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An Assessment of AI Regulatory and Compliance Issues in the U.S. Healthcare Sector

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A B S T R A C T

This paper examines AI Regulatory and Compliance Issues in the U.S. Healthcare Sector, especially in medicine and radiology to identify the positive influences and opportunities that AI systems can enforce to deliver the best outcomes for patients while dealing with ethical, legal, and data protection pitfalls that are present in AI systems. In pursuit of the research questions, the study employs a literature review and a content analysis of regulatory laws as the main data collection methods in addressing the current research question. The findings of the paper indicate several important challenges that can define AI adoption issues including the lack of defined regulations, cybersecurity risks and concerns associated with holding parties for AI decisions as well as the changing fiduciary relationships between patients and AI systems. It was revealed that certain difficulties such as concerns over safeguarding patient information from cyber threats and ensuring data privacy, difficulties in establishing accountability and duty when AI systems are involved in medical decision-making, the evolving nature of trust and responsibility between patients and AI-driven medical systems, and potential risks associated with the improper or unethical use of AI in healthcare settings impede AI development. The study identified significant opportunities for AI to enhance diagnostic accuracy and improve patient treatment effectiveness. However, it also highlighted critical challenges, including the need to ensure patient confidentiality, data protection, and the proper use of personal information. This paper thus delves into ways to resolve these challenges since they are critical for AI's practical and safe implementation in healthcare. Medical devices that are built with AI should have an imposed and architected ethical framework that works with traditional ethical norms and should have a policy and state-of-the-art programming enforcing it. It is important that this technology is regulated properly and used ethically as its application can improve healthcare delivery, however, its misuse can be hazardous; therefore, creating partnerships between the patient, care providers, and regulators is crucial. The paper, therefore, recommends that a click with a dash of caution is needed to address security and privacy concerns, together with the ethical handling of data for the compassionate practice of AI in healthcare.

Keywords: Artificial intelligence, Cybersecurity, Healthcare, AI medical devices, Data compliance

1. Introduction

AI is a field within computer science that focuses on developing machines using various technical techniques that can accomplish activities that typically need human intelligence (Chartrand et al., 2017). Russell & Bohannon, (2015), “Computer programs that simulate cognitive processes like learning and problem-solving are referred to as artificial intelligence (AI)”. These systems are now built on artificial neural networks (ANNs), which are adaptable to mathematical models that find complex nonlinear patterns in enormous datasets (sometimes referred to as "big data") by utilizing a variety of procedures (Miller & Brown, 2018). Electronic archives hold vast amounts of data that are difficult to analyze, search, or understand with conventional data-processing techniques. Krittanawong highlighted that “Large-scale data sets comprise information gathered from a variety of sources, such as wearable technology, social media, mobile applications, environmental and lifestyle factors, sociodemographic information, omic information (such as genomics, metabolomics, proteomics, and radiomics), standardized electronic health records, and precision medicine platforms” (Krittanawong et al., 2017). Medical images from tests such as computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, and X-rays are among the most intriguing categories of health data, with great promise for both clinical and research applications.

According to Pesapane et al., (2018), “These data could be used, among other things, to improve automatic disease detection (while minimizing human errors), develop study protocols, enhance image quality and reduce radiation dose, shorten the time spent in MRI scanners, optimize staffing and scanner utilization, thereby reducing costs, and provide the opportunity to conduct costly and time-consuming screening programs in nations that would not otherwise be able to afford them (Sachs et al., 2013, Chen et al., 2017, Golkovet al., 2016, and Lakhani et al., 2018). Big data analysis has made substantial use of machine learning, a phrase coined by Arthur Samuel in 1959 (Angelov et al., 2021) to describe a branch of artificial intelligence in which computers learn automatically from accumulating data (Lee et al., 2017). Deep learning has become a very promising method for image processing in the machine

learning space (King Jr, 2017). In contrast to software, which needs explicit instructions to finish a task, deep learning enables the system to identify patterns on its own and generate predictions (King, 2018).

2. AI Applications in the Healthcare sector

As the healthcare industry embraces AI systems that can learn on their own and interpret complicated algorithms, the trend is of a new age where AI is being integrated into clinical practice to inform diagnosis more sharply and to streamline the workflow through the help of risk assessment models. AI tools powered by AI which can sift through raw data can help in improving the quality of myriads medical fields which include drug development, treatment decision-making, patient care, and financial and operational pipeline management by identifying patterns. (Gallego et al., 2021, Elsayed et al., 2017, Lamanna & Byrne, 2018 and Anderson & Anderson, 2019). Current applications of AI in medicine demonstrate that humans are unable to solve complicated issues quickly enough on their own without AI's help (Johnson et al., 2021). Thus, radiologists, physicians, and other healthcare providers may find AI to be a useful tool. AI gives them exact decisions before performing treatments, enabling doctors to make greater use of their experience.

Doctors are under extreme pressure as diagnostic assays tend to be cumbersome and time-consuming. Consequently, deep learning algorithms have recently made astounding advances in disease detection autonomously and at scales that provide cost reductions and scaled-up access to diagnostics (Pérez-Ramírez et al., 2014). Better systems would combine multiple sources of data (genomics, proteomics, CT/MRI images, patient records, etc) to predict disease or progression.

The healthcare industry is improving the standard of care through the creation of improved medications, patient condition monitoring, and the use of AI-based models are widely utilized in clinical trials, especially for information such as forecast and medical records processing and interpreting, as well as analyzing CT and MRI images. Right now, medical institutions are trying to improve how efficiently they operate, which will help both the people within the healthcare institutions who provide the services to the patients, as well as improve the quality of the patient’s experiences. The operational databases such as those that track patient flow, wait times, staff schedules, utilization of hospital resources, and current costs are crucial and are mostly under the purview of information technology rather than clinical research (Erickson et al., 2017, Calo, 2017).

Predicting the medical requirement: ML approaches are utilized through the data of healthcare facilities, and drugstores to track the demand for medicine, medical staff, devices, and supplies in various hospitals or health centers (Habehh & Gohel, 2021). This minimizes pharmaceutical waste and ensures prompt delivery of equipment, particularly that which is malfunctioning or out of stock. All of this lowers the high expenses associated with the health industry and raises the efficiency of medical facilities. A prime example of a mismatch between equipment supply and demand occurred in 2020 during the COVID-19 pandemic, when there was a major shortage of surgical masks.

Automatic radiation analysis: To offset the risk of radiation exposure healthcare providers face daily; radiologists are among the most respcted medical professionals in hospitals. Currently, DL technologies are more accurate than physicians in the diagnosis of lung and cancer disorders (Thrall et al., 2018). Using AI to automate the radiologist's work makes the position economically viable. In actuality, the discipline of radiology is where artificial intelligence is most often used (Ravì et al., 2016). This is due to the astounding advancements in image recognition, which have resulted in significant growth in both the volume of data gathered and computing power (Christenses et al., 2016). Certain diagnostic domains, such as the detection of lymph node metastases and mammography malignancy diagnosis, have shown remarkable effectiveness with the application of deep learning (Zittrain & Ito, 2017). Meningioma detection in MRIs serves as another evidence of the enormous potential and usefulness of AI.

3. AI Regulatory and Compliance Issues in Healthcare Settings

The growth of algorithm development, together with the ease of access to computer resources, now permits AI applications to be applied in medical decision-making tasks with promising outcomes (King Jr, 2017). The application of AI algorithms in radiology is an important area researchers ought to consider for regulatory and compliance issues. Deep learning algorithms are currently employed in mammography for breast cancer detection (Dheeba et al., 2014), CT for colon cancer diagnosis, chest radiographs for pulmonary nodule detection, MRI for brain tumor segmentation, and for the diagnosis of neurologic disorders, such as Alzheimer's disease (Erickson et al., 2017).

The highly positive trend of publications in the literature over the last decade demonstrates the broad enthusiasm and dynamism surrounding the development of AI-based software in healthcare settings: from 100 to 150 to 700-800 yearly (Pesapane et al., 2018). However, certain ethical issues are clear and should be avoided. One of these concerns is that algorithms may reflect human biases in decision-making. Because healthcare delivery already differs by ethnicity, some ethnic biases may be mistakenly introduced into medical algorithms. AI applications in nonmedical sectors have been demonstrated to make biased conclusions based on training data (Char et al., 2018). A program that was created to forecast an offender's likelihood of recidivism and assist judges in sentencing has recently revealed an unsettling tendency toward discrimination (Angwin et al., 2016). Likewise, if there is no genetic research conducted in a particular community, an algorithm created to forecast results based on genetic discoveries may be skewed (Char et al., 2018).

Since some technologies can be programmed to act unethically, it is also necessary to take into account the purpose behind the construction of artificial intelligence. For instance, Uber's "Greyball" algorithmic technology was created to discover and get around local restrictions by predicting which ride hailers might be undercover law enforcement officers (Char et al., 2018). Additionally, Volkswagen's algorithm reduced the amount of nitrogen oxide emissions produced by the cars during testing, enabling them to pass emissions tests (Char et al., 2018). Similarly, designers in the private sector who

develop AI algorithms for clinical applications may face comparable incentives, programming AI systems to direct users toward clinical decisions that would increase profits for their clients (e.g., by advising medications, examinations, or medical equipment in which they have stock, or by changing referral patterns), but which might not necessarily result in better care (Char et al., 2018). The aforementioned instances highlight the pressing need for significant legislation and regulatory measures concerning AI utilization, particularly in intricate healthcare settings where accurate disease detection and optimal patient treatment can be contentious.

4. Regulatory Concerns and Policy Initiatives in AI Utilization in Healthcare Settings

AI systems are capable of more than just processing data and helping decision-makers make important choices. Numerous systems have direct physical control over items in the human environment, such as the software that operates an autonomous automobile or an airplane (Calo, 2017). Other systems, such as medical and radiological devices, offer delicate services for which doctors must be certified and trained (Ravì et al., 2016). These applications bring up more issues regarding the standards that apply to AI systems and the methods and approaches that can be used to make sure those criteria are being fulfilled (Christenses et al., 2016). What about current technological advancements like self-driving image scanners, whose value lies in introducing expertise into a lackluster environment? And what are the thoughts on platforms that claim to provide health advice, which is dependent on human judgment and involves complicated fiduciary and other duties (Molteni, 2017)?

Since definitions are the foundation of any legislation, legislators must address them first when regulating any new subject. This element turns into a real problem with AI, a word riddled with contradictions: what exactly is intelligence? Which human skills should be regarded as the benchmarks that AI systems must meet (Majambere, 2011)? The absence of a unified, stable definition or instantiation for AI makes it more difficult to create a suitable policy framework. People may wonder whether ‘ethics’ is the best word to describe society’s attempts at shaping AI in service of the public good since other words are beginning to see use as well. Take, for instance, the new initiative by the Massachusetts Institute of Technology's Media Lab and Harvard University's Berkman Klein Center for Internet and Society, called the "Ethics and Governance of Artificial Intelligence Fund." However, radiology and medicine necessitate a policy framework for handling AI.

One remaining question for policymakers is whether the AI software used in healthcare should or could be legally considered a medical device. While the EU and the US have divergent notions of what constitutes medical devices in healthcare, they both use a purpose-based framework. In this paper, the researchers investigate what constitutes a medical device and the different regulations between those two regions. However, it should be noted that not all healthcare AI software will be medical devices. Programs for the purpose of analyzing large datasets to better understand a disease condition, instead of determining the best treatment for a particular patient may or may not meet the definition of medical purpose or medical device, as Tsang et al. (2017) note. It makes the distinction between research projects to make progress in medical knowledge and advocacy for changes in healthcare practice.

Depending on how they regulate AI systems, two main approaches suggested by Thierer et al., (2017) to policymakers are. The first is the precautionary principle, and this prevents applications from being allowed, or banned entirely, on the basis of probable risks without testing for the worst-case scenarios. Second is permissionless innovation which is free to experiment with anything and address issues as they come up. In 2016, (Scherer, 2015), made the distinction between ex-ante and ex-post regulation. Ex-ante regulation anticipates risks, similar to the precautionary principle (Thierer et al., 2017), whereas ex-post regulation addresses harm after it has occurred (Considine, 2019), similar to the permissionless innovation approach (Thierer et al., 2017). Ex-post regulation is challenging due to the unpredictability of AI systems' evolution and learning (Kohli et al., 2017).

In contrast, ex-ante regulation is a difficult concept to implement when applied to AI applications. Some of these include opacity (having difficulty for external observers to fully understand all of what an AI system is and does), diffuseness (where participants in a project can be geographically separated and still work productively together), discreteness (where often little physical infrastructure is needed to develop an AI system), and diffuseness again (where the formation of parts of an AI system frequently occur by distinct people for discrete purposes with no direct communication).

Time is another big challenge for policymakers. Today’s companies are aware of the impact of deep learning and machine learning, endlessly picking up new datasets for analysis and application (Mitchell & Brynjolfsson, 2017). As time goes by in this highly changing technological and AI world, they must be implemented in an efficient and timely manner. Such factors show that regulating medical devices typically involves contentious politics and often ambiguous interpretations by policymakers. In this paper, we look at the regulatory environment and when the software is covered by EU and US software device regulations. In the U.S. technology sector, which includes AI, generally, the U.S. has developed a policy environment that strongly favors permissionless innovation (Thierer et al., 2017), while the EU has chosen a different regulatory path.

This is good for manufacturers, because AI-enabled medical devices are approved faster, and doctors are getting new tools. The primary purpose of making new devices available, however, must be to improve disease prevention, diagnosis, treatment, and prognosis to improve outcomes for the patient. The regulatory processes that allow new medical devices that make a major difference for patients to be approved must strike an appropriate balance between allowing them to be brought to market and ensuring patient safety. The EU and the US employ various strategies to accomplish these objectives (Kramer et al., 2020). For this paper, the U.S. data approach is discussed and considered.

5. The U.S. Approach

There is still a major hurdle, however, required regulatory approval for robots to perform tasks ordinarily conducted by well-trained radiologists in the United States. It takes an ocean of testing and effort to get the FDA to let computers make the primary interpretations of imaging studies without a

radiologist looking in. The 21st Century Cures Act of 2016 (Vogeser et al., 2022) clarified the FDA's identity as to the software that it regulates in healthcare. A medical device is 'any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) recognized, by the codified regulation or by other federal authority, as being capable of presenting a reasonable opportunity of harm to the user, and, (2) is intended for use in the diagnosis of disease or other conditions, to affect the structure or any function. This is the most relevant for our purpose though it is not the only one. Thus, any AI system that fits this definition is the subject to regulatory scope of the Federal Food, Drug, and Cosmetic Act (Tsang et al., 2017).

There are three classes of medical devices. The FDA categorizes them based on their intended use and associated risks, from least to most regulated as the risk increases. These devices pose the highest risk, and therefore the highest degree of oversight, and fall under class III. The continuous development of new medical devices means the FDA must extensively test and verify, and has a difficult time authorizing them quickly, especially as many AI systems are both complex and 'black box' in nature—and machine learning itself is fast growing. For example, in 1998, computer-assisted detection (CAD) software was introduced for mammogram (Pesapane et al., 2018), but it took a lot of years and advocacy to get FDA approval as a second screening tool (Azavedo et al., 2012). Even more than CAD systems, an AI system that runs without radiologist supervision would require FDA clearance.

Additionally, AI systems are difficult to compare to medical devices, which aim to replace radiologists. In this way, modern developers present AI systems as tools to help and support radiologists' work rather than as a complete replacement (Recht & Bryan, 2017). Regulatory or not, it increases its own weight in the room by raising questions of ethical responsibility as we discuss below.

6. Data Protection and Digital Security Implications

Following the Cambridge Analytica/Facebook scandal, in the aftermath of which personal data was abused, there is a heated discussion about the proper balance between privacy and improving user experience with personal data. Especially sensitive information such as medical records requires even more attention in this debate. While it increasingly seems alarming and risky to think that many of these unregulated companies could determine sharing of large amounts of sensitive data across multiple times. It follows that we have seen a resurgence in legislation concerning personal data protection and privacy worries (Stark, 2018).

However data is still necessary for technological advancement, particularly in the case of artificial intelligence. As the paper already covered, deep learning algorithms need a tonne of data and powerful processors, and because they have so many variables to take into account, training them typically takes a long time (Paul et al., 2018). One major barrier to the widespread adoption of AI systems in radiology is the absence of substantial, well-annotated datasets for training algorithms (Krittanawong, 2018). In order to give AI devices, the training material they need to identify imaging problems, access to large datasets of medical pictures is required (Kruskal et al., 2017). One of the issues is that, due to a lack of distinct and precise restrictions, sensitive data may be obtained illegally or from unidentified sources (Castelvecchi, 2016, Dilsizian & Siegel, 2014). Artificial intelligence (AI) exacerbates the already complicated cybersecurity environment in the age of electronic medical records (Allen & Chan, 2017): to maintain true confidentiality, a doctor must omit information from the medical record (Char et al.,2018). Withholding information from electronic records will get harder once AI-based clinical decisions are incorporated into clinical care since patients without recorded data cannot benefit from AI analysis (Char et al.,2018).

Therefore, it will be necessary to rethink confidentiality and other fundamental principles of medical ethics in order to deploy deep learning systems. We must address the technological consequences of cybersecurity and data protection before resorting to excessive government regulation. Current technologies that facilitate the dissemination of personal data and need extensive, uncontrolled data sharing are no longer sufficient for data protection (Helbing et al., 2019). AI medical devices in radiology and medicine generally should employ deep learning to give patient data without demanding personally identifying information from patients. Two concerns about the data that the devices gather are currently brought up by the usage of AI. Data needs to be shielded, on the one hand, from the organizations that are gathering it. However, assaults on these organizations and the devices themselves pose a hazard to the same data.

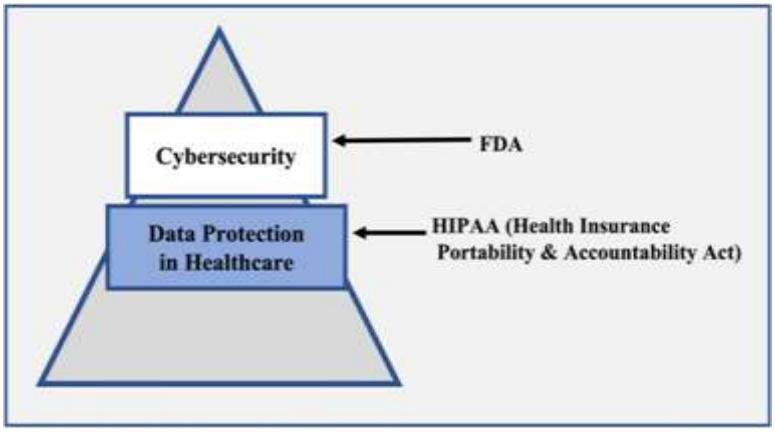

Fig. 1 -American healthcare industry's regulatory and compliance needs (Tettey et al., 2024)

The diagram shows the American healthcare industry's regulatory and compliance needs in a logical order. The ultimate level is cybersecurity, which includes more comprehensive safeguarding of private patient information and systems against loss, theft, or damage. Ensuring the confidentiality, integrity, and accessibility of healthcare information is contingent upon this fundamental layer. The next section, "Data Protection in Healthcare," focuses on protecting patient health records, which are governed by strict laws like HIPAA. HIPAA requires that physical, administrative, and technical security measures be put in place to secure patient data and guarantee its availability, confidentiality, and integrity. In contrast, the FDA is a major player in monitoring the cybersecurity and data security procedures of medical software and devices. Through the implementation of stringent safety and security protocols, the FDA plays a role in safeguarding patient data throughout the healthcare system. To sum up, this hierarchical architecture highlights how cybersecurity, data protection, and regulatory supervision are intertwined in the US healthcare industry. Respecting patient privacy, preserving data integrity, and guaranteeing the safety of healthcare operations all depend on compliance with these laws.

7. Accountability and Responsibility: An “Internal Perspective” of AI in the Context of the United States Health Sector

Aside from actual legislation and data protection, there are other legal consequences for AI and its application, whether in healthcare or elsewhere. One of these is accountability. When AI begins to make autonomous decisions regarding diagnoses and treatments, it raises the question of accountability for its developers (Habli et al., 2020). The first question is, who will be prosecuted if an AI-powered device makes a mistake?

AI errors occur mostly when confounding factors are associated with pathological entities in training datasets rather than genuine indicators of disease. When AI devices make decisions, they do so based on the data they have acquired, the algorithms they use, and what they have learned since their development. The reasons for their surprising decisions are twofold (Scherer, 2016). AI devices, albeit resembling human neural networks, have distinct cognitive processes. Better, they think faster and more precisely (Scherer, 2016).

There are numerous alternatives in any given scenario, and humans are unable to understand and analyze all of them in order to make a decision. Our brains only consider what is obvious, whereas AI systems can consider any imaginable circumstance or consideration (Mnih et al., 2015). As a result, when presented with a decision, we do not have a common base with AI devices. We cannot foresee their decisions based on certain conditions. AI systems, on the other hand, are supposed to learn from real-world experiences, which are inherently unpredictable (Hagendorff & Wezel, 2020). Because it is not feasible to predict what experiences a system will face or how the system will develop. For these reasons, when something 'goes wrong' as a result of an AI application's choice, it is important to assess whether the machine itself or its designer/builder is to blame. Will the designer be held liable for failing to anticipate what we have characterized as unforeseeable? Or for having left open the potential of developing the AI gadget that would lead to that decision? (Yang et al., 2020).

Over the coming years, AI will become more and more involved in the interactions between physicians and patients (Verghese et al., 2018). As such, AI will require to be constrained by fundamental ethical principles, like beneficence and respect for patients, which have guided medical professionals throughout history (Char et al., 2018). It is important to keep in mind that a radiologist is a medical professional who does much more than just read pictures. In addition to these and many more functions that cannot be completed by computer programs, a professional radiologist's responsibilities also include policymaking, education, interventional radiology treatments, quality assurance, and quality improvement (Russell & Bohannon, 2015). It is hard to measure and more harder to replicate with AI systems the capacity to offer a complex interpretation for complicated findings, medical judgment, and experience of a radiologist (King Jr. 2018). It is nearly a given that part of AI technology's internal operations will appear to be a "black box" to everyone save the very few who can understand how they work, given the technology's rising complexity (Castelvecchi. 2016). However, that does not mean that accountability is unassailable.

Crucially, within a more comprehensive theoretical framework, this paper ought to differentiate between data analysis (namely, the output of the AI device) and decision-making. In the framework of evidence-based medicine (Sardanelli et al., 2010), we must use our own medical/radiological skills to integrate the best available external evidence data from high-quality studies and meta-analyses, guidelines from governmental agencies and medical societies with the preferences and values of the patients. One may argue that with the introduction of artificial intelligence (AI) to radiology, we also have some form of internal evidence derived from the use of AI in the patient's imaging procedure(s). It is possible to claim that, at some point in the future, AI could be able to perform this function in place of doctors. According to Pesapane et al., (2018), “Human interaction and empathy between a physician/radiologist and a patient remain a crucial dimension when patients' preferences and values play a non-negligible part (and hopefully this aspect will not lessen its weight in the future)”. In fact, radiologists will have more time to interact with patients and consult with other members of multidisciplinary teams since AI will free them up from having to spend as much time on repetitive, boring jobs that computers can handle more efficiently (Recht & Bryan, 2017).

For insurance purposes, accountability for AI output might also be a straightforward thing. Physicians' natural intelligence will continue to hold the reins of ethical and legal decision-making responsibility. According to this perspective, interdisciplinary boards are likely to assume responsibility in complex instances because the data AI generates is pertinent but not always definitive.

8. Conclusion

There are several hurdles to overcome in the integration of AI in American healthcare, especially in areas like radiology and medicine. The use of AI is essential for improving patient care and treatment despite these obstacles. New regulatory initiatives, cybersecurity and data protection laws, challenges with accountability and duty, and the changing nature of the fiduciary relationship between patients and AI-driven medical systems are some of the major

concerns. It is critical to address these issues if AI is to be used in an ethical and practical manner. AI-based medical devices should be designed to align with the ethical standards traditionally followed by other stakeholders in healthcare and held to those standards through a combination of policy enactment and advanced programming techniques. A well-regulated and ethically implemented AI system can greatly enhance healthcare delivery, whereas misuse of this technology poses risks. Therefore, collaboration among patients, healthcare providers (including radiologists), and regulatory bodies is crucial. A balanced approach must be established to ensure security, privacy protection, and the ethical handling of sensitive patient information, fostering responsible and humane management of AI in the healthcare sector. AI-based medical devices must be created in accordance with the moral principles that other healthcare stakeholders have long upheld, and they ought to be held to those principles by means of sophisticated programming methods in conjunction with the adoption of policies. Healthcare delivery can be substantially improved by an AI system that is ethically and well-regulated, but there are risks associated with using this technology improperly. Collaboration between patients, medical professionals (such as radiologists), and regulatory agencies is therefore essential. In order to promote responsible and compassionate management of AI in the healthcare industry, a balanced strategy must be devised to assure security, privacy protection, and the ethical handling of sensitive patient information.

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