Diagnostic Medical Imaging: En Route to AI-backed Future

Abstract
Technological advancements have made diagnostic medical imaging the de-facto standard for health screening and diagnosis with early and accurate results. In particular, diagnosis using AI techniques during the early stages of the clinical decision-making process is gaining importance¹ given its reliable and efficient results when compared with and validated by a radiologist. Conventional surgeries and/or biopsies that were treated as a prerequisite for the initial diagnosing of cancer-related conditions, are now being considered as the secondary step with the initial screening done by diagnostic medical imaging and in some cases AI diagnosis. AI is demonstrating advantages in early and accurate diagnosis that could have been missed by the radiologists. The future will see the integration and innovation of AI technology into intelligent diagnostic medical imaging systems.

However, despite new developments in the field of AI and machine learning with new CAD tools, there are many challenges with adoption and implementation in clinical environments. In this paper, we will elaborate on some of these challenges and discuss how to address them to embrace widespread AI-based diagnostic medical imaging.

Technology-powered evolution in diagnostic medical imaging

Diagnostic medical imaging technologies play a crucial role in clinical decision-making, a gold standard in accuracy with rapid diagnostic capabilities. With these non-invasive or minimally-invasive disease detection abilities, healthcare facilities and laboratories identify life-threatening diseases and underlying conditions at a much earlier stage allowing for early interventions with increased patient survival and reduced use of invasive diagnostic and treatment choices.

For instance, in X-ray radiology, advancements allow portable devices to use colors as cues to identify microfractures with great precision while wirelessly transmitting these images to a PACS infrastructure². Another example is AI-enabled tools that allow for the use of lower dosages of radiation during diagnostic studies improving patient-safe and cost-effective means of screening and treatment.

While innovations in this industry have reached a peak in image acquisition capacity, there is a massive need to manage image processing and insight derivation. Enter AI supported by deep learning. In the past four years, AI-based diagnostic medical imaging has opened new avenues for cost savings, better clinical decision-making, low exposure, and enhanced treatment efficacies³.

The Pennsylvania School of Medicine recently built an AI model that increased the accuracy in the detection of brain tumors by 99 percent. Similarly, at MIT’s AI lab, there is an ongoing study for the accurate classification of the different stages of breast cancer, with deep-learning-based CNN models. More than 60,000 digital mammograms are tested to train this mammographic imaging system. Further, AI also shows promise in identifying skeletal injuries and fractures, cardiovascular malformations, general cancer screening, and even neurological conditions.

However, the adoption of such AI-based diagnostic medical imaging tools by healthcare providers has been relatively slow owing to certain challenges. Let us look at some of the high-level hurdles that need immediate addressing.

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- **Regulatory Impediments**

  The rapidly evolving definition and application of healthcare regulations has slowed down the adoption of AI-based diagnostic medical imaging tools. There are several developments in how the US FDA approves AI for digital health and diagnostic medical imaging as clinical decision support, medical device data systems (MDDS), or diagnostic devices. Most medical device data systems (MDDS) devices come under Class I classification, whereas diagnostic devices come under Class III classification of the FDA, (Class I posing lower risks and Class III, higher risk to the patient), and take longer time to clear the approval process.

- **Slow Time to Market**

  AI-based diagnostic medical imaging devices have a longer journey to market entry due to the prolonged time it takes to build, design, and train these systems.

- **Prevailing Hesitation**

  The idea of delegating care delivery or clinical decision support independently to machines is something that most patients and physicians have yet to accept. While AI is already making headway into other industries, there is a gap to be bridged for adoption within the healthcare ecosystem.

- **Complex Image Processing Demands High-End Computing**

  In diagnostic medical imaging, the image data generated is in 3D, 4D, and higher dimensions, and this adds additional pressure on the existing infrastructure, like memory and processing systems. In order to manage the data effectively, the existing systems must be augmented and supported to handle the high volume and speed required from this data.

- **The AI ‘Black Box’**

  For many years now, whenever any revolutionary AI-based technology enters the market, it is accompanied by the ‘black-box’ tagline. This means that AI solutions, unlike other technologies, come with an obscure ‘under the hood’ section about how they work. This makes healthcare providers and laboratories hesitant to invest in an AI-based diagnostic medical imaging solution that isn’t transparent with how data and solutions are generated. There is also a fear around deep learning models lacking mathematical and theoretical foundations, which could lead to outcomes with false positives⁴. These ambiguities make it hard for consumers to decide which model had better quality results in better outcomes than the others models.
Boosting AI adoption

The path to widespread consumption of AI-based diagnostic medical imaging tools demands collaborative efforts from all stakeholders across the healthcare continuum. From regulatory authorities and device manufacturers to healthcare providers, physicians, and patients, it presents a case for prioritizing better healthcare outcomes. Here are some ways, we believe will help, the healthcare industry overcome skepticism and embrace intelligent imaging models.

First and foremost, standard legal policies and regulations have to be introduced globally within the healthcare ecosystem for acceptance and use of AI-related technologies. This means that new AI-related technologies have to be approved by internationally recognized global approval bodies.

The FDA has proposed a new regulatory framework⁵ to deploy and modify any new AI or ML solution. It proposes to analyze the benefits and risks through the framework in an iterative manner. Further, these regulations have to be adapted for improvement from time to time. The FDA expects commitment from manufacturers of AI and ML software/models to demonstrate transparency in the performance of their products considering patient safety as a crucial factor. The proposed framework enables FDA and manufacturers to evaluate and monitor the product together over time from pre-market development to post-market performance in delivered products.

Secondly, advancements in high-performance systems have overcome computational limitations. There are already systems that provide fast, reliable, and real-time AI-based outcomes, such as NVIDIA GPUs that provide a cloud-based platform for imaging and signal processing with deep-learning capabilities.

Cloud based AI solutions provide the ideal platform for huge data storage and computation, which is typical to medical imaging data. Moreover, cloud offers flexibility, agility, and scalability of imaging data from PACS onto virtual drives enabling the sharing, archiving, and transferring of information securely over the existing infrastructure.

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Future market trends

Over the next five years, the AI diagnostic medical imaging market is estimated to grow by 61% as per Roche’s market survey\(^6\).

It is believed that the Asia-Pacific AI diagnostic medical imaging market will witness an increased surge greater than the rest of the world, mainly due to increased investments in medical R&D, pharmaceutical, and bio-technology segments. Increased population and rise in patient number is also a reason for the surge.

Figure 1: AI Market growth in diagnostic medical imaging - Source - Roche Holding

Figure 2: Growth in AI market by Geography (2020-2025), Source Mordor Intelligence

\(^6\) Alan Alexander, Adam Jiang, AB, Cara Ferreira, Delphine Zurkiya, “An Intelligent Future for diagnostic medical imaging: A Market Outlook on Artificial Intelligence for diagnostic medical imaging”, American College of Radiology, 2019

\(^7\) https://www.mordorintelligence.com/industry-reports/ai-market-in-medical-imaging
AI models and systems are projected to reach a point of global maturity in the near future with full integration within the healthcare industry as models and technology achieve global acceptance.

**Conclusion**

With factors like additional financial investments and increasing performance pressure demanding both early and accurate diagnosis, it is only a matter of time before the barriers are overcome and AI and deep learning become essential components within diagnostic medical imaging.
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