Imaging the Future: Ethical Challenges of AI in Diagnostic Radiology

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Amalie Harrison

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Advisor

Caitlin D. Wylie, Department of Engineering and Society

Generative Artificial Intelligence in healthcare is a rapidly growing market, expected to grow from $2.7 billion in 2025 to $17 billion in 2034, according to North (2025), a writer for the World Economic Forum. Despite this rapid growth, there are concerns about the transforming landscape of medicine and the potential risks it may bring. The advancement of Artificial Intelligence (AI) is expected to have one of the largest effects on the field of diagnostic radiology. Without the proper regulation for the implementation of AI, the risk of misdiagnosis, improper handling of data, and lack of patient or physician understanding of the technology could have potential consequences on the relationships within healthcare settings and the patient outcome following diagnosis. To understand the true scope of the issue from different perspectives, I will utilize both utilitarianism and ethics of care frameworks to analyze the benefits and risks of the advancement of AI in this field and identify regulations necessary to mitigate these risks (Chukwuneke & Ezenwugo, 2022; Maio, 2018). In the context of this paper, I will define AI as any artificial intelligence or machine learning model used by physicians in diagnostic radiology to both provide diagnosis and aid doctors in their ability to diagnose conditions.

Utilitarian Evaluation and Success Metrics for AI in Radiology

Utilitarianism is an ethical principle commonly used in a variety of scenarios, both professional and personal, to solve moral dilemmas. Chukwuneke & Ezenwugo (2022), writing in the International Journal of Medicine and Health development, define utilitarianism as a society centered framework aiming to generate the greatest amount of utility from the chosen course of action. In the context of the use of Artificial Intelligence (AI) in diagnostic radiology, this translates to the decision that is most beneficial to the majority of stakeholders, including most prominently: physicians, patients, AI model developers, and hospital leadership. The

outcome of the minority of stakeholders, however, is unimportant if a majority still benefits. Using this ethical lens, I will dive into the reasons why AI, when used in conjunction with expertise from radiologists, creates the greatest overall benefit to the entire health system.

The output of a situation is central from a utilitarianism lens, with less emphasis on input or motivation for the desired outcome (Chukwuneke & Ezenwugo, 2022). When a patient undergoes a diagnostic radiology procedure, the output they are seeking is a clear understanding of a diagnosis and next steps. The process by which this is achieved, however, is secondary in the utilitarian framework. While for years, board certified radiologists have undergone the task of analyzing by hand different radiological methods, including X-rays, CT scans, ultrasounds, and echocardiograms, the development of AI has proposed a potential for a greater level of accuracy and efficiency in analysis.

Success in healthcare, specifically in radiology, can be measured by the equation for Value-Based Healthcare, a concept introduced by Porter & Olmstead (2006), which divides the desired outcome by funding and resources required to achieve it. Through an analysis using this framework, Heller (2016) notes that radiology is structurally unique from other fields of medicine as the patient outcome of treatment can be further removed from the practice. The NCI Dictionary of Cancer Terms defines radiology as "the use of radiation or other imaging technologies to diagnose or treat disease," focusing on image analysis (NCI, 2011, n.p.). In diagnostic radiology, a diagnosis is generally followed by a transfer of the patient to another department for treatment. Heller (2016) argues that to support AI implementation, patient outcomes must improve through greater accuracy and speed.

Accuracy can be measured by comparing doctors directly with AI image processing models by having each complete the same diagnostic task. Madani et al. (2018) tested this by using an

AI image processing model on different standard echocardiographic views to measure accuracy in diagnosis. The model achieved a diagnosis accuracy level of 91.7%, compared to the average accuracy of 79.4% for board-certified echocardiographers classifying the same images. This significant improvement in accuracy suggests that AI implementation will improve diagnostic radiology by improving patient output, and potentially decreasing costs. From a utilitarianism perspective, an improvement in this Value-Based Healthcare equation supports the use of this technology. With any new technology, however, it is important to consider the major risks associated and making sure that they do not outweigh the benefits.

AI-Generated Errors and Security Threats

While this improvement in accuracy is promising, the processing and storage of huge amounts of healthcare-related image data introduces risks to reliability and security. Studies tested potential errors or bias in these models by attempting to trick physicians with model-generated images. In one study by Mirsky & Mahler (2019), AI-generated images with altered signs of lung cancer successfully fooled radiologists, with a 99.2% success rate for the images with cancer added and a 95.8% success rate for images with cancer removed. The false diagnosis was also confirmed by the model itself. This highlights the potential for harm to radiology, as a malicious hacker could alter thousands of images and the resulting diagnosis. Chu et al. (2020) cite this study in an opinion piece on the dangers of AI, noting that there have been nearly 3,000 breaches of medical records in the United States between 2010 and 2020; the risk of a widespread breach combined with malicious intent and the ability to infiltrate electronic medical records could be catastrophic. Although these breaches could reveal a critical vulnerability in AI systems, some may argue that the rate of development for risk prevention techniques equates that of the models themselves. If this technology continues to transform the digital framework of the

healthcare system, it is imperative that investments are also made into highly sophisticated security measures alongside AI.

AI as a Tool Rather than a Replacement

Another concern when considering the effect of AI implementation in diagnostic radiology is job displacement for radiologists. The evidence and data to fuel this concern, however, would have to prove that AI models, when used as an alternative to a trained radiologist, are both cheaper and more accurate in diagnosing different conditions. According to an article from MedPage Today (2024), these models are actually most effective when used in conjunction with a radiologist, allowing greater efficiency in work without displacing jobs. This article, however, only evaluates the state of the technology in the present at a more surface level, failing to assess the job displacement that could result from the continued improvement of these models beyond human capabilities. Nonetheless, the general assumption from healthcare personnel now is that the sophistication of AI models used in radiology is not yet, and not expected to be, enough to replace jobs entirely.

From the utilitarian perspective, if the implementation of AI models causes some displacement of trained radiologists in the distant future, this effect would not be great enough to outweigh the potential benefit of a cheaper, quicker, and more accurate diagnosis for patients. In hospitals, the number of patients greatly outnumbers the number of physicians, with peaks in the COVID-19 era of care estimated in a study by Bhatla & Ryskina (2020) to range from 13:1 to 18:1 patient-physician ratios. With these numbers alone, any improvement to patient outcome outweighs worsening of the job security for radiologists using a utilitarianism framework.

Balancing Innovation and Ethical Responsibility

Through these considerations, there are cases in which the implementation and continued development of AI models in diagnostic radiology can be deemed ethical and produce a greater overall benefit to the healthcare system than would be produced without the technology. This scenario, however, must include advanced techniques to prevent hacker infiltration in the event of a breach of electronic medical records. Federal regulation of the use of these models and clear guidelines for the handling and transfer of electronic medical records is a necessary next step to mitigate the risk that security breaches pose. With these precautions and the use of these AI models alongside radiologists, there is potential to make diagnosis cheaper, faster, and more accurate, providing patients with the information they need for next steps.

While utilitarianism considers the situation holistically, determining the greatest good for the greatest number of stakeholders, there are flaws in this framework, as it does not consider the experience of the minority of stakeholders. The use of other ethical frameworks is necessary to make an informed suggestion for the future of radiology. Focusing more on the human relationship between players, the physician and patient in this case, the ethics of care considers how to optimize this relationship, an important contrast from a more external perspective.

Ethics of Care in Medical Decision-Making

The ethics of care is a lens in which to view a situation through the value of the relationship between individual stakeholders, as opposed to relying on external logic and reason like in utilitarianism. Ethics of care is described by D'Olimpio (2019), a professor of philosophy, as an ethical approach that is more rooted in feminism. She argues that other theories do not place as heavy emphasis on values and virtues that are often described to be feminine, such as compassion and empathy. This, however, could be a limiting definition to claim that values of compassion and care are pertaining only to women. In contrast, Kwan (2023), an assistant

professor of philosophy, argues that the ethics of care is simply centered around the relationships between people and the impact they have on decision making, tailoring each ethical issue to the dynamics of the conflict. From a healthcare perspective, Maio (2018), a professor specializing in medical ethics, argues that complex scenarios in medicine cannot be solved using abstract principles that are far removed from the situation at hand. In my argument to follow, these interpretations are used to highlight the importance of complexities within relationships, outweighing universal moral rules.

Impact of AI on Patient-Physician Communication

A key concern for the use of AI in medicine is the impact on the quality of patient-physician communication. This debate extends beyond healthcare, with leaders in industries like customer service questioning whether the efficiency of AI is worth sacrificing the value of human-to-human interaction. Ori Faran (2024), the CEO of an AI customer service platform, notes that 81% of customers prefer a delayed response from live agents over instant chatbot replies. In medicine, however, communication errors can be life threatening. O'Daniel & Rosenstein (2008) argue in their research of the communication within hospitals that unclear delivery of information can jeopardize patient safety.

The quality of patient-physician communication is a key factor when considering any moral quandary in healthcare through the care ethics framework. This element of healthcare can often be overlooked, as the focus for care is often physical healing rather than patient understanding. A qualitative observational study of patient-physician interactions conducted by Beckman & Frankel (1984) notes that in the initial interaction between patients and their physicians, it took an average of 18 seconds before the patient was interrupted by the physician. With the disparity

in knowledge of medical terms, it is imperative that physicians confirm the patient's comprehension of diagnosis before proceeding with a treatment plan.

One hope for the implementation of AI in radiology, specifically, is to improve the readability of patient education materials using well known AI models such as ChatGPT-4 and Google Gemini. One study conducted by Gupta et al. (2024) concludes that these models are not only able to reduce word count of the materials presented to patients, but also reduces the average reading level from the 11th grade level to the 7th grade level. This finding highlights a way in which AI can be used to strengthen patient-physician communication, but introduces new concerns relating to data privacy.

Data Privacy Concerns and HIPAA Implementation

While the care of patients in a clinical setting is of upmost importance, the conflict of the ownership of Electronic Medical Records (EMR) once reported to the system is a topic of frequent conflict in the world of ethics. This can be viewed from the ethics of care lens by assessing the importance of trust in a patient-physician relationship, and the consequences of breaking that trust. Chiruvella & Guddati (2021) note in their analysis of data ownership that the adoption of digitized files allowed for more efficient care, but at the risk of a breach in patient privacy.

The digitization of information allowed the ability to duplicate or share records to other parties without the consent of the patient, a concern that was addressed with the establishment of the Health Insurance Portability and Accountability Act (HIPAA) in 1996 (HHS, 2008). With the potential for radiology to adopt AI across the United States, there are increasing concerns regarding the training data used to develop these models. For developers planning to implement protected health information (PHI) into their AI models, there are current regulations set in place

that Mayover (2024), data privacy compliance expert, argues to be vague and non-specific steps to avoid HIPAA non-compliance. There is merit to this argument, as unintentional HIPAA violations by clinicians have occurred using external platforms such as Chat GPT to consolidate confidential patient notes, violating the trust established in the patient-physician relationship. This wave of accidental HIPAA violations is documented by Hetrick (2023) in an article discussing the data privacy risks associated with these platforms. The lack of transparency in the understanding of chatbots, leading to non-compliance, Hetrick argues, must be addressed through education, training, and a potential ban of chatbots on hospital networks.

The ambiguity of AI regulation in healthcare exists even on the developer side, where models can be built to keep information internal to hospitals. For developers to remain compliant with HIPAA, Mayover states that after de-identifying patient information, the developer must use "the minimum amount of PHI necessary for its intended purpose" (Mayover, 2024, n.p.). This, however, raises multiple questions. Who decides how much PHI is necessary, and what level of accuracy for the model is suitable in a healthcare setting? The emergence of AI and the use of this data to train models without clear guidelines or patient knowledge could erode the trust between patient-physician relationships.

The loss of trust in a patient-physician relationship, identified from an ethics of care framework, would have a macro-scale effect on the healthcare system if left unaddressed. However, if viewed from a utilitarian perspective, it could be argued that a minor breach in data or lack of transparency could not cause enough harm to the system if the ability to share mass amounts of data improves the quality of diagnosis for the majority of patients. The ethics of care is an essential perspective that allows policy makers to view ethical situations from the perspective of the individuals involved, highlighting the significance of the trust. Through this

lens, there are two main issues that must be addressed by legislators if AI is to continue to advance into the healthcare sphere: the transparency of the data used to train the AI models, and the handling of the data by physicians once these models are in use.

Healthcare Regulation Structure

The regulation of healthcare is a process that must evolve at the same rate at which lifesaving technologies are developed and implemented in hospitals. With the unprecedented advancements in AI over the last decade, it is more important than ever to ensure that the regulation of these technologies keeps up with the development. When a new device is developed with the intended use in hospitals, it must undergo the extremely long and comprehensive process of approval by the Food and Drug Administration (FDA). This is a process that some physicians and developers of new drugs and technology consider to be "subject to gaps, internal tensions, and conflicts of interest," yet still a necessary step to maintain the delicate balance of increasing access to new healthcare technologies to a wide population without sacrificing safety (Deyo, 2004, p.142). Adams (n.d.) on the tech development side, however, argues that the FDA deserves praise for its initiative to create accelerated approval processes for technology and medicine to be used for life threatening conditions that do not currently have effective therapeutic methods. Regardless of the public opinion on the FDA, the framework for an approval process must be expertly tailored to meet the criteria for the new technology developed.

Current State of Regulation

According to Palaniappan et al. (2024), there is currently no existing regulatory framework for the specific use of AI/ML (Artificial Intelligence/Machine Learning) in healthcare. Instead, the FDA uses existing regulatory framework for medical devices,

specifically the Software as a Medical Device (SaMD) classification (FDA, 2024). To categorize AI in healthcare simply under the umbrella of "software" does not account for the complexities of the technology and the considerations that are unique specifically to AI and ML, such as its ability to continuously learn and adapt even after approved for use.

To combat the shortcomings of this regulation framework, Harvey & Gowda (2020) note the FDA's proposal of an updated framework, specifically the Proposed Regulatory Framework for Modifications to AI/ML-based Software as a Medical Device. This proposal includes the ability to regulate the software even after its initial approval using Algorithm Change Protocols (ACPs), which enforce the establishment of methods used by the manufacturer of the AI/ML-based SaMD to control risks associated with expected adaptations to the algorithms (FDA, 2025). The language used in the proposal is vague enough to encompass these specific SaMD's in every avenue of healthcare, but whether the actual approval process is tailored to different fields of medicine and the unique risks in each cannot be determined from the document. While different AI/ML algorithms could be similar in structure and process, the risk setting of the field of healthcare in which they are implemented is arguably more important to consider than the technology itself.

AI in Diagnostic Radiology: Case Studies and Challenges

According to the Dell Medical School (2024), over 900 AI/ML-based SaMD's were approved by the FDA for use in the field of radiology between May and September of 2024. One example of a technology recently gaining FDA approval is qXR, an AI chest x-ray solution developed by Qure (2023). This technology, used in conjunction with a board-certified radiologist, improves the diagnostic accuracy of a range of conditions in emergency settings. In

fact, according to Qure, the image processing ability can provide a diagnosis in under 20 seconds.

AI technology with the ability to rapidly diagnose has been received well by physicians in some cases, as it allows them to direct focus towards other areas. The website of the product developer includes praise from Dr. Neil Roy, emphasizing the tools ability to "rapidly triage" by "alerting to critical pathology far before a radiologist… [has] time to review the film" (Qure, 2023, n.p.). The inclusion of this quote to market the technology ensures that it is not only appealing to patients, who would benefit from the increased accuracy and efficiency, but also to the radiologists. In fact, with this technology, physicians may experience a decrease in the negative effects caused by the current strain on diagnostic radiology due to high demand and low supply of physicians, an issue that Mirak et al. (2025) highlight in their concern for the growing shortage of radiologists nationwide. The device, and many others like it, proposes a win-win solution by helping radiologists meet public demand without causing worry of job displacement.

The Need for an Evolving Regulatory Framework

The control of AI/ML-based technology for use in healthcare systems is not only an issue of federal regulation through the FDA, but also through states. In fact, 20 bills across 12 different states have been proposed to regulate AI in different avenues of the healthcare system as recently as February 2025 (American College of Radiology, 2025). These bills target key risks and criticisms of AI and provide clear actionable steps to mitigate risks, rather than providing a vague description of potential solutions like in the FDA proposed regulatory framework.

One issue identified with the implementation of AI models for clinical use, argued previously under an ethics of care framework, is the lack of transparency in the early-stage development and continuous evolution of these models using training data. Unawareness of

where the training data originates has the potential to erode the trust of Americans in the healthcare system. To combat these issues, state legislators from both Maryland and Washington have introduced House Bill 823 and House Bill 1168, respectively, to enforce transparency to the public for the methods used to train AI/ML models. While the language differs slightly in each bill, they both aim to allow physicians and patients to gain a better understanding of this technology, an especially important consideration for radiology.

The second issue with the existing framework for AI/ML-based SaMD is the lack of instruction for the continued regulation of these devices as they evolve even after FDA approval is granted. Without methods in place to standardize the continued evolution of these devices, healthcare systems become vulnerable to privacy risks as medical records are exchanged between hospitals and device developers. Legislators from Michigan are attempting to address this with House Bill 4037, requiring the selection of a health information exchange to operate a health data utility as a standardized way to manage the exchanges of AI-based health data. If passed, this bill would prevent a breach of records and regulate the data used for the continuous training of these ML models, preventing bias, another consideration addressed by the New York Assembly Bill 3993, prohibiting discrimination through clinical algorithms.

The Future of AI and Radiology

The introduction of these bills is a positive step towards increased transparency and regulation in the use of AI/ML-based SaMD, but similar measures must be taken on the federal level to prevent disparities in the quality of care in hospitals based on region or state. Utilizing multiple ethical frameworks to determine potential cause and effect scenarios for different levels of regulation is essential to consider all affected stakeholders. To stay on track with the development of these models, investments must be made by developers into sophisticated risk

prevention techniques with required implementation through the FDA and HIPAA to prevent security breaches. Additionally, HIPAA and FDA guidelines must evolve to define and closely monitor the transparency of model development and maintenance, preventing the erosion of trust between the public and hospitals. Future research should involve the identification of any bias in models or a lack of comprehensive data available for underrepresented groups. Although there is no way to mitigate every risk associated with new technologies, these measures would help allow AI to advance and transform healthcare to improve efficiency and outcomes for all.

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