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The ethical considerations including inclusion and biases, data protection, and proper implementation among AI in radiology and potential implications

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ABSTRACT

Artificial intelligence (AI) has an enorgmoust potential to improve radiologic diagnostics, efficiency, and consistency, through implementation of evidence-based regulations is crucial to prevent ethical violations pertaining to patient privacy, data management, and diagnostic accuracy. Several key terms were searched on PubMed such as “Artificial Intelligence”, "COVID-19", “Ethics” and “Radiology”. Ultimately, 32 articles that were published from June 2016 - November 2020 were included in our review given their presentation of original information and relevance to clinical AI imaging and ethics. Several themes appeared and allowed for the following recommendations: 1. Protocols explaining how patient data will be utilized should be provided to and implemented by providers. 2. Differences in data regulations among industry partners must be considered for successful implementation of AI in radiology, and protections against entities with a financial interest in patient data must be included. 3. Providers should receive education and training on basic AI algorithm methodology to allow them to explain risks to patients and obtain informed consent. 4. Radiologists and AI programmers should work together to allow for feedback, collaboration, and the development of more clinically impactful and ethical AI applications. We conclude by recommending collaboration between providers and programmers with a focus on existing AI platforms over developing new algorithms, as there is a lack of consensus on the proper applications of and regulations needed for already existing technologies. Future research should examine and aim to addressimplicit biases in AI technologies.

1. Introduction

Artificial intelligence (AI) is a branch of computer science where machines simulate intelligent human behavior. Machine Learning (ML) is an application of AI and is defined as the process of teaching a computer system how to make accurate predictions when provided with data. Deep learning (DL) is a branch of ML that uses multiple neural network layers to produce higher-level outputs, or predictions, from lower level inputs [1–4]. Computer-aided diagnosis (CAD), including image processing, was used prior to AI to aid in image-based diagnosis including cancer detection [1]. Unlike CAD that only aids in detection,

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Abbreviations

Artificial intelligence (AI)
Machine learning (ML)
computer-aided diagnosis (CAD)
Deep Learning (DL)
Supervised Learning (SL)

AI has the suggested potential to be diagnostic, with AI analysis of orthopedic radiographs comparable to senior orthopedic surgeons [5,6]. However, limitations remain as some uncommon or rare conditions in chest radiographs or computerized tomography (CT) scans may be detectable by radiologists but not represented in datasets. Therefore, they may go undetectable by AI [5,6].

Since AI applications can make predictions independently of human supervision, it is necessary to formulate appropriate indications/applications of AI, rigorously test these systems, and develop optimal health protocols. Finally, there is a need for preventive measures towards biases in AI training data [7–10]. This review will focus on ethical issues of AI and how physicians should approach the ethics of using AI in clinical practive.

2. Materials and methods

2.1. Data sources and searches

PubMed was searched for articles published between November 11, 2011, and November 15, 2020. Two sets of keywords were used. The first set included ("Artificial Intelligence" or "Machine Learning" or "Deep Learning" or "Supervised Learning") and "Ethics" and ("Radiology" or "Imaging"), n = 365, and the second set included ("Artificial Intelligence" or "Machine Learning" or "Deep Learning" or "Supervised Learning" or "AI or "ML") and ("COVID-19" or "Coronavirus") and ("Radiology" or "Imaging" or "CT"), n = 111.

2.2. Study selection and quality assessment

After screening out several dozen books as well as documents (n = 73), the remaining articles were evaluated based on the use of keywords in the abstract and/or title. Of these, the exclusion criteria included articles with a broad scope and minimal focus on ethical discussions and articles that presented a primary focus on mathematical concepts or technical issues with AI; articles that did not prioritize clinical implications or were not directly related to our review topic were excluded. Ultimately, 365 articles were excluded [Fig. 1].

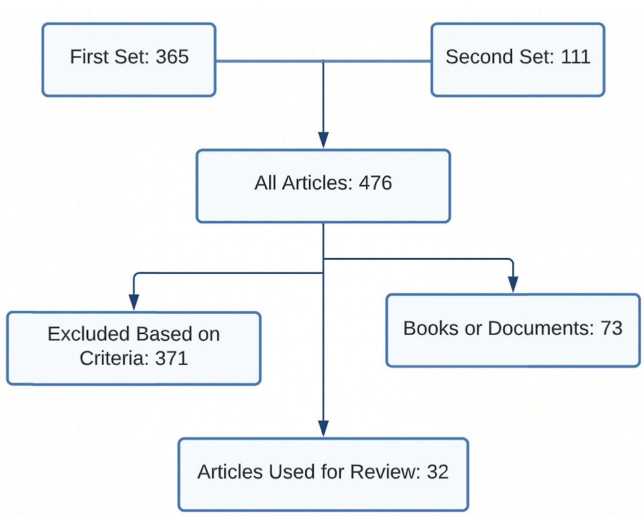

Fig. 1. Flow chart demonstrating study selection and quality assessment.

2.3. Data synthesis and analysis

In this review, we focused on articles that evaluated the use of AI in guiding diagnosis, and the associated benefits and drawbacks. Ethical guidance, clinical implications, current regulations, expert opinions, and clinical studies involving imaging and AI were summarized in short passages. These summaries were sorted into categories, and several themes emerged – sources of bias in ML training, data protection, proper clinical implementation, and AI application in emergency medicine, including COVID-19. These themes created a cohesive look at current AI use in imaging. Guidance for providers was emphasized.

3. Results

3.1. Sources of bias in ML training

AI may experience distributional shift issues, where it struggles to diagnose patients with cases it has not seen before, making it vulnerable to bias [4]. AI suffers from the "frame problem," which essentially means there is a risk of AI applications that are out-of-context to yield inaccuracies given their a underlying assumptions are only accurate in context [11]. For example, AI faces challenges when working with different races and genders [12]. Facial recognition software has had difficulty with those of different races, which could be a result of poor representation in the population used to train the AI [12]. ML requires high quality images in order to produce accurate segmentation in training and perform well in clinical practice. Inconsistent imaging artifacts between different samples or data-points can both vary and introduce biases into the algorithm. Imaging artifacts and poor imaging quality can lead to misinterpretations when algorithms are used in clinical diagnostic settings [11,13]. Data processing experts and radiologists are important in ensuring the success of AI implementation in clinical practice [13]. However, human involvement can introduce human bias into AI algorithms [14] during data selection, segmentation, training, and even at the time of implementation if the appropriate patient population is not selected. Biases can also arise from the overrepresentation of underlying comorbidities or differences in hospital imagining protocols or methods [14]. A potential way to reduce bias is to view AI via the philosophical perspective known as relational ethics, which is guided by four core principles of mutual respect, embodied knowledge, environment and uncertainty [15]. Reflecting on data science and ML as activities that create, alter, and support the social environment is required initially when reflecting on AI use in relational terms [15]. The anticipated increase in deep learning applications in the radiology field [16], will require physician's who are equipped to acknowledge, identify and engage in ethical actions with relation to AI.

3.2. Data protection

AI programs need training with accurately labeled data to yield accurate AI-derived conclusions. There are many ethical considerations with providing commercial access to patient data. It is important to protect patient privacy and prevent unethical data use [14]. Information from radiologic images may contain sensitive patient data, creating a need for clinicians to safeguard such data [17,18]. This should be kept in mind during all steps of developing AI algorithms, as the dignity and privacy of patients should be respected [14]. In addition, it is important for algorithms to demonstrate validity, reliability, and transparency [14]. The industry vendor should be able to clearly state who will own, access, share, and monitor patient data to ensure privacy will be protected [19]. It is important to obtain clear, documented, informed consent from patients, such as in research studies, as opposed to consent language being contained to the terms and conditions [19].

3.3. Proper implementation

AI research historically has not had the same oversight as other more tightly regulated investigational research studies, typically not needing IRB approval [19]. Additionally, start-ups and technology companies may not have the clinical knowledge needed to assess the clinical utility and benefit of implementing AI into clinics. It is important then for providers to actively investigate patient risks after AI implementation, check if testing data reflects the targeted clinical cohort and the general population and understand processes to monitor AI accuracy [14]. It is also essential to use AI applications in conjunction with a comprehensive overview of a patient's health history and treatment [20,21]. Consistent quality control and quality assurance processes must be in place after implementation of AI based algorithm to assess the impact on patient safety and healthcare quality [11,14].

Humans also experience automation bias, or a likelihood to automatically agree with technology-based suggestions despite contrary data [8]. In oncological radiology, some evidence has demonstrated a risk for human providers to over-diagnose malignancies in cases where AI programs may not [22]. Given patient safety is a priority of the clinician, great attention must be placed on AI algorithms to avoid False Positives that may cause harm to the patient [4]. It is also important that patients are not excluded due to access to technology barriers. It has been demonstrated that vulnerable populations require additional protections regarding sharing of patient data [9]. It is important to note that lower socioeconomic classes have had an increased likelihood of receiving care involving automated decision making tools as compared to patients from higher socioeconomic backgrounds [12]. This is especially concerning given that training data is not reflective of minority patients . Caution should be used when applying clinical ML algorithms to such populations as this might affect outcomes in an unpredictable, potentially harmful manner [14,23].

3.4. AI ethics during emergency situations and COVID-19

Emergency medicine has used AI systems and research to assist in reducing wait times. In addition, emergency medicine departments have also used AI to aid in triaging and treating patients more efficiently so as not to miss patients with more urgent presentations [24]. There are now techniques for surveillance, triage, prediction and quantification in AI applications for imaging acute strokes [25]. Great efforts have been made to utilize AI technologies in aiding in emergency room triage given the significant workload involved in the process. This has been done by completing AI-assisted reviews of images for patients with acute conditions like pulmonary embolisms, strokes, and embolisms [26–28]. There has been use of this application in intracranial hemorrhage (ICH) detection where the radiologist receives a notification when AI determines the presence of an ICH [27]. The application of AI in this situation an initial scan and not the final diagnosis, allowing for the Food and Drug Administration (FDA) approval process to run more effectively [26].

While there have been positive results, specifically in predicting outcomes of pediatric patients, the authors of these papers acknowledge that there is potential for selection bias in multiple steps of the process [24,29,30]. In a study demonstrating the use of AI in triaging for acute stroke care, previous provider's medical decisions included in training data allowed for implicit biases to be included and propogated in the algorithm [29]. However, researchers are able to identify these biases, which is the first step in the process of improvement [30].

Given the tremendous strain on our healthcare systems brought on by the COVID-19 pandemic, researchers have sought to detect imaging findings consistent with COVID pneumonia using a combination of AI and chest CT [31]. Researchers created a deep learning neural network (COVNet) to extract visual structures from volumetric chest CT exams, though the model was not very interpretable nor transparent [32]. The Italian Society of Medical and Interventional Radiology has published AI research to determine prognosis and predict outcomes; it does not encourage CT used with AI as a screening tool [33]. Its guidelines note that chest CT in general cannot replace nose swabs, as CT has low specificity for COVID-19 [33]. Given a lack of transparency in AI algorithms and the inconsistencies in the resulting clinical interpretations, AI algorithms currently come with a myriad of ethical considerations before their proper clinical implementations. Given these ethical and medico-legal implications, it is still too early to apply AI technology in clinical practice as a first-line modality despite this emergent situation.

3.5. Current and emerging trends in ethics of radiology AI

In recent times, there has been an increase in the use of AI across the world and with that brings changes in the understanding of AI by physicians as well as ethical standards and opinions related to ethics [34,35]. Even if there is strong understanding of AI by physicians it can be difficult to explain its use to patients [35,36,37]. In addition, there is progress in the legal aspect of AI in radiology as to who takes responsibility for the AI and what AI training is required for residents [37–39].

4. Discussion

Ensuring data is secure is essential to protecting patients. Digital health technologies may not be as strictly regulated as in the clinical research space. It is vital that AI programs used in patient treatment first undergo significant testing in the clinical setting before more broad hospital uses to avoid AI errors that can impact patient care [19]. The involvement of large technology companies interfacing with healthcare professionals can make regulation more difficult, especially determining cases of data ownership and the regulation of that data. It must be clear who owns, has access, shares, and monitors the patient data to ensure privacy is protected [19]. In a practical sense, training AI requires a lot of patient data, more pertinently, the data provided would likely come from the community it will be used in [30]. Having providers partnering with algorithm developers to develop a safe and secure data storage system in addition to validating results would be a good safeguard.

Research to assess a product's effectiveness is variable in terms of standards and methods, and may not align with current clinical practice. Providers priorities is safety, and ML algorithms need to be weighted similarly towards safety [4]. Introducing AI can provide an advantage by making decisions based on subtle data variations that humans may not detect [8]. Implementation of an autonomous AI based system in populations without access to care, automation bias risks may occur more often, as there may not be a radiologist present to oversee AI [8]. As AI algorithms can sometimes be proprietary, health disparities could be worsened in places without the means to aquire AI, especially in smaller, rural hospitals orhospitals serving disadvantaged populations. There may also be a lack of transparency as proprietary algorithms are privately owned. It may be unclear whehter the training data was accurate and representative and if the ethical guidelines of human subject research were met [19].

Major social changes have historically harmed the most vulnerable communities, and we must ensure potential harms are not made worse by unethical distribution [9]. There are cross-discipline challenges, as clinical AI technology requires multidisciplinary knowledge [9]. Tech companies may not understand clinical practice, and physicians may not have full confidence in AI algorithm's suggestions particularly if systems lack transparency [9]. Institutional Review Boards (IRBs) may not be able to regulate this new technology appropriately due to a lack of understanding while data scientists may not have clinical ethics training [9]. A critical mistake would be utilizing a ML system that is not well understood, as it can be applied to cases with unintended consequences

[4]. There have been occurrences of this happening in municipalities; patients believed that they were participating in something that is beneficial to their health yet were unaware the company had ownership of their patient data [9]. Another example is the application of an AI based system for healthcare screening among minority populations where training data for the system came from a majority population [9].

AI use in clinical settings requires transparency. In the case of an adverse outcome from AI decision making, it is important to understand how the algorithm produced its result. One challenge with AI programs such as DL is an inherent issue with interpretability. On the other hand, transparent models may be vulnerable to security issues [14], such as data leaks. [14].

Issues with AI applications in radiology does not only tinclude already present socioeconomic health disparities and gender bias in traditional care settings, but it also includes the selection and relational inductive biases that can come from human diagnostic patterns [7]. It's important that efforts are made not to replicate errors made in the traditional clinical setting under an AI-based imaging setting. [6]. If such algorithms are applied to large populations e.g., in the setting of screening, the propagation of bias can become a huge healthcare problem.

Gender and racial biases may be transferred to AI algorithms[40]. Black patients have been shown to be underdiagnosed with occult hypoxemia due to pulse oximetry readings overestimating oxygen saturation in non-white patients [40]. Female patients also face disparity in care when looking at myocardial infarction diagnosis, as much of the data used in studies is based on male patient's who present with different symptoms [40]. In a clinical setting the implementation of an AI system trained with data from a single hospital or multiple hospitals, has had difficulty with generalizability [41]. If the AI was unable to accurately detect pneumonia in a new population after reviewing thousands of scans [41], it could prove difficult for an AI system trained in a largely white population to be used effectively in a more diversely population. In addition to clinical biases, social biases relating to socioeconomic status can also play a role. It has been seen that AI recommended less visits for black patients due to health costs, rather than the health needs of the patient [42].

AI algorithms require massive and accurately labeled datasets to train and learn from, but marginalized populations are often misrepresented or lacking in existing datasets. For example, if an AI system is trained in a population with a high incidence of drug seeking behavior but then is used in an elderly patient population with chronic pain, there is a possibility that the AI will not recommend providing the patients with pain medication. It is important the dataset use in AI accurately represents the population it is being implemented in, otherwise there is a possibility of misdiagnosis and potentially harmful outcomes [14,23,43].

Alternatively, there has been discussion on the concept of physicians working alongside AI, termed "AI-assistance." AI-assistance is AI used in a limited supervised capacity to help improve the workflow of physicians in clinical diagnosis and patient management. This has shown promising results in other fields such as pathology [44] in addition to radiology [30,45,46]. Researchers working on CT angiograms were able to produce an AI system that could detect cerebral aneurysms. However, the group still noted that the AI-assistance was not capable of being used widely due to the selection of a small local population used from data and sample collection to train the system [45]. Another group was able to take a step further in AI-assistance, creating AI that was able to detect active TB in patients based on chest x-ray scans and showed a small but statistically significant improvement when using AI-assistance in detecting positive cases [46]. The AI had an even larger improvement in diagnosing cases of pathologies being present but had poor specificity [46].

Deep learning shows promise for aiding in diagnosis. AI-driven software used in stroke diagnostics have been shown recently to be accurate and improve treatment times [6]. In a study by Matsoukas et al. (2022), an AI software engine was used to analyze potential large vessel occlusions (LVO) undergoing computed tomography angiography (CTA). The software demonstrated high sensitivity and negative predictive value (NPV) as a stroke triage tool for certain LVOs [6]. It was shown to be a useful adjunct in triaging patients with a LVO stroke. Also, there's uncertainty over the extent to which diagnosticians will have power over AI-assisted or conducted tests. Will most of the diagnostics be conducted under the discretion of the practitioner? Does each system need to be approved by a legislative body? Efforts to develop protocols for ethics and practice in radiology are needed prior to implementation.

4.1. Limitations

There was limited research about the implementation of AI in healthcare, with many articles focusing on theory. [47]. In addition, few studies addressed how patients felt about AI being a possible part of their care decisions [48–50].

Responsibility for AI misdiagnoses is an uncertain area and for this reason, healthcare systems should not implement AI without clinical oversight [14,51]. There is a further need to explore this ethical consideration in AI, as there is limited information at the time of this review. This limitation has been brought to light by the COVID-19 pandemic as healthcare providers look to use AI models for clinical diagnosis. Despite encouraging results with AI models, small sample sizes and potential selection bias pose limitations [31]. Patient data in the training and test set are from the same hospital, making it challenging to identify issues regarding calibration with other hospitals [31], inherent biases based on a small sample size, lack of heterogeneity of the training model and difficulty of generalization to larger populations. It is essential that diversity of the dataset be considered prior to clinical implementation.

5. Conclusion

For healthcare workers to provide high quality standard of care, they must fully understand possible negative implications in event of premature AI implementation in the medical practice. This review aims to bridge the gap between physicians and programmers. The aim is to teach providers about concepts regarding ethical considerations in imaging AI and to share potential pitfalls that providers should be cognizant of in practice.

Ethics approval

Not applicable.

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Author statement

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Consent

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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