce in order to meet this problem (Kimaro, 2006). In order to discover and create digital health solutions, the corporate sector, universities, and government agencies work together.

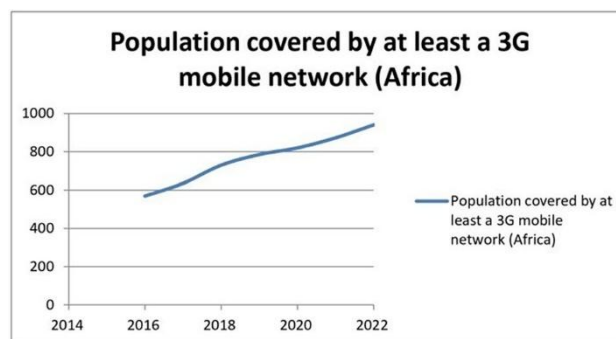


Figure 1. Prepared by the authors based on ITU data (International Telecommunication Union, n.d.).

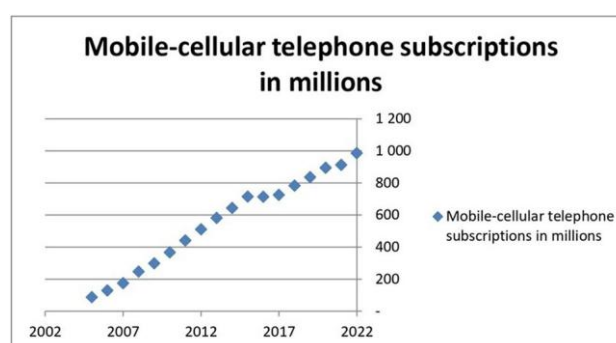


Figure 2. prepared by the author based on ITU data (International Telecommunication Union, n.d.).

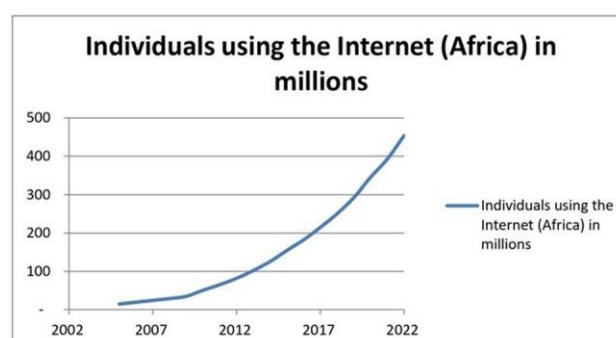


Figure 3. Prepared by the authors based on ITU data (International Telecommunication Union, n.d.).

talent in Africa. It is essential to improve working conditions by providing competitive salaries and benefits and providing opportunities for career advancement. This helps attract and retain healthcare workers in the region, including those with the necessary digital health skills and experience (Mechael, 2009).

State of legal mechanism in healthcare digital transformation in Africa

Data protection laws

One of the fundamental human rights guarantied by the International Covenant on Civil and Political Rights is the right to personal privacy, included in Article 17. Building on this foundation, laws at the state level

Table 1. Examples of African data protection regulations.

African Union		
	African Union Convention on Cyber Security and Personal Data Protection (2014)	
South Africa	Protection of Personal Information Act (POPIA) 2013	Data Protection Law 2018
	Nigeria	Data Protection Regulation 2019
	Egypt	Data Protection Law 2020 Nienaber et al., 2024; Leghari et al., 2024.

European Parliament and the Council of 27 (April 2016) on the protection of individuals with regard to the processing of personal data and the free movement of this data. Article 11 of the African Convention includes an obligation on African member states to form national authorities tasked with protecting personal data. Furthermore, Article 13 also included the principles that apply to the processing of digital personal data in the health sector, which are as follows: the principle of consent in processing personal data, the principle of legality, the principle of goal restriction, the principle of accuracy, the principle of transparency, and the principle of confidentiality and security. Article 19 of the agreement also includes the right of people to delete and change personal data.

In Nigeria we find three texts to regulate personal data in the medical field. The first is the Health Law of 2014, a law that requires hospital institutions to protect patients' medical records. The second is a data protection law that was introduced in Nigeria in 2019. This law sets rules for collecting and storing personal data (Akintola & Akinpelu, 2021). The law requires organizations that collect and process personal data to obtain the consent of individuals and implement appropriate security measures to protect the data (Udoh & Olajide, 2021). The third relates to cybercrimes, as it includes measures to suppress and punish this type of crime and places an obligation on financial institutions to protect personal data. In South Africa the Personal Information Protection Law was issued in 2013, setting new conditions in the field of personal data. It establishes responsibilities towards institutions that work in the field of personal data management, and it plays a fundamental role in protecting personal data in the

started to set legal standards to safeguard people's right to privacy by preventing unauthorised access to their personal information. The significance of these rules grew as the number of digital activities rose. According to Paul et al. (2023), patients' medical records are now subject to regulations that safeguard personal data.

Some examples of data protection treaties and regulations in Africa are included in Table 1: Our reference here should be the African Union Convention on the Protection of Personal Information and Cybersecurity. The treaty establishes guidelines for the safeguarding of individual data, which including medical records (Ball, 2017). In many ways, it mirrors the data protection system in Europe, including EU Regulation No. (2016/679).

health field. It established the principles of personal data management, centered on responsibility, transparency, and patient consent (Staunton et al., 2020).

In Algerian law, legal provisions relating to the protection of personal data have been in effect since 10 August 2023. The law includes the establishment of the National Authority for the Protection of Personal Data. The National Authority ensures respect for human dignity and the right to privacy during the process of processing data of a personal nature. It provides consultations to persons and entities who are involved with processing personal data or who conduct studies or experiments that are of a nature to lead to such processing. The National Authority also receives protests, grievances and complaints related to the processing of personal data, and informs those submitting them of their results. When it comes to rules of conduct and ethics governing the processing of personal data, this law is considered among the most advanced legislation in this field.

Egypt issued a Personal Data Protection Law in 2020. This law, in turn, established the Personal Data Protection Center, where this center is responsible for setting general policies in the field of personal data, as well as receiving reports related to personal data violations and issuing decisions regarding them (Abdou, 2023).

Intellectual property laws

Intellectual property protection laws are particularly important in the process of digital transformation in the field of health services. This transformation requires creativity and invention initiatives, as protecting rights to privacy in these critical areas is indispensable (Kudlinski,

2013). Some basic protections are already in place. For example, if someone illegally copies a copyrighted work and sells it on the market without permission from the copyright owner, that person may be liable for damages to the copyright owner (Nicholson, 2006). Existing protections still need to be expanded to meet new developments in the field of electronic health services.

Lack in EHealth legal regulation

We note that there are no explicit laws in Africa dedicated to digital health and digital health services. For example when it comes to smart contracts in the medical field, they are fast contracts and are characterized by not needing an intermediary. Hence, there are problems in the legal framework for this type of contract. The 27th (April 2016) on the safeguarding of personal data processing and the free flow of this data, published by the European Parliament and the Council. African member nations are obligated to establish national authorities responsible for data protection under Article 11 of the African Convention. The following principles are included in Article 13 and apply to the processing of digital personal data in the health sector: confidentiality and security, accuracy, openness, purpose limitation, authorisation, legality, and processing personal data with consent. Individuals have the right to access, amend, or delete their personal data as outlined in Article 19 of the agreement. There are three codes of conduct in Nigeria that govern the handling of sensitive patient information. The first is the Health Law of 2014, which mandates the security of patients' medical information and makes it a requirement for hospitals to comply. Second, in 2019, Nigeria passed a legislation protecting personal information. Akintola and Akinpelu (2021) state that this legislation establishes regulations for the gathering and preservation of personal data. Organisations that handle personal information must get people's permission before doing so and must also put safeguards in place to keep the information safe (Udoh & Olajide, 2021). The third one is about cybercrimes; it mandates that financial institutions safeguard customer data and provides methods to penalise and reduce cybercrime. New regulations pertaining to personal data were introduced in 2013 by the South African government in the form of the Personal Information Protection Law. It is crucial in preserving personal health information and sets forth duties for organisations involved in personal data management. It laid up the ground rules for managing personal data, which revolve on accountability, openness, and obtaining patients' permission (Staunton et al., 2020). Starting from 10 August 2023, personal data protection laws in Algeria went into force. One provision of this legislation is the creation of the National Data Protection Authority. When handling personally identifiable information, the National Authority always keeps people's dignity and privacy

rights in mind. It offers consulting to individuals and organisations who handle personal data or undertake research that might result in such handling. Data processing-related protests, grievances, and complaints are also received by the National Authority, which notifies the individuals who lodged them of the outcomes. This law is among the most progressive statutes pertaining to standards of behaviour and ethics controlling the use of personal data.

Egypt passed a law protecting individuals' privacy in 2020. In turn, this legislation created the Personal Data Protection Center, which is in charge of receiving complaints of personal data infractions, making judgements on such reports, and formulating general regulations in the area of personal data (Abdou, 2023).

Rules governing intellectual property

When it comes to health care's digital transition, intellectual property protection rules are crucial. Due to the fundamental importance of safeguarding individuals' right to privacy in various domains, this transition necessitates innovative thinking and new product development (Kudlinski, 2013). A few fundamental safeguards have been established. One example is the potential liability of those who make unauthorised copies of copyrighted works and then sell them without the owner's consent (Nicholson, 2006). Advances in electronic health services need further strengthening of current safeguards.

Regulating electronic health care is lacking

It has come to our attention that no specific legislation in Africa addresses digital health or digital health services. When it comes to healthcare, for instance, smart contracts are known for being quick and characterised by not requiring a middleman. Therefore, the legal structure for such a contract is flawed. Using blockchain technology in healthcare also raises the same problem. The lack of a defined legislative framework belies the security and transparency that characterise this technology (Namara et al., 2018).

Healthcare providers may greatly benefit from using smart contracts. Manual tasks like patient registration, insurance verification, and payment processing may be automated with its help. According to Article 1174 of the French Civil Code, an electronic contract must adhere to the electronic mode of creation. Under the circumstances as forth in Articles 1366 and 1367, as well as in cases when an official document is also necessary, a contract that is written and kept electronically may be legal (Cornelius, 2018).

A growing number of healthcare organisations are embracing blockchain technology (Tang et al., 2022). Having clear regulations around blockchain helps to alleviate some of the problems and ambiguities that come with its implementation

(Faneela et al., 2023). Private sector health practitioners may also help shape this technology by creating industry-specific professional charters (Khatoun, 2020).

Recent years have been a rise in the use of AI to healthcare (Albakjaji & Almarzouqi, 2024). Since no legal texts comparable to those produced at the EU level or to be issued in the near future exist in Africa, we have noticed the lack of laws governing this emerging industry (Pesapane et al., 2018). It is expected that Africa would provide strong support and develop its skills in the area of artificial intelligence in healthcare, since many African nations do not have the necessary infrastructure or trained personnel to enforce AI regulations (Wang et al., 2022). As a consequence, laws need to define the legal culpability for harm produced by AI in the medical industry as a result of software mistake (Alsamara & Ghazi, 2024).

Conclusion

Last but not least, we should highlight a few critical takeaways from the research. To guarantee the ethical deployment of digital healthcare technologies in Africa, legislative frameworks are crucial. A legislative framework pertaining to Blockchain technology and artificial intelligence in healthcare is being requested from the African Union. An Ehealth legislative framework is required on a national level.

We highlight the lack of data from an African source on the realities of health sector digitisation under the study's Limitations section. As a result, African nations are requesting that their international organisations back and promote their initiatives. Finally, it is difficult to make strong conclusions due to the lack of data on the implementation and effect of legislative procedures for digital healthcare transformation in Africa. Overall, however, we can see the broad strokes of several tendencies. How the rule of law affects Africa's digital health system might be the subject of future studies.

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