Implications of the European Union's New Regulation on Artificial Intelligence (2024) on its Clinical Implementation

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Abstract

On March 13, 2024, the Parliament sanctioned the inaugural comprehensive artificial intelligence (AI) statute globally. The European Union deems the governance of this technology as crucial, in light of potential infringements upon fundamental rights and public freedoms, detrimental impacts on the environment, and the integrity of democratic frameworks. Conversely, the undeniable advances in the medical domain necessitate the regulation of such technology to bolster investments and research, thereby providing the requisite legal certainty for users/patients, professionals, enterprises, and investors.

The Regulation acknowledges the potential perils certain AI applications pose to fundamental rights, enacting prohibitions on practices such as biometric categorization, emotion recognition, and social scoring, among others. Nevertheless, the Regulation does not neglect the significance of medical research and, recognizing the imperative for support of new technologies and innovation, permits research with fewer constraints compared to the commercial use of AI algorithms in healthcare.

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ABSTRACT

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Keywords: Artificial Intelligence, Fundamental Rights, Medicine, Europe, European Union

1. Introduction

The integration of Artificial Intelligence (AI) systems into medical practice is anticipated to enhance healthcare efficiency, accuracy, and personalization. This includes everything from expedited and precise diagnostics to bespoke treatment regimens and chronic disease management. Instances of such advancements encompass intelligent real-time remote monitoring—Internet of Medical Things—of physiological constants and parameters such as blood pressure, oxygen saturation, blood glucose levels, heart rhythm, and beyond, laying the groundwork for reliable, objective telemedicine. Additionally, the detection of patterns in imaging or tabulated data, often in real-time through machine learning, and the potential of generative AI for information management and report generation are notable. Nevertheless, the swift progression of these technologies presents substantial challenges in terms of ethics, patient safety, data privacy, and civil and criminal accountability, thereby underscoring the pressing necessity for a robust and adaptive regulatory framework.

In this regard, the European Union (EU) has advanced with the proposed Regulation on Artificial Intelligence presented on April 21, 2021, and approved on March 13, 2024[1], which aims to establish a harmonized legal framework for the governance of AI. This framework emphasizes

safety, transparency, and the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union (CFREU), particularly democracy, the rule of law, environmental protection, and public freedoms, as well as fostering innovation. It is noteworthy that, with the adoption of this Regulation, the EU ensures the free transborder flow of AI-based goods and services, including healthcare services utilizing AI. Unless the Regulation imposes restrictions, member states are obliged to refrain from instituting them, thus guaranteeing free movement within the EU and the security of minimum standards predicated on safety.

This article scrutinizes the ramifications of the new European regulations on the clinical use of AI, with a particular focus on "high-risk systems." Through an exhaustive analysis of the regulatory proposal and its annexes, it delves into the consequences for developers, providers, and users of AI systems in the health sector. The requisite regulatory and operational shifts are discussed, assessing their potential impact on technological innovation and patient safety. Specifically, the paper pinpoints the principal challenges for the effective enactment of the regulation, including the necessity for regulatory clarity, the adaptability of AI systems, and the professional development of healthcare practitioners. Additionally, the article contemplates the future landscape for normative development in the realm of clinical AI, considering emerging trends and the evolution of AI technologies.

To this end, a methodological approach is adopted that amalgamates juridical-normative analysis, a review of specialized literature, and the examination of pertinent case studies. This approach will enable not only a profound understanding of the legal stipulations and their practical implications but also a critical evaluation of the proposed regulatory framework's capacity to confront the unique challenges posed by AI in the clinical domain.

Initially, the article will inspect the current legal framework of AI in Europe, establishing a baseline to comprehend the preexisting regulatory context. Subsequently, a thorough examination of the proposed AI Regulation will be undertaken, highlighting its structure, primary provisions, and, in particular, the classification and management of high-risk AI systems in the clinical arena. The potential impact of the new regulation on clinical practice will then be assessed, identifying both the opportunities it presents for healthcare enhancement and the challenges it poses for developers, providers, and end-users of health-related AI technologies. This examination will include a discussion on the practical and normative challenges for the effective implementation of the regulation, as well as reflections on future prospects and the need for the regulatory framework's continuous adaptation to technological evolution. In summary, the article aims to provide a comprehensive and critical overview of the new European regulation on the clinical use of AI, highlighting its significance, implications, and challenges from a legal perspective. With this, the paper seeks to contribute to the academic and professional debate on how to harmonize technological advancement in the healthcare sector with the protection of patients' rights and safety.

2. Current legal framework of Artificial Intelligence in Europe.

2.1. Brief review of existing legislation

The digitalization of society, and AI in particular, bestows tangible and significant benefits. With this understanding, the EU aims to bolster its sovereignty in this field and establish its own standards. To this end, the European Commission outlined the “Digital Decade of Europe” [2] program which includes specific targets and objectives for 2030. These encompass empowering healthcare professionals with digital competencies, reinforcing and sustaining digital infrastructures with a focus on security and efficacy, committing to the digital transformation of businesses—particularly in the healthcare sector—and digitalizing public services, among other initiatives.

The EU acknowledges that online platform economies, while vital communication channels for the market, also bear inherent risks. These risks are recognized and addressed through EU legislation on digital services, with the aim to ensure a level playing field for all digital enterprises, including those in the healthcare field, regardless of their size.

The contemporary legal framework of AI in Europe is characterized by its multifaceted nature, consisting of a network of regulatory instruments at both the EU and member state levels. This framework has evolved incrementally, responding to the emerging challenges posed by the swift progression of AI technologies. The following delineates the key components of this legal framework, highlighting their significance and application in the context of AI.

1. General Data Protection Regulation (GDPR)[3]. Although not specifically tailored for AI, the GDPR stands as a cornerstone of the legal framework that directly affects AI applications, particularly regarding personal data processing. The GDPR institutes fundamental principles such as data minimization, informed consent, and transparency, in addition to the right to explanation, which becomes particularly pertinent in the context of AI systems engaged in automated decision-making. An exemplar scenario could be the regulation of data movement between EU member and non-member countries. Since in many instances AI can only be trained or operationalized in cloud environments (e.g., big Large Language Models), the GDPR imposes significant considerations in tool design.
2. Directive on Security of Network and Information Systems [4] (NIS Directive). While focused on network and information system security, this directive has implications for AI in terms of ensuring the security and resilience of AI systems, especially those deemed essential for maintaining critical social and economic activities. Healthcare services are directly associated with so-called critical social activities.
3. Digital Markets Act [5] (DMA). With this regulation, the EU aims to curb unfair practices by companies that control access in the online economy. The DMA designates as "gatekeepers" those large digital platforms that act as gateways between professional users and consumers, a position which can effectively grant them the capacity to act as private regulators.
4. European Strategy on Artificial Intelligence. The European Commission has set forth a comprehensive strategy for the ethical development and deployment of AI, including establishing a European approach to excellence and trust in AI. While this strategy is not legally binding, it lays out guidelines and key objectives for future regulatory development in the field of AI, promoting an ethical and human-centric approach.
5. White Paper on Artificial Intelligence [6]. Released by the European Commission, this document proposes measures to foster the adoption of AI and address associated risks. Although also non-binding, the White Paper lays the groundwork for specific AI regulatory proposals, such as the April 2021 AI Regulation proposal.

6. National and Regional Legislations. Various member states have developed their own strategies and normative frameworks to regulate AI, addressing specific aspects such as ethics, privacy, security, and liability. These national legislations complement the EU legal framework and reflect the particularities and priorities of each member state.
7. Standardization and Certification Initiatives. At the European level, technical standardization initiatives and certification schemes are being developed to ensure the safety, transparency, and reliability of AI systems. These initiatives, although still in the process of definition, will play a crucial role in the effective implementation of the AI regulatory framework.

Collectively, this legal framework delineates the essential principles and guidelines for the implementation and utilization of AI in Europe, aiming to strike a balance between the promotion of technological innovation and the protection of fundamental rights and freedoms (FR&F), as well as the safety of citizens. The Artificial Intelligence Act, adopted on March 13, 2024, is situated within this context, striving to consolidate and expand the existing framework to specifically address the challenges and opportunities presented by AI.

2.2. Introduction to the European Union's Artificial Intelligence Act adopted on March 13th, 2024

The proposal for the Artificial Intelligence Act presented by the European Commission on April 21, 2021, and recently adopted on March 13, 2024, as the Artificial Intelligence Act [1], marks a watershed in the development of international regulatory norms intended to govern the deployment and use of AI technologies. This regulatory project, unprecedented in its scope and breadth, stands as a pioneering effort to establish a comprehensive legal framework that governs AI applications within EU member states and in their interactions with third countries.

The European Union acknowledges the potential benefits of AI for our society, particularly in critical sectors such as healthcare, providing legal coverage in anticipation of avoiding health risks that AI usage may entail. The legislative initiative encompasses various applications such as biometric identification or AI-based decision-making that have a direct or indirect impact on healthcare services, among others. The EU recognizes and champions the clear benefits that the implementation of AI systems can bring to the field of health. Moreover, it perceives not only patients as the ultimate beneficiaries of these systems but also considers the economic boost, innovation, and competitiveness on a European and global scale. Nonetheless, it is undeniable that new risks associated with user safety and their impact on the Fundamental Rights and Freedoms recognized in the Charter of Fundamental Rights of the European Union (CFREU)[7] are identified. Specifically, the Right to human dignity, the Right to life, the Right to the integrity of the person, Protection of personal data, Freedom to conduct a business, Equality and non-discrimination, the Rights of the child, the Right to access social security benefits, and Health protection.

Thus, the EU acknowledges that due to the risks associated with the violation of such rights and a clear lack of legal certainty when using this technology, both companies and citizens may decelerate their acceptance and use of AI, owing to a lack of trust in its effects. Moreover, considering that the EU is composed of 27-member states with legislative authority, there is a potential for each state to regulate AI in very disparate ways, catering to more specific interests, such as national interests. To

prevent this possible fragmentation of the internal market, which would result from a lack of AI regulatory norms at the European level, this Regulation is adopted. With this new framework, the EU can provide legal certainty, not only to users of AI tools in the field of health but also to innovative companies and investors wishing to commit to such technology with the EU market as their interest.
The Regulation aims to apply to both public and private entities, within and outside the EU, to the extent that the AI system in the healthcare sector or its use affects individuals within it. Thus, it may affect both providers and implementers of the AI system. Referring to importers of systems, with the new Regulation they will have to ensure that the foreign provider has carried out the appropriate conformity assessment procedure, bears the European conformity marking (CE), and is accompanied by the necessary documentation and instructions for use.

Inscribed within the framework of the EU's digital strategy, the Regulation's principal objective is to ensure that the implementation and use of AI in the European space is carried out safely, ethically, and respectfully, upholding fundamental rights and freedoms, public liberties, and democratic values. To this end, it introduces a classification system for AI applications based on the associated level of risk, establishing a spectrum ranging from unacceptable risk to minimal or negligible risk.

AI systems deemed high-risk, which include numerous applications in clinical and health contexts, are subject to particular scrutiny. For these systems, the regulatory proposal establishes a suite of mandatory requirements ranging from transparency and information provision to accuracy, security, and data governance. These stipulations are designed to ensure that high-risk AI systems are reliable, verifiable, and implemented in a manner that minimizes potential harm or detriment to individuals or society.

It is crucial to note that the proposal adopts a risk-based approach, eschewing overly prescriptive regulation that could stifle innovation. Instead, a flexible framework is proposed that allows regulatory requirements to be tailored to the specific nature and context of each AI system's use, thereby fostering a balance between promoting technological innovation and protecting public interests—in this specific instance, health protection.
Furthermore, the proposal introduces oversight and compliance mechanisms, including the establishment of national supervisory authorities and a European Artificial Intelligence Committee (EAIC), which will be responsible for monitoring the application of the regulation and ensuring its uniformity across member states. These bodies will play a vital role in assessing high-risk AI systems, certifying their compliance with established requirements, and imposing sanctions in the event of non-compliance.

3. Analysis of the Regulation on Artificial Intelligence

3.1. Structure and Main Provisions of the Proposed Regulation on Artificial Intelligence

The Regulation on Artificial Intelligence proposed by the European Commission on March 13, 2024, encompasses 113 articles organized into XIII chapters and XIII annexes. The chapters that have a direct impact on AI systems in the health sector are as follows.

Preamble: The preamble sets forth the context, objectives, and guiding principles of the proposal, emphasizing the significance of ensuring safety and fundamental rights in the development and application of AI.

Chapter I - General Provisions: This chapter delineates the scope of the regulation by defining key terms, fundamental principles, and objectives of the regulation. It specifies the AI systems subject to regulation and clarifies the exceptions. With respect to AI systems impacting the health sector, it applies to providers and those responsible for deploying AI systems in the EU market or putting them into service in the health sector, regardless of whether they are located in a third country or within the EU. It is essential to note that the Regulation does not apply if the sole purpose of the AI systems or models, including their output information, is research and development.

Chapter II - Prohibitions and Obligations: This chapter delineates the practices and applications of AI deemed unacceptable and are therefore prohibited due to their clear risk to safety, fundamental rights, or human dignity. Additionally, it details the specific obligations for providers and users of AI systems, focusing on transparency, human oversight, and risk management. Among the prohibitions with direct implications for the healthcare field are techniques that could exploit the vulnerabilities of specific individuals or groups due to age or disability, biometric categorization systems, and others.

Chapter III - High-Risk AI Systems: This chapter is pivotal in the proposal, outlining the specific requirements and obligations for AI systems classified as high-risk. It addresses aspects such as data quality, technical documentation, traceability, and security. A framework to categorize AI systems into different levels of risk is developed within this chapter. The Regulation considers an AI system to be high-risk where there is a significant potential to cause harm to individuals' health and safety or to fundamental rights. It also references the list in Annex III of the Regulation, which enumerates activities considered high-risk. This chapter is critical in the clinical sector as one of the activities listed as high-risk in the aforementioned Annex III.

Chapter IV - Supervisory Authorities and Compliance: This chapter outlines the framework for the oversight and compliance of the regulation, including the appointment of competent national authorities and the establishment of a European AI Compliance Board. It delineates the functions and responsibilities of these entities in monitoring and ensuring adherence to the regulation.

Chapter VIII - EU Database for High-Risk AI Systems: The establishment of a database is described. It will compile information to be submitted by those responsible for deploying high-risk AI systems, specifically in the healthcare sector.

Chapter X - Codes of Conduct and Guidelines: This chapter encourages the promotion of soft law codes of conduct, which support the voluntary application of the established requirements for high-risk AI systems, and hence for AI systems in the healthcare field. These codes of conduct may be developed by the AI system providers and those responsible for deploying the AI system, among others.

Chapter XII - Sanctions: The chapter details the sanctioning regime that EU member states may establish. The Regulation sets forth a framework of sanctions for both prohibited activities and non-

compliance with the obligations of providers, authorized representatives, importers, distributors, and those responsible for deploying the AI system. It also envisages penalties for non-compliance with the notification and transparency requirements.

Final Provisions: It contains stipulations regarding the periodic review and updating of the regulation, considering the evolution of AI technology and its impact on society.

3.2. Definitions and Classifications of AI Systems According to Risk Levels

The Regulation introduces a risk-based approach to AI governance, classifying AI systems based on their potential risk level to citizens' rights and safety.

Low or Minimal Risk Systems: The majority of AI systems fall into this category, where existing regulations are deemed sufficient to handle associated risks. These systems must comply with transparency requirements and provide adequate information to users.

Limited Risk Systems: This category encompasses AI systems that necessitate specific transparency measures, such as chatbots. Users must be clearly informed that they are interacting with a machine, allowing an informed decision about their utilization. Chatbots in the medical field warrant special attention due to the implications for fundamental rights and health safety.

High-Risk Systems: AI systems utilized in critical contexts such as healthcare, transportation, judiciary, and public safety are classified as high-risk due to their potential significant impact on individual safety and fundamental rights. For these systems, the proposal mandates stringent requirements, including the accuracy and reliability of data, transparency, human oversight, and robustness.

Unacceptable Risk Systems: This category comprises AI applications that subliminally manipulate human behavior to cause harm or exploit vulnerabilities of specific groups, as well as mass surveillance systems and social scoring. Such applications are prohibited as they pose a clear threat to fundamental rights and freedoms.

The classification of AI systems according to their risk level is pivotal for determining the applicable regulatory framework. However, how can one ascertain whether an AI system is high-risk? The Regulation articulates a clear definition of what is considered “high-risk,” specifically mentioning, “...access to and enjoyment of essential private services, essential public services and benefits, including essential public assistance services, healthcare services, as well as the services to grant, reduce, revoke, or reclaim such services and benefits...” The Regulation aims to provide legal certainty for enterprises based on risk classification according to the intended use of the AI system, taking into account existing EU product safety legislation. Therefore, the risk classification depends on the AI system’s function, its intended purpose, and the specific modalities of the system.

The Regulation itself includes Annex III, listing AI systems considered high-risk. Nevertheless, this list will be kept up to date with reviews by the Commission to ensure its relevance. It is important to

note that AI systems performing limited procedural tasks, improving the outcome of prior human activities, not influencing human decision-making, or carrying out exclusively preparatory tasks will not be considered high-risk. However, an AI system will always be considered high-risk if it involves profiling of natural persons. Table 1 presents the categories defined in the Regulation, along with examples, requirements and obligations, data protection principles, and consequences of non-compliance.

Table 1. Original synthesis based on the risk categories of AI systems, examples, requirements and obligations, principles of data protection, and consequences of non-compliance according to the Regulation on AI (European Commission 2024).

Risk Category	Examples of AI systems	Primary requirements and obligations	Data protection principles	Consequences of non-compliance	Relation to healthcare regulations
Low or minimal risk	Email spam filters, product recommendations	Transparency, adequate user information	Transparency; Lawfulness, Fairness, and Transparency	Fine of up to €10 million or 2% of worldwide turnover	Minor direct relevance to specific healthcare regulations
Limited risk	Information chatbots, virtual assistants	Información clara sobre la interacción con IA, consentimiento del usuario	Consent; Clear information on AI interaction, user consent	Fine of up to €20 million or 4% of worldwide turnover	Limited relevance; emphasis on transparency and informed consent (e.g., GDPR, Art. 7)
High risk	Diagnostic software in medicine, surveillance systems in transportation	Conformity assessment, activity logging, data quality and management, human oversight, robustness, and security	Integrity and Confidentiality; Accuracy; Data Minimization	Maximum fine as prescribed by GDPR	High relevance to Medical Devices Regulation (2017/745) to ensure safety and efficacy
Unacceptable Risk	Behavioral manipulation technologies, mass surveillance systems	Prohibition due to threats to fundamental rights and freedoms	Prohibition of certain processing categories; respect for fundamental rights and freedoms	Prohibition of use; Maximum fine as prescribed by GDPR	Prohibitions may align with ethical and legal principles in healthcare (e.g., respect for human dignity, Charter of Fundamenta

					l Rights)

4. High-Risk AI Systems in Clinical Use

4.1 Identification of High-Risk AI Systems in the Healthcare Sector

Within the realm of healthcare, AI systems are deemed high-risk when their application could significantly impact patient safety, well-being, and health. A system is not considered high-risk if it only performs a limited procedural task aimed at enhancing an outcome previously achieved by human activity, if the AI system's purpose is pattern detection, and it is not intended to substitute human evaluation. Thus, the integration of AI (e.g., an algorithm) into clinical decision-making processes is as crucial as the tool itself.

A provider who considers a system listed in Annex III as high-risk when it is not so will document their assessment before such a system can be introduced to the market. The EU Regulation on Artificial Intelligence establishes specific criteria for classifying these systems, focusing on those used in critical environments such as medical diagnosis, clinical decision-making, and health monitoring.

Examples of High-Risk AI Systems in Healthcare

- **AI-assisted diagnostic software:** Tools that analyze medical images, such as X-rays, MRI scans, or skin photographs, to detect conditions like tumors or fractures.
- **AI systems for disease prediction:** Algorithms that assess risk factors and clinical data to predict the likelihood of diseases such as diabetes or cardiovascular diseases.
- **AI-assisted surgical robotics:** Systems that aid in surgical procedures, enhancing precision and reducing the risk of complications.

The European legislation, particularly the Medical Devices Regulation (2017/745)[8], already provides a framework to ensure the safety and efficacy of medical devices, including those incorporating AI. However, there is a need to define what constitutes a medical product within the EU context. Thus, the aforementioned regulation stipulates that if an algorithm is exclusively used in the healthcare domain, it would be considered a medical product and would need to comply with the regulation. Conversely, if the product is not exclusive to the healthcare domain or is only registered for lifestyle purposes, it would not be considered a medical product and would fall outside the scope of application. For instance, a smartwatch collecting data such as heart rate and sleep patterns would fall into this category.

However, the Proposal for an AI Regulation delves into the necessity of addressing specific risks associated with AI, such as algorithm transparency, explainability of decisions, and management of potential biases, regardless of whether they are considered medical products or not.

4.2. Potential Adverse Health Effects

The World Health Organization (WHO) highlights the potential risks and thus the need for caution when using AI systems such as large language models (LLMs). The risk arises from the possibility that the data used to train AI may be biased, leading to inaccurate results that pose a risk to health:

- **Diagnostic errors:** Excessive reliance on AI systems can result in diagnostic errors if algorithms are not adequately validated or trained with representative data, or if the epidemiological reality of the target population has changed (e.g., during the COVID-19 pandemic). There are numerous examples in the literature, such as diagnostic algorithms for diabetic retinopathy that, when implemented in populations different from those used for training, yielded inadequate results for clinical use [9].

- **Decision-making biases:** AI systems can perpetuate or exacerbate existing biases in training data, leading to disparities in the treatment of different patient groups. An example is diagnostic algorithms for rare diseases, as a disease considered rare in one country (e.g., schistosomiasis in Spain) may not be uncommon in another (e.g., Uganda).

- **Lack of transparency and explainability:** The "black box"[10] nature of some AI systems, especially Deep Learning models, can hinder understanding of clinical decisions, eroding trust between patients and healthcare professionals. Lack of explainability can be addressed through clinical validation studies (external validity), both at the outset of production and at regular intervals (perhaps monthly) to adapt to any epidemiological changes occurring in that population.

4.3. Analysis of Specific Requirements and Obligations for High-Risk Systems

High-risk AI systems in the healthcare sector are subject to a series of rigorous operational and compliance requirements before their introduction to the market, regardless of whether the provider is within the European Union or located outside of it. The objective is to mitigate risks and ensure the protection of patients, among other considerations, given their potential to significantly impact safety and fundamental rights. These requirements include:

- **Compliance assessment:** Before deployment, high-risk AI systems must undergo a comprehensive compliance assessment demonstrating their safety, efficacy, and adherence to ethical standards, in addition to verifying compliance with the requirements established in the Regulation. This assessment may be internal or involve certification bodies, depending on the nature and use of the AI system. This process enables them to demonstrate that the system meets the criteria to be considered trustworthy (i.e., data quality, accuracy, cybersecurity, and robustness, among others). It should be noted that biometric AI systems will always require a third-party compliance assessment.

- **Data quality:** Data used by high-risk AI systems must be treated to ensure accuracy, completeness, and freedom from undue biases, to ensure the reliability and objectivity of

system operations. The quality of data used for training and operating AI systems must be guaranteed, including representativeness and accuracy.

- **Information and transparency:** Clear and adequate information must be provided to users about the capabilities and limitations of the system, including explanation of algorithmic decisions when necessary to ensure transparency. AI systems should be designed so that their decisions and operations can be understood and explained to healthcare professionals and patients, thereby ensuring trust and acceptance. Users should understand how they work and how decisions are made.

- **Robustness and security:** Adequate measures must be implemented to ensure the security, integrity, and robustness of AI systems against errors, failures, or attempts at manipulation.

- **Risk management:** A risk management system must be implemented as a continuous, planned process executed throughout the life cycle of the AI system. Risks to be addressed are those that can reasonably be reduced or eliminated. The system will consist of the following stages:
    - Determination and analysis of known and foreseeable risks that the high-risk AI system may entail for health or fundamental rights;
    - Estimation and evaluation of risks that may arise when the high-risk AI system operates for its intended purpose and when it may be misused;
    - Evaluation of other possible and foreseeable risks that may arise from the analysis of data collected with the post-market surveillance system;
    - Adoption of appropriate risk management measures to address previously identified risks.

Examples of Obligations:

- **Detailed Documentation:** Providers of high-risk AI systems must maintain exhaustive documentation elucidating system design, characteristics, functionality, EU declaration of conformity, and the rationale behind system decisions. This documentation, accessible in a clear and understandable form to both users and regulatory authorities, must be preserved for a decade following the market launch or commissioning of the AI system.

- **Activity Logging:** To ascertain transparency and traceability, detailed records of data processing activities and algorithmic decisions must be upheld by providers of high-risk AI systems. Automatically generated logs should be retained for a period commensurately aligned with the system's specific intent, extending to a minimum of six months, unless otherwise stipulated by relevant EU or Member State law, with particular attention paid to data protection regulations.

- **Effective Human Oversight:** High-risk AI systems must be architected to enable effective human supervision, mitigating safety risks and safeguarding individual rights. A mechanism should be in place allowing for health professionals to review and adjust clinical decisions made or aided by AI systems. Providers must implement real-time monitoring mechanisms for performance and risk assessment, with provisions for corrective actions upon issue

detection.

- **Risk Mitigation and Quality Management System:** High-risk AI system providers are mandated to enact procedures for the ongoing identification, evaluation, and mitigation of risks associated with AI utilization in clinical environments. The quality management system must assure compliance with this Regulation, methodically establishing documentation encompassing public policies, procedures, and instructions. This includes, at a minimum:
    - A strategy for regulatory compliance;
    - Procedures and techniques employed in the design, control, and quality assurance of high-risk systems;
    - Necessary protocols for thorough examination and validation before, during, and following the AI system development;
    - Technical specifications and applicable standards;
    - Data management procedures and systems encompassing data acquisition, collection, analysis, labeling, storage, filtering, prospecting, aggregation, preservation, and other related operations;
    - Documentation pertaining to the risk management system;
    - Procedures regarding potential notifications of a serious incident to the competent authorities.

5. Challenges and practical considerations in regulatory adaptation

The transition to new regulations within the healthcare sector, among others, poses a significant challenge, necessitating a thorough analysis to comprehend the barriers and formulate effective implementation strategies.

5.1 Assessment of industry and healthcare sector adaptability to new Regulation

The healthcare industry's capacity to adjust to new regulations is contingent on various factors, including the state of existing technological infrastructures, the availability of human and financial resources, and the preexisting regulatory framework. The World Health Organization emphasizes the critical nature of a robust health infrastructure capable of integrating new technologies and processes without compromising service quality [11].

Notable implementation hurdles include inadequate technological infrastructures and the absence of modern, interoperable health information systems, particularly in developing countries. The successful implementation of new regulations will demand adequately trained healthcare personnel. Yet, the knowledge gap may be substantial, especially in burgeoning fields such as AI in medical diagnostics [12]. Furthermore, the necessary investments for systems upgrades and new technology deployments could pose a significant financial challenge. Small and medium-sized healthcare enterprises may face a nearly insurmountable obstacle in absorbing the costs associated with new technologies [13].

Furthermore, as argued by Ricón Andreu [14], the strategic exploitation of strengths in industrial and professional markets is essential. The aim is not merely to be users of AI but to become creators and producers thereof. Central to the new regulatory framework with the Regulation's adoption is the generation of trust among patients/consumers. Undoubtedly, a European regulatory framework will engender confidence not only among AI users but also among innovative firms and investors, thereby accelerating the widespread operational deployment of this technology. The newly approved Regulation addresses the lack of harmonization regarding liability, simultaneously covering an extensive range of case scenarios in the application of AI.

Adapting to new technologies, specifically AI, entails the introduction of novel regulations in the healthcare sector, presenting challenges ranging from the need to modernize technological infrastructure to personnel training. However, with strategic investments, ongoing education, and adequate financial support, it is possible to surmount these barriers. The collaboration among governments, industry, and health organizations is pivotal to ensure a smooth transition towards the adoption of new regulations while concurrently assuring that patient quality and safety remain uncompromised (Meza Rivas 2024)[15].

6. Future Outlook and Regulatory Development in Health AI

6.1 Emerging Trends in Health AI Regulation

The rapid advancement of artificial intelligence (AI) in the healthcare sector poses new challenges and opportunities for regulatory evolution. Given current trends, attention must be directed to the following areas:

- **Ethical Framework and Accountability:** The establishment of a clear ethical framework and accountability mechanisms for decisions made by healthcare AI systems has become paramount. This encompasses algorithmic transparency and the capability to elucidate AI decisions to both patients and healthcare professionals [16].

- **Data Interoperability and Standards:** Regulatory progression is focused on fostering data interoperability and the establishment of data standards that enable the secure integration of AI systems within the existing health ecosystem while simultaneously safeguarding patient privacy [17].

- **Risk Assessment and Categorization:** There is ongoing development of risk assessment systems specifically designed to categorize AI applications according to their potential risk to patients. This categorization will influence the level of regulatory scrutiny required [18].

6.2 Potential Future Revisions and Areas for Regulatory Development

The technology underpinning AI systems in healthcare is burgeoning, signifying a new economic and social revolution. This environment necessitates the consideration of future landscapes and the

attempt to anticipate possible risks and, at a minimum, to engage dynamically in the regulatory field. Considerations should include:

- **Adaptive Dynamic Regulations:** In light of rapid technological advancement, future regulations will need to be dynamic and adaptive, capable of responding to new evidence and developments in AI without compromising patient safety.
- **International Collaboration and Harmonization:** International harmonization of regulations will be pivotal for the global adoption of AI healthcare solutions, preventing regulatory disparities that could impede innovation and access to cutting-edge technologies [19].
- **Stakeholder Participation and Ethics:** Involving various stakeholders, including patients, healthcare professionals, AI developers, and regulators, in the regulatory development process will ensure that regulations are equitable, ethical, and patient-centered [20].
- **Training and Education:** Establishing training and education programs for regulators and healthcare professionals regarding the capabilities, limitations, and ethical use of AI is essential for the effective and safe implementation of these technologies [21].

Regulation of AI in healthcare is at a critical juncture, facing the need to balance innovation with patient safety, ethics, and privacy. Emerging trends suggest a regulatory framework that is more flexible, ethical, and risk-based, capable of adapting to the pace of technological development. International collaboration, stakeholder involvement, and education are paramount for developing regulations that harness the transformative potential of AI in healthcare while safeguarding patient rights and safety.

7. Conclusions

The European Union's proposed Artificial Intelligence Regulation represents an ambitious effort by European institutions to establish a legal framework that, while respecting principles of innovation and technological development, ensures the protection of fundamental rights and citizen safety in the digital era. The final adoption of this regulation sets a significant precedent in the governance of AI, not only within Europe but also globally, potentially influencing future legislative initiatives in other jurisdictions.

With the new Regulation, AI service providers in the medical field, both within and outside the EU, will find a legal framework that dictates the extent and manner in which an AI system can be deployed in the healthcare domain.

The risk categorization system frames the AI system, enabling its operational deployment while respecting fundamental rights, public freedoms, and specifically health risks.

The Regulation provides the legal certainty necessary for investors, suppliers, and representatives to target Europe to promote their AI systems, with the assurance of a rule that covers the needs of both innovation and the protection of individual rights.

The EU Artificial Intelligence Systems Regulation marks a significant step toward creating a safe and ethical environment for the integration of AI into clinical practice. However, the success of this initiative will depend on a balanced approach that encourages innovation while protecting patient

interests and rights.

Conflicts of Interest

None declared.

Abbreviations:

AI	Artificial Intelligence
CFREU	Charter of Fundamental Rights of the European Union
DMA	Digital Markets Act
EAIC	European Artificial Intelligence Committee
EU	European Union
FR&F	Fundamental Rights and Freedoms
GDPR	General Data Protection Regulation
LLMs	Large Language Models
NIS	Network and Information Systems
WHO	World Health Organization

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