Adapting to the Age of Data-Driven Medicine: Analysis of Healthcare Systems on the Deployment of Artificial Intelligence in Medical Imaging

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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

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Introduction

Due to the endless possibilities for its applications, artificial intelligence (AI) and machine learning (ML) are under the focus of intense scientific, business, and governmental interest. The number of global publications in AI have increased 6-fold over the past 20 years to more than 60,000 per year. Additionally, the global AI market is growing by 40-50% each year, and is projected to exceed $300 billion by 2025.(Harrison et al., 2021) Amongst all major industries however, medicine and healthcare are the most difficult yet important domains of application for AI and ML. Modeling the complexity of individual patient's health patterns, tailoring medical decisions and care, and providing accurate predictions of a patient's clinical outcomes is a difficult yet necessary path towards reaching the upcoming gold standard of personalized, data-driven medicine.(Harrison et al., 2021)

AI and ML tools are especially vital in the field of medical imaging, which is being overwhelmed with the ever increasing amount of complex and rich data that is being collected to make medical diagnoses and clinical decisions. Medical imaging consists of various technologies that are used to view the location and function of the human body in order to diagnose, monitor, and treat medical conditions. AI and ML are currently being researched and integrated into these technologies by automating image analysis; aiding in disease detection, classification, and localization; and facilitating informed and efficient decision-making.(Langlotz et al., 2019) Although the development of these AI and ML tools is occurring at a rapid rate, the healthcare system has yet to fully apply and adapt to the AI/ML-based medical imaging devices. Deployment of these technologies in the modern healthcare system is proving to be extremely difficult due to the lack of infrastructure needed to handle the technologies' disruptive effects on information processing and management. The complexity and lack of understanding for these technologies by doctors and patients also leaves them distrustful of the ability of the medical imaging tools to provide accurate information and make decisions that impact patient health and care.(Spatharou et al., 2020) With an expected standard of use set by other industries on the application of artificial intelligence, a lack of AI/ML-based medical imaging tools will leave the healthcare industry behind and labeled as relatively inefficient and backwards. This paper aims to understand and analyze the problems faced by healthcare systems and its constituents in the deployment of AI/ML-based medical imaging applications while providing insights into the steps which need to be taken to successfully deploy these technologies and adapt to the new age of data-driven medicine.

Background

Artificial intelligence (AI) and machine learning (ML) are rapidly growing technologies used to handle the enormous amounts of information that is available today. Established by Alan Turing in the mid-20th century, artificial intelligence is a field of computer science focused on enabling computers to behave in ways that are similar to those exhibited by humans and are considered intelligent.(Langlotz et al., 2019) While replicating all human behavior is not realistic in the foreseeable future, current AI systems aim to assist humans in specific tasks within a defined context. Machine learning is a more popular form of artificial intelligence applied to systems today, allowing computers to learn how to complete a task successfully based on positive and negative feedback from the data and the environment. When used to its highest capabilities, AI and ML can be used to tackle complex tasks that may be extremely time-consuming or difficult to solve by humans alone.(Pesapane et al., 2018)

AI and ML are currently being applied to solve a variety of complex problems in the field of medical imaging with the ultimate goal of improving patient outcomes. Novel image reconstruction and enhancement methods are developed using AI to produce higher quality images from lower resolution source data obtained from the imaging device. Machine learning and deep learning classifiers are designed and trained on complex medical image datasets consisting of high resolution, 3D, 4D, multimodal, and multichannel data to automatically detect and identify clinically relevant features that indicate a specific pathologic state. Improved pattern-recognition methods across data obtained from different parameters and sources lead to rapid image processing and analyses that would increase support for clinical decision making.(Langlotz et al., 2019) The AI/ML tools are then packaged into a software to be automated and integrated into the patient's electronic health records in order to increase the efficiency and efficacy of healthcare, while reducing the rate of medical errors and making better use of hospital resources. These AI/ML-based medical imaging software show considerable promise in improving the accuracy of medical diagnoses, reducing reporting time and costs, and increasing the productivity of radiologists once they are successfully deployed in practice.(Gerke et al., 2020)

While research and development of AI/ML software is flourishing, its deployment in current healthcare systems is occurring at a much slower pace with few guarantees for its safety and effectiveness. In 2020, more than 600 papers on machine learning and artificial intelligence were published in PubMed Radiology; however, there were only 21 AI/ML based medical imaging devices and software approved by the Food and Drug Administration (FDA).(Benjamens et al., 2020) There is a stark contrast between the research and deployment of these medical technologies. Additionally, the FDA has only recently begun developing a modernized regulatory framework for AI/ML-based software, suggesting that few of the technologies which are currently deployed meet the expected levels of regulation and rigorous quality control required for medical applications. Minimal reports exist on the true reality of the benefits and costs associated with the utilization of AI/ML algorithms in clinical practice. Prospective, longitudinal studies or randomized controlled trials on the application and utility of AI/ML software are rare to come by, which leaves significant questions on the performance and long-term benefits of currently deployed technologies.(Davenport & Kalakota, 2019)

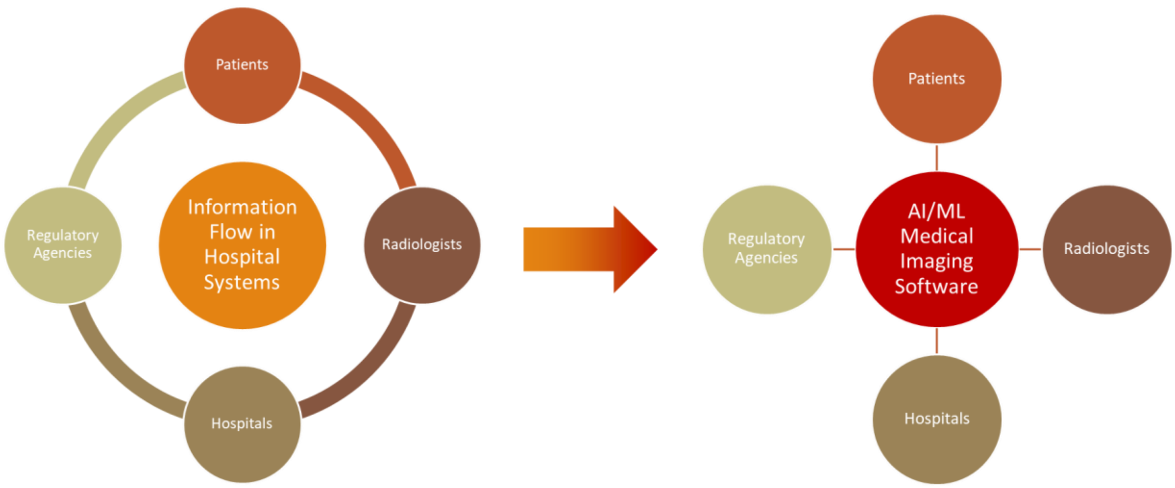
Methodology

The current state of the deployment of AI/ML-based medical imaging software must be further investigated and understood to make the incredible promise of data-driven medicine an achievable reality. Analysis of this state was conducted through the lens of the Actor-Network Theory (ANT) framework. This theory studies the associations and socio-technical connections between actors, which can be either human or non-human, in the form of a complex, modularized network. ANT constructs a heterogeneous network of actors that allows one to discover intricate relationships between social and technical entities. Also, the addition of actors and connections to a network can be used to open up black boxes that were previously less understood.(Cressman, 2009) However, a common criticism of this framework is that the network can become too complex and detailed such that it loses its ability to gain any insight on the system or technology. The choice of where to "cut the network", or decide which actors to include or exclude, is also difficult and often an uncertainty or arbitrary assumption of the framework.(McLean & Hassard, 2004) In order to overcome these criticisms, the scope of the network was limited to only the key constituents which directly interact with medical imaging technologies.

First, the structure of the actor network was established without the addition of the AI/ML-based medical image software technologies. Specifically, network analysis was used to understand how the different actors of the healthcare system including radiologists, patients, hospitals, and regulatory agencies connect with each other based on related to healthcare information flow and medical imaging (Figure 1). Analyzing how healthcare systems handle data collection, processing, management, and privacy presents a systematic method to understand the changes caused by the introduction of artificial intelligence in medical imaging technologies and data. A combination of keywords such as “medical imaging”, “hospital systems”, “data-driven medicine”, “medical data”, etc. were used to search for primary and secondary sources that describe each actor’s role in the information flow system. Once the actor network was established with all relevant information, further primary and secondary sources were used to identify and describe cases of AI/ML-based medical imaging tools that faced challenges in clinical deployment (Figure 1). The cases were analyzed for their effects on the generated actor network as the addition of this new technological actor created strains and challenges among or within other actors in the network. Having the information organized into a network aided significantly in discerning distinct effects and problems caused by the AI/ML tools on each of the relevant actors.(Cresswell et al., 2010) Potential solutions were then identified through further discourse analysis to reduce these strains in the actor network that would eventually allow healthcare systems to successfully integrate and deploy AI/ML software in the near future.

Figure 1

Methodology for the Construction and Analysis of the Actor Network for Healthcare Systems.



Note: The left diagram describes the analysis of the information flow in hospital systems amongst its four primary constituents. Next, AI/ML-based medical imaging software is introduced to the same actor network as shown in the right figure, and its effects are investigated further.

The Actor Network of the Healthcare System

In relation to medical imaging, the constituents of the healthcare system include radiologists, patients, hospitals, and regulatory agencies. Each actor plays a different and active role in managing the flow of medical and clinical information throughout the network. Patients act as the primary source of the clinical information and the primary determinant of how much medical information is available to be distributed through the network. Data collection consumes plentiful resources from the patient including their time, money, patience, trust, and even their health. For example, small doses of radiation can be delivered to the patient through X-ray machines and CT exams, which could lead to harmful effects on the body if the radiation begins to accumulate over time through multiple imaging scans.(Oren et al., 2020) A balance must be made between the need to reduce the cost of these resources and the need to obtain a thorough image of the patient’s medical profile to provide maximum care. Consequently, radiologists manage and limit their use of medical imaging technologies such that they have just enough information to diagnose and treat the patient’s disease and symptoms.(Giger, 2018)

Once the data is collected, whether it is from a form or through imaging technology, it must be processed and interpreted to make clinical decisions. Radiologists spend a significant portion of their role processing and analyzing images obtained from medical imaging tools to characterize and interpret the images for clinical diagnoses and care. The amount of imaging data is constantly increasing due to the possibility of identifying previously undetectable clinical findings with advancing technologies. Progress in radiology is causing it to move from a subjective perceptual skill to a more objective science.(Spatharou et al., 2020) Radiologists are often limited by their subjectivity as there can be variable interpretations between different subjects and by different radiologists. The routine detection, characterization and quantification tasks required for processing imaging data can often overwhelm and fatigue the radiologists, potentially pushing them away from their primary duties as clinicians, decision makers, and care-takers for the patient.(Pesapane et al., 2018)

Next, the data must be digitized, integrated, and stored in the hospital’s electronic health records system. Digitization is necessary to easily move clinical information through different departments of the hospital and to organize the information for easier access and functionality. In 2009, the Federal Trade Commission (FTC) was tasked with enforcing the Health Information Technology for Economic and Clinical Health Act (HITECH), a policy which encouraged and provided guidelines for the adoption of electronic health records and other health information technology.(McGraw & Mandl, 2021) As of 2017, 99% of hospitals have an electronic health records infrastructure, replacing the use of paper-based workflows and technologies (Mount-Campbell et al., 2020). However, electronic health records are just the tip of the iceberg towards a modernized, data-driven hospital system. Standardization and quality-control protocols for medical information is vital for successful health interoperability, yet it remains a major challenge for hospitals due to the lack of existing guidelines and regulations. Extensive amounts of patient-sensitive data have to be stored in the cloud, often sourced from expensive third-party vendors, or on hospital premises. Digital storage spaces have their own set of issues including network and security errors that can lead to the spread of misinformation, loss of access to patient data, and even disastrous breaches of patient privacy. Consequently, hospitals are approaching the digital shift with caution and restraint; yet they are determined to eventually reach a modernized, paperless healthcare system. (Kashaboina et al., 2021)

The HHS Office for Civil Rights (OCR) enforces the Health Insurance Portability and Accountability Act of 1966 (HIPAA) which provides a comprehensive set of protections and regulations for data inside the healthcare system. However, HIPAA struggles to regulate health-relevant data that is shared and sourced by other companies outside the healthcare system. An arrangement between Google and Ascension Health to improve data analytics for Ascension led to an uproar of public dissatisfaction, even though their contract complied with HIPAA regulations. Many doubt the ability of large technological companies to be trusted with health-relevant data given their previous lapses in protecting personal information, thus demanding for the reevaluation of HIPAA to be protective against such associations. The HITECH act attempted to improve these privacy concerns of HIPAA by requiring entities handling health-relevant data to report data breaches to the media and providing rules on how to disclose and transfer a patient's health information with or without their consent.(McGraw & Mandl, 2021) While a strong foundation has already been established by regulatory agencies and policies, the introduction of AI and ML in handling large-scale data such as medical images might just show the agencies' limits.

Challenges in Deploying AI/ML Medical Imaging Software

The insertion of AI/ML-based medical imaging technology into the actor network of the healthcare system revealed significant disruptions and novel relationships between and within each of the actors in relation to the flow of medical imaging information. These changes explain the specific challenges and benefits experienced in the current deployment of AI and ML in medical imaging technology. By revealing the exact problems and how they affect constituents of the healthcare system, concrete and methodological solutions were proposed that are more likely to be successful in improving the rate and quality of the deployment of AI/ML-based medical imaging software.

Patients

Patients act as both the primary input and ultimate output of the machine learning tools applied in medical imaging. While imaging datasets need to be substantially large to provide sufficient training data for ML models, they also need to be unbiased and representative of the patient population that is referred to the hospital for treatment. Often, clinical algorithms in development may score high in benchmarks, but perform poorly in real world scenarios as they are more accurate for certain patient subpopulations over others. Such biases have previously been demonstrated in various ML-based applications in chest X-rays, retinal imaging, brain imaging, histopathology, and dermatology.(Varoquaux & Cheplygina, 2022) Consequently, data collection methods need to be applied to all patients to ensure representative sampling when training ML-based medical imaging technology.

Similarly, the types of data that are collected need to be relevant to the clinical tasks that are feasible for current ML-based technology. In 2016, a large dataset consisting of lung cancer images was uploaded to the public data hub, Kaggle, garnering significant attention which led to a steep increase in the rate of publications in AI literature. However, the rate of lung cancer studies published in medical oncology related to medical imaging remained relatively constant, indicating that there was little use for the machine learning tools that were developed from the dataset.(Varoquaux & Cheplygina, 2022) Although the availability of datasets significantly influences which applications are studied more extensively, it is common for these applications to be unsuccessful due to the broadness and scope of the tasks that are being targeted. Researchers and healthcare professionals must aim to first design technologies that will be practical and successful when deployed in the physician's current workflow before collecting data specific to the development of the designed technology.

Lastly, ML/AI-based medical imaging technologies must be able to explain how they were able to make a clinical decision. Modern ML algorithms use deep learning methods that are often described as "black boxes", as its learning and decision-making mechanisms are close to impossible to understand and decipher. While these algorithms are extremely accurate in face of complex imaging data, their lack of explainability makes them infeasible for clinical deployment.(Yang et al., 2022) When AI systems are incorporated into decision making processes, doctors and patients alike need to understand how the decision-making technology operates and why a specific clinical decision is reached. Without an explanation, patients cannot place their trust in such technology when it is making clinically relevant and life-changing decisions for them. Researchers must promote the development and use of explainable AI (XAI) to increase transparency and interpretability of novel medical imaging software.(Holzinger et al., 2019)

Radiologists and Pathologists

Radiologists and pathologists are the primary health care providers affected by the new AI technology. Many of the current analytical tasks that were conducted by these doctors are being replaced by automated AI tools, thus causing them to adapt to their changing professional statuses and roles. Radiologists are now able to utilize these AI tools as assistants to process images faster and gain more insight into the patient's state of health while spending more time and cognitive ability into making and discussing clinical decisions with the patient. Overall, this will lead to better health outcomes for patients, an increase in doctor-patient interactions, and improved efficiency in providing treatments and care.(Spatharou et al., 2020) However, a higher efficiency and shift in roles might indicate that fewer radiologists will be needed to handle all the patients. Radiologists must be trained in computer science and machine learning to better understand the tools they are using. The role of the doctors must become more clinical, focusing more on interacting with patients than handling imaging data.(Pesapane et al., 2018) Doctors have to be ready to face these changes head on in order to meet the standards that will accompany the addition of such a disruptive technology.

Hospitals

The primary challenge AI/ML based medical imaging software could face in hospitals is with interoperability. These technologies rely heavily on data sourced from the hospital's electronic health records, and they need the hospital's computational resources to efficiently perform clinical and medical tasks. As such, hospitals will have to adapt rapidly and extensively to integrate the new software into their system to allow for easy transfer, storage, and processing of medical imaging data. They must also train healthcare professionals on how to use, interpret and maintain the new software as well. Hospitals might even have to hire data scientists and engineers in the future to act as skilled experts for the software. At the same time, the novel software must be generalized so that it can be incorporated into any hospital without significant modifications. Each hospital has its own set of protocols to store, organize and standardize data that may be different from the protocols of another hospital. The software must be able to efficiently find and manipulate the incoming data from the electronic records and adhere to hospital protocols when outputting its results.(Spatharou et al., 2020)

Regulatory Agencies

Regulatory agencies play an important role in managing standards, expectations, and guidelines for AI/ML-based medical imaging software so that patients and doctors can place their trust into these tools to make sound clinical decisions and provide reliable insights. As stated earlier, few AI/ML-based medical imaging technologies have been approved by the FDA. The first software, a cardiac ultrasound technology which uses AI to guide users, was only approved by the FDA in February of 2020.(Health, 2021) The primary difficulty that is encountered when regulating such technologies is that the AI and ML algorithms are generally built into products as a part of its software. Currently, the FDA and its sister regulators view such technology as a part of other devices and products and thus undergo regulatory processes that do not necessarily tackle the problems associated with AI and ML specifically.(Gerke et al., 2020) Fortunately, the FDA is working towards developing a regulatory framework to handle AI/ML-based medical software. An action plan for the implementation of such a framework was released in January 2021, in which a greater emphasis was placed in the system and lifecycle analysis of the technology both in its development and deployment phases.(Health, 2021)

Conclusion

Artificial intelligence and medical imaging-based medical imaging technology face several challenges in its deployment in the current healthcare system. By analyzing the actor network composed of patients, radiologists, hospitals, and regulatory agencies, this paper obtained significant insight into how these challenges affect the flow of information through the healthcare system. Additionally, several solutions were proposed to assist in overcoming the barriers in deployment which would increase the application of AI and ML in healthcare in the near future. Medical imaging is only the first step for this disruptive technology as there is tremendous potential for artificial intelligence to be applied to other sections of medicine and healthcare. Data-driven medicine will soon become a reality, improving people's health and lifestyles with personalized and efficient care.

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