



The legal and regulatory framework for digital health in Algeria

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Abstract:

The health sector in the country is experiencing rapid changes as a result of the adoption of digital technologies. This has contributed to improving the quality of health services and facilitating access to them. However, this development poses challenges related to protecting health data and ensuring its confidentiality, which raises the need for an effective legal and regulatory framework that frames the use of digital health data.

The importance of this study lies in highlighting the role of the legal and regulatory system in achieving a balance between digital transformation and safeguarding the privacy of individuals. This study concluded that the development of this framework is an imperative necessity to enhance the security of health data, ensure the continuity of digital services and keep pace with technological development in the health sector in Algeria.

Keywords: digital health, legal and regulatory framework.

ملخص:

يشهد القطاع الصحي في البلاد تغيرات سريعة نتيجة اعتماد التقنيات الرقمية. وقد ساهم ذلك في تحسين جودة الخدمات الصحية وتسهيل الوصول إليها. ومع ذلك، فإن هذا التطور يفرض تحديات تتعلق بحماية البيانات الصحية وضمان سريتها، مما يثير الحاجة إلى إطار قانوني وتنظيمي فعال يوطر استخدام البيانات الصحية الرقمية.

وتكمن أهمية هذه الدراسة في تسليط الضوء على دور النظام القانوني والتنظيمي في تحقيق التوازن بين التحول الرقمي وحماية خصوصية الأفراد. وخلصت هذه الدراسة إلى أن تطوير هذا الإطار ضرورة

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حتمية لتعزيز أمن البيانات الصحية وضمان استمرارية الخدمات الرقمية ومواكبة التطور التكنولوجي في القطاع الصحي في الجزائر

الكلمات المفتاحية: الصحة الرقمية، الإطار القانوني والتنظيمي

Introduction :

Today, many sectors and organizations are witnessing rapid changes and developments in various fields, perhaps the most prominent of which is the significant expansion in the use of modern technologies, as most sectors and organizations have moved to the number of their services because of their positive impact on the achievement of performance and the facilitation of methods of health in general, and in this context, digital health has become one of the most important areas affected by this transformation, as the digital health has become a strategic ground for modernizing the health organization and enhancing its efficiency.

However, this transformation cannot achieve its desired objectives without the existence of a solid legal and regulatory framework that accompanies and frames it, as this framework constitutes the cornerstone in ensuring the effective functioning of digital technologies. In this context, Algeria has sought to devote this approach to the development of its legal and regulatory system to ensure the protection of sensitive health data, the identification of responsibilities, and the organization of collecting, storing and exchanging them. This also contributes to increasing trust among various actors, especially patients and health service providers, which supports the sustainability of this digital transformation. Therefore, the importance of studying the legal and regulatory framework and the security of digital health data is highlighted as one of the main determinants of the success of the digital health path in Algeria .

Problematic:

The health sector is witnessing blind transformations due to technological progress, which led to the emergence of the concept of digital health as a tool to improve the quality of services and enhance the efficiency of health systems. The success of this transformation depends on the existence of a legal and regulatory framework that keeps pace with these developments and ensures the protection of health data and the regulation of the use of technology. In Algeria, a trend towards digitization of the health sector has emerged, but the effectiveness of this path remains linked to the integration and appropriateness of the legal and regulatory system. Hence, the need to ask about the extent to which this framework is able to keep pace with



the requirements of digital health.
How effective is the legal and regulatory system in Algeria in framing and developing digital health applications?

Sub-questions:

- What is digital health and what are its most important applications?
- What is the regulatory framework for digital health in Algeria?
- How effective is this framework in keeping pace with digital transformation in the health sector?
- What are the most prominent legal and regulatory challenges hindering the development of digital health in Algeria?

Sub-objectives:

- Clarify the concept of digital health and its most important applications in the neighborhood;
- Identify the components of the legal and regulatory framework regulating digital health in Algeria;
- Highlighting the role of legal actors in protecting health data and ensuring its security;
- Evaluation of the framework's response to technological developments in the health field;
- Diagnosing the legal and regulatory challenges that hinder the activation of digital health;
- Propose ways and mechanisms to develop the legal framework in line with the digital transformation in the health sector.

Methodology of the study :

The nature of this subject, which combines the legal and technological dimension, requires reliance on the descriptive analytical approach, as it is the most appropriate to study and analyze the legal and regulatory framework for digital health in Algeria. This approach is based on collecting data and information from various legal and scientific sources, including legislative and regulatory texts, previous studies and research, with the aim of describing the reality of digital health and analyzing the adequacy and effectiveness of the legal rules regulating it. This approach also allows explaining the various aspects related to the subject, diagnosing shortcomings, and submitting proposals that contribute to the



development of the legal framework in line with the requirements of digital transformation in the health sector.

Structure of the Study :

This study relies on addressing the subject of the legal and regulatory framework for digital health in Algeria through an integrated methodological plan. The first aspect dealt with the conceptual framework for digital health by defining its concept and distinguishing it from the concepts associated with it, highlighting its most important applications and importance. As for the second aspect, it was devoted to studying the reality of the legal and regulatory framework in Algeria, by presenting various texts and legislation framing digital health and analyzing its effectiveness in keeping pace with digital transformation. The third aspect dealt with the most prominent legal and regulatory challenges that hinder the embodiment of digital health while anticipating future prospects and proposing mechanisms to develop the legal framework in line with the requirements of digitization in the health sector in Algeria .

1-Digital Health Conceptual Framework:

1-1 Definition of Digital Health:

Digital health is defined as the use of contemporary digital technology to provide and improve health care services. That is, digital health is a set of digital technologies and electronic services aimed at improving health care and health management in an ideal way. This technology includes a wide range of tools and systems, such as medical devices connected to the Internet, health applications and electronic health record systems. (Al-Shuli, n.d.)

In its Strategy on Digital Health (2020-2025), who defines digital health as the use of digital technologies and data to enhance health outcomes, improve health system performance and enable individuals to make informed decisions about their health and well-being. It also emphasizes the principles of transparency, accessibility, scalability, replicability, privacy, security and confidentiality.

Through these two definitions, we find that the term digital health is an umbrella term that includes a variety of computer devices and electronic technologies. The term refers to digital technological uses that aim to improve and develop health at the level of the individual and society.

1-2 Digital Health Applications:



The components of digital health include several integrated systems, the most prominent of which are (Ben Jilali,2025, p. 119)

-Electronic record (EHR): It allows the patient's medical data to be stored in an orderly and secure manner, and is easily accessible by various health care providers, which enhances the accuracy of diagnosis and the speed of treatment decision making.

-Telemedicine: It is one of the vital applications for digital health, as it allows the provision of remote medical consultations, which reduces the need for mobility and relieves pressure on the infrastructure of hospitals.

-Smart wearable devices: such as biomarker tracking watches and glucose and blood pressure monitors, providing a continuous real-time monitor of patient health.

-Personal health apps: that contribute to health education and promote healthy lifestyles, through activity tracking, medication reminders, and nutrition and sleep guidelines.

1-3 Importance of Digital Health:

1-3-1 For Healthcare Organizations:

- Improving work efficiency: Digital transformation contributes to simplifying the procedures and meeting needs of relying on paper transactions, which leads to accelerating the processes of quota and enabling quick and accurate access to patient health data;
- Enhancing patient interaction: Online digital communication (such as video chats and interactive platforms) provides a more flexible and effective experience, and strengthens the relationship between the health service provider and the patient.
- Reduce operational costs: Process automation helps to deliver health services of higher quality and lower cost while reducing expenses associated with traditional methods;
- Establishing integrated health databases: digital transformation contributes to improving communication between medical personnel, which reflects positively on the accuracy of diagnosis and the speed of information exchange;

1-3-2 For Patients:

- **More accurate and specialized health services:** digital systems can support accurate diagnosis and provide appropriate treatments for each condition, improving the quality of health care;



- **Easy access to health information:** gives patients the ability to access and manage their medical records independently, enhancing their health awareness and participation in decision-making;
- **More convenient scheduling:** allows to choose the most convenient date for the visit and plan the future time
- **Tracking health metrics:** Important in real time using wearable digital health care devices.

2- Legal and regulatory frameworks for the digitization of the health sector in Algeria:

2-1 Legal frameworks regulating digital health in Algeria:

The success of practicing medical activities from digital health lies mainly in establishing trust relations between the main actors concerned (users, health professionals and suppliers of ICT services). This trust can only be obtained through the establishment of an appropriate legal and regulatory environment. In this field, the health sector in Algeria has witnessed a remarkable transformation due to technological development and digitization, which contributed to the emergence of the concept of "digital health" as a strategic tool to improve the quality of health services. This digital transformation, despite its promising opportunities, poses new legal challenges that require clear regulation. Among the most prominent legal texts that establish the regulation of digital health in Algeria, we mention the following:

2-1-1 Law No. 09-04:

Issued on 14 Sha 'ban 1430 corresponding to 5 August 2009, which contains the special rules for the prevention and control of crimes related to information and communication technology. The law also included in its fifth chapter (05) the establishment of the National Authority for the Prevention and Combating of Crimes Related to Information and Communication Technology. (Law 09-2009,04)

This law is one of the first texts that established the legal protection of information systems in Algeria, as it criminalized various electronic attacks that may target data and digital systems. Despite its importance in enhancing information security, it does not include provisions for the protection of digital health data or crimes related to telemedicine and electronic health records, which makes its contribution to the regulation of digital health an indirect contribution, and requires its



completion with specialized legislation that takes into account the privacy of the health sector.

2-1-2 Law No. 18- 07:

Issued on 25 Ramadan 1439 corresponding to 10 June 2018 related to the protection of natural persons in the processing of personal data, and this law referred in its content to the data related to the health field "as information related to the physical and/or mental apparatus of the person concerned, including his genetic data." (Law 18-2018,07)

This law forms the cornerstone for the protection of personal data in Algeria, where it has given health data legal protection as sensitive data that requires special conditions for processing. However, its provisions were general and did not address in detail the peculiarities of digital health data, such as regulating electronic health records or exchanging data between health institutions, which limits its effectiveness in keeping pace with the rapid development of digital health applications

2-1-3 Health Law No. 18-11:

In an attempt to keep pace with social, economic and health changes and transformations, a new health law was issued in 2018, under No. 18/11 dated July 02. This law deals with laying new foundations for the health system. Article (05) of the law states that "the national health system is based on a strong public sector."

In an attempt to establish a legal framework that guarantees the digitization of the health system, Section Six (06) of Chapter Three of Law No. 05-85 on Health allocates the emphasis on obliging all public and private health structures and institutions to join the National Health Information System (SNIS), which Article 319 defines as "a national health information system based on every current or future technology" (Mennad, Ziad, 2025, p. 232).

The Health Law is the basic legislative framework for regulating the health system in Algeria, and it has contributed to consolidating the trend towards digitization by providing for the establishment of the national health information system and the adoption of technological means in the management of the health sector. However, the law did not accurately regulate modern digital health applications, such as telemedicine, medical artificial intelligence, and the electronic medical file, which highlights the need to review its provisions in line with digital developments.



2-1-4 Presidential Decree 20- 05

dated January 20, 2020, which provides for the security of information systems, and also represents the regulatory framework for the preparation of the national strategy for the security of information systems. (Ben Mouloud,2024, p. 07)

This decree represents an important step in building a national cybersecurity system, as it aims to protect information systems from various cyber threats. It is important for digital health in providing protection for the digital infrastructure of health institutions. However, its provisions are of a general nature and do not include technical or organizational measures for the protection of health systems or medical data, which requires the issuance of more specialized sectoral regulations.

2-1-5 Executive Decree No. 22-251 of the National Agency for Digitalization in Health:

This agency was established for the purpose of reorganizing the public institution called the National Agency for Health Documentation. This agency (the National Agency for Digitization in Health) has adopted two processes to implement and follow up the national strategy for health in the development of digitization. Its main task is to develop a national health information system that ensures the digitization of health activities and encourages the exchange, security and confidentiality of health data between health professionals, structures, health institutions and users within respect for medical and professional confidentiality, among other things, the National Agency for Digitization in Health.

- Placing the digital hospital on a floor that enables the health professional to see the therapeutic course in real time in a safe manner;
- Developing a medical file that includes all data that encourages the exchange, sharing and security of data of a personal nature;
- Implementation of telemedicine and telemedicine;
- development and development of disease coding and occupational works;
- The land is lively;
- Digitization of the medical archive;
- Contribute to the design and preparation of legislative and regulatory measures. (Executive Decree 2022,251,22 Page 14)

The establishment of the National Agency for Digitization in Health is one of the most prominent institutional steps to embody digital transformation in the health



sector, as it was entrusted with the tasks of preparing and implementing the national strategy for digitization, completing the electronic medical file, developing telemedicine, and ensuring the security and confidentiality of health data. However, the success of this agency depends on the provision of the necessary human, technical and financial capabilities, as well as effective coordination with various health institutions

2-1-6 High Preservation of Digitization (HCN):

Established by Presidential Decree No. 314-23 in September, it is the supreme body responsible for leading digital transformation at the national level, including the health sector. Its objectives include developing digital infrastructure, improving digital governance, promoting the digital economy, and building an integrated digital society under the supervision of the President of the Republic.

The establishment of the High Governorate of Digitization represents a strategic direction for the state towards unifying digital transformation policies in various sectors, including the health sector. This body contributes to the development of the national vision for digitization and the coordination of major digital projects. However, the effectiveness of its intervention in the field of digital health remains linked to the extent of coordination with the Ministry of Health and the National Agency for Digitalization in Health, in addition to the need to develop clear mechanisms for follow-up and evaluation

2.3 Regulatory Framework for Health Digitization in Algeria:

Like many countries in the world, Algeria has witnessed an accelerated digital transformation that has affected all sectors, including the health sector, which was aimed at facilitating access to quality health service. However, this digital transformation requires a clear regulatory framework that includes health data security and preserves the privacy of patients, which Algeria has begun to develop and activate through a number of policies and strategies that frame the digitization of the health sector.

Algeria has adopted the national health strategy, and this was manifested through the development of the electronic health vision by identifying the priorities of health institutions and identifying capacities in order to develop future plans that contribute to the development of health services.

In the same context, Algeria has adopted a health strategy based on the vision of the World Health Organization, where the World Health Organization (WHO) urges Member States through the first item to: "Consider developing a long-term strategic plan for the development and implementation of e-health services in



various areas of the health sector, including living management, so that this plan includes an appropriate legal framework, appropriate infrastructure, and encourages partnerships between the public and private sectors" (Zidane, Ben Kadi,2023, p. 163)

As a first step to implement this vision, the World Health Organization has formulated a set of goals that should be reached at least by the end of 2025.

*Use digital technology efficiently, confidentially, equitably and sustainably.

*Employing artificial intelligence to simulate the processes of human intelligence, and interacting with it, as the diagnosis has become based on three-dimensional (3D) imaging

*The need to establish a national digital health ecosystem that is interoperable and means all types of digital information technology infrastructures, which are established at the national level involving health institutions and research laboratories at the level of university institutions, as well as patients. (Dabushi, Razak,2024, p. 606/607)

In order to improve relations between health professionals and the population, and to strengthen the medical research process in Algeria, five (05) strategic objectives have been identified for the formation of the National Strategy for Health Digitization, including the following:

*Strengthening the National Health Information System (SNIS) to contribute to the improvement of medical care and the development of research;

*Building the National Integrated Hospital Information System (SNIH) to enhance the common electronic file;

*Contribute to training and research in the health sector;

*Improve community information and awareness to contribute to epidemiological surveillance and disease control;

*Strengthening the management and governance of the health sector.

Algeria has been working on establishing infrastructure with the aim of accelerating the pace of digital transformation by:

* Work to connect all health structures to the Intranet, and establish an information network that included 225 health institutions across the country;

* Equipping some health units with automated media, fingerprint attendance recording devices and appointment ticketing devices.....etc);



* Digitizing radiology and laboratory services, relying on the internal network for transmission, and transferring the results of analysis and imaging to the treating doctor.

The follower of the efforts made by the Algerian public bodies aimed at promoting public health realizes that they are very much in harmony with the vision launched by the World Health Organization (WHO) on the future of digital health for the period between (2020-2025), as Algeria responded to the recommendations of the World Health Organization, by working to develop infrastructure in addition to adopting common applications that enable the use, exchange and benefit from big health data nationally and globally. (Dabushi, Razak,2024, p. 606)

3- Challenges of developing the legal and regulatory framework for digital health in Algeria:

The shift towards digital health is not limited to the development of infrastructure and technology or the formation of its users, but extends to a range of regulatory challenges, along with legal deficiencies that may hinder this path. These constraints can be classified into two main types.

3-1 Legal Obstacles:

The lack or weakness of legal frameworks governing health activities, most notably

3-1-1 Limited legislative rules in line with digital health:

The expansion of the use of information networks and the growth of information crime have led to the emergence of the need for modern legal frameworks to keep pace with this development, as well as considering traditional laws and adapting them to the new digital pattern to keep pace with the nature of emerging crimes, which has created a real barrier to digital health as one of the major challenges that must be addressed.

3-1-2 Absence of a reference legal framework regulating digital health:

Algeria continues to face difficulties in establishing a clear legal system that regulates the path of digital health, as a unified law has not yet been enacted that serves as a comprehensive reference that frames digital health and provides accurate legal solutions to the various challenges at hand.

3-1-3 The Problem of Determining Legal Liability:

The problem of determining legal liability is one of the most prominent legal challenges facing digital health, especially when remote medical errors or leakage of health data occur, as it is difficult to accurately determine liability between the service provider, the technical platform and the doctor.

Regulatory Hurdles:



Organizational obstacles are one of the main axes in the study of digital health, as they are related to the structure of the health system and how to organize it and coordinate the work of the various actors. In this context, the most important of these obstacles can be highlighted in the following:

3-2 Lack of planning and coordination at the central level:

There is no unified national vision or clear plan at the level of senior management to implement digital health programs, which leads to a lack of consistency and a multiplicity of scattered initiatives that lack harmony

3-2-1 Weak qualification of cadres:

Many health sector employees in Algeria lack the necessary training and experience to use digital systems, which makes the introduction of technology within health institutions complicated and sometimes met with resistance.

3-2-2 Scarcity of technical specialties within health institutions:

There are no specialized IT cadres within most health institutions and this is what fails to advance the digital health path.

3-2-3 Failure to activate the role of the media and communication:

National media is not invested in spreading awareness about the benefits of digital health, nor is it used as an effective means to educate employees and citizens about the importance of digital health

3-2-4 Poor monitoring and follow-up:

Weak monitoring and follow-up is a fundamental obstacle to the activation of the digital health system in Algeria, as it limits the effectiveness of the implementation of legislation and weakens the level of health data protection and the quality of health services.

3-2-5 Lack of e-culture (e-illiteracy):

This is one of the most prominent obstacles and challenges facing the digital health project in Algeria, where electronic, technological or information illiteracy indicates that a large percentage of society members are ignorant of modern technology and do not know how to deal with it and use it. This poses a problem in the inability of individuals to use digital health applications and media.

It is clear from the above that organizational obstacles are not only related to weak technical capabilities, but also extend to aspects of governance, coordination and strategic planning, which affects the effectiveness of the



application of digital health. Therefore, the success of digital transformation in the health sector requires the development of administrative organization mechanisms, the promotion of coordination between various actors, the unification of information systems, as well as investment in the formation of human resources and the improvement of digital infrastructure.

5. The future and prospects of digital health in Algeria:

Algeria, like the rest of the world, seeks to adopt a modern model in the conduct of its health affairs through a shift towards digitization as an effective way to improve the quality of health services and achieve speed and ease in health transactions.

Despite the initial steps that have been achieved in this field, the future of digital health in Algeria is still linked to a number of critical factors, including the development of digital infrastructure, the rehabilitation of the human resource, and the adaptation of the legal framework to the requirements of digital health. This opens the way for great opportunities to modernize the health sector and achieve the quality of health services.

The future prospects for digital health can be presented through the following points:

- Introducing new laws in line with technological development;
- Strengthening the cyber security and communications infrastructure;
- Strengthening coordination between health institutions and regulatory bodies;
- Strengthening digital governance within the health sector by improving coordination between health and administrative bodies;
- Adjusting the application paths of digital health services to ensure effectiveness, transparency and quality of performance.

Conclusion

At the end of this article, it is clear that the building of an integrated legal and regulatory framework for digital health in Algeria is no longer a secondary option, but rather a process imposed by rapid technological transformations. The study showed that the current legal system, despite containing some relevant texts, still suffers from deficiencies in specialization and failure to keep pace with digital development, especially with regard to framing modern applications such as electronic health records and telemedicine, due to the limited mechanisms to protect health data and poor coordination between various actors.



The results also showed that the effectiveness of this framework is not only related to the existence of texts, but also to the extent to which they are embodied in the field, which is confronted by a number of challenges, including the weakness of digital infrastructure and the lack of qualified competencies to keep pace with digital transformation in the health sector. Based on this, a number of recommendations emerge:

- The need to enact legislation on digital health that takes into account the privacy of health data;
- Establish a data protection regulator through the adoption of advanced information security standards;
- Development of applied regulatory texts related to digital health services;
- Enhancing coordination between the brain of the concerned sectors;
- Intensifying training and qualification programs for health cadres;
- Employing the best international experiences and expertise in the field of digital health and adapting them to suit national specificity.

Accordingly, the real bet lies in moving from the stage of theoretical framing to actual application, by adopting a comprehensive forward-looking vision that makes digital health a key element of health system reform, in order to ensure the achievement of an integrated, safe and sustainable digital health system that responds to the aspirations of society and improves the quality of health services.

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