

AI in Healthcare: Bridging the Gap between Research and Clinical Implementation

Srinivas Lanka¹

Consultant - Clinical Research,
Data Science & Data Engineering

Pavithra Madala²

University of North Carolina at Chapel Hill

Abstract:- Artificial intelligence (AI) has the potential to revolutionize healthcare by enhancing diagnostic accuracy, reducing administrative burdens, and providing personalized treatment. However, the slow adoption of AI in healthcare is due to obstacles associated with ethical considerations, data management, regulations, and technological capabilities. The results of our study highlight specific challenges related to ethics, technology, regulatory, social, economic, and workforce barriers that affect the implementation of AI in healthcare. We aim to improve current knowledge by providing a more comprehensive understanding, by bridging the gap, and addressing the barriers to implement AI in the healthcare sector.

Keywords:- Artificial Intelligence, Implementation Gap, Machine Learning, Barriers.

I. INTRODUCTION

Artificial intelligence (AI) has had a significant impact on patient care, medical diagnosis, and treatment outcomes. It can analyze data with/without human intervention. Its integration into the healthcare industry brought about a transformative paradigm shift. (1) Incorporating new and novel technological advances into clinical practice has led to many exciting medical developments over the last five decades. Among current areas of research, Artificial Intelligence (AI) stands out for capturing attention and imagination, with the potential to revolutionize every field. (2) AI systems offer a smart solution to reduce the workload of clinical staff within increasingly saturated healthcare systems. It is important to note that AI goes beyond simple data management, providing direct suggestions and recommendations that shape the clinical decision-making process. (3–5)

Artificial intelligence (AI) has seen remarkable growth in recent decades, expanding its capabilities and applications. In the summer 1956, McCarthy, and colleagues (6) introduced the concept of AI. Since then, rapid advancements in computational power, internet connectivity, digitalization, and cumulative knowledge have revitalized academic interest in AI across various industries. For example, within a year of its launch, OpenAI's Chat Generative Pre-Trained Transformer (ChatGPT) gathered over 1000 citations in the medical literature (7), showcasing the active interplay between AI innovation and academic research. Healthcare leaders are using emerging technologies like the Internet of

Things (IoT), cloud computing, and wearables, to improve patient experience, reduce costs, and enhance better health outcomes. (8) They aim to process and analyze large amounts of digital medical data accurately and efficiently to shift towards a value-based care model where personalized patient care is prioritized. (9,10)

Machine learning (ML) is a fundamental element of artificial intelligence (AI) that comprises, models capable of iterative learning. ML is becoming increasingly common in all major sectors, including healthcare. (11–13) It has significantly improved clinical data interpretation in radiology, pathology, and dermatology, thanks to convolutional neural networks, standardized data formats, and extensive repositories. (14)

Today, artificial intelligence (AI) is omnipresent, significantly more advanced, and user-friendly than it was two decades ago and has become a reliable part of our daily lives. Recently, there has been a noticeable increase in the implementation of AI in healthcare services. In AI, technological implementation typically involves developing software components to implementing an algorithm. (5)

We should also acknowledge that only a fraction of these algorithms is being utilized in practical clinical settings. Even a few esteemed medical centers with advanced technological capabilities are not embracing AI in their daily workflows. A recent assessment of Deep Learning (DL) applications using health record data emphasized the critical need to shift focus towards effectively implementing these models to have a direct, positive impact on clinical practice. The algorithms trained on historical data and published in the literature are not implemented in practical use. This research-implementation disconnect is a major reason AI is not deployed more in clinical settings. To make AI a healthcare reality, we need to bridge this gap. (15)

Multiple studies have looked at AI implementation in healthcare. Ali et al. (16) reviewed the integration of AI in health systems and the challenges in healthcare professionals' acceptance of AI. Petersson et al. (17) discussed AI adoption frameworks and highlighted the need for more understanding of AI acceptance among patients, health workers, and policymakers. Secinaro et al. (18) reviewed ethical challenges related to AI in healthcare, such as accountability, privacy, and transparency. The AI integration in healthcare presents opportunities and challenges for industry and academia. (10) Our study aims to understand the barriers inhibiting the

potential of AI implementation in healthcare. Extensive literature exists concerning the challenges and support for implementing AI in healthcare. (19–21) However, a significant portion of this body of knowledge is based on anecdotal evidence, narrative commentaries, small-scale studies, and reviews lacking empirical support. Consequently, our understanding of the contributing factors of AI implementation success in healthcare remains incomplete. (22)

In the subsequent sections of our paper, we will explore the fundamental aspects of the gaps and challenges associated with the implementation of AI in healthcare, using real-world experiences.

II. RESEARCH METHODOLOGY

This review was performed using specific keywords to search through scientific databases such as PubMed, Science Direct, Google Scholar, and Springer Link. A thorough examination of relevant studies was conducted. The keywords (“Artificial Intelligence,” “Implementations,” “Applications,” “Barriers”, “AI in healthcare”, etc.) were employed in various combinations to discover relevant material. The titles and abstracts were evaluated to verify that the papers focused specifically on the “Research gaps in AI,” “Implementations of AI in healthcare,” and, “Challenges in implementations of AI in healthcare” The review encompasses the data extracted from research papers, reviews, systematic reviews, debates, workshops, and conference papers published exclusively in the English language.

III. RESULTS AND DISCUSSION

Implementing AI-enabled tools in clinical settings has emphasized the need for ongoing monitoring and refinement of prediction models. (23–26) It is increasingly evident that there is a temporal decline in model accuracy across diverse clinical domains, despite the use of advanced AI algorithms. (27–30) The decrease in performance emphasizes the importance of ongoing improvement of AI-enabled tools, and their clinical efficacy in upholding user trust and safety in decision-making processes. (23,27,29,31,32) The performance of temporal models in real-time clinical settings has been largely unexplored, with most studies focusing on retrospective research data. (33) However, transitioning from research to real-time implementation can significantly impact the performance, as inputs and data availability changes. (34).

A. Aspects of AI model Design for Bridging the Gap between Research and Implementation as Identified by Literature Review

The long-term stability of any AI model performance raises concerns within health systems because of the absence of comprehensive guidance for implementing & post-implementation maintenance procedures. (35) When we observe the promising performance of an AI model during the development phase, it raises the question of why there is a disparity between this stage and the deployment phase. To resolve this implementation gap, we should redirect our focus from merely optimizing this area to encompass three crucial & practical aspects of model design: actionability, safety, and utility. (15) (Figure 1)

➤ Actionability

Clinicians or patients should be able to directly use the AI algorithm results to take specific actions. Machine learning models, though powerful, often lack clear follow-up actions, leading to uncertainty about the next step. De Fauw et al. conducted a deep learning optical coherence tomography scan interpretation study, in which they segmented the scan and categorized several disorders, then gave the clinician a straightforward recommendation. (36) To ensure user-friendliness, we must connect machine learning tools to clinical actions and easily implement them into the clinical environment. (37)

➤ Safety

Patient safety should be a fundamental concern in the design of medical AI models. The medical community is familiar with the rigorous regulatory process for testing new pharmaceutical or medical devices, but the safety of AI algorithms is a significant concern because of issues such as interpretability and external validity. (38) There is a lack of empirical evidence to demonstrate the safety and efficacy of algorithms in real-world settings. For widespread use, we need empirical validation for ongoing algorithmic and technical resilience. Model developers should engage with regulatory bodies and consider additional dimensions of patient safety, such as protecting against algorithmic bias and model brittleness. It is vital to involve clinicians and patients in the process to ensure the translation of algorithms into true clinical benefit. (39)

➤ Utility

The final step of any AI project should involve a cost-utility assessment. This assessment compares the impact of working with and without the algorithm, considering the clinical and financial outcomes of false positives and negatives. For instance, if we use an AI algorithm to screen Electronic Health Records (EHR) for undiagnosed cases of a rare disease like familial hypercholesterolemia, we need to weigh the cost and utility of early detection against the expenses and potential harm of false-positive cases and the costs associated with deploying & maintaining the algorithm. This model implementation necessitates an early and ongoing execution of this utility assessment. (40)

Actionability	Safety	Utility
• Using AI algorithm for specific clinical actions • Should provide clear guidelines through rule-based risk scores • The systems should ensure user-friendliness through easy integration into clinical environments.	• Patient safety is a crucial aspect • Empirical validation is needed for technical resilience • AI Model developers should engage with regulatory bodies to protect patient safety against algorithmic bias.	• Impact of algorithm use with and without the algorithm should be compared. • Clinical and financial outcomes of test results should be considered. • Early and ongoing utility assessment for AI model implementation is required.

Fig 1 Summary of Three Aspects of AI model Design for Bridging the Gap between Research and Implementation as Identified by Seneviratne et al. Paper (15)

B. The Gaps between Research and Implementation as Identified by Literature Review

In 2019, “Heart Flow” received FDA approval for its non-invasive, real-time, virtual modelling tool for coronary artery disease intervention. (41) However, FDA regulatory processes can impede the development of such AI systems. Comprehensive standards for approval processes will assist researchers and developers in meeting clearance requirements more quickly, decreasing delays and rejections of their applications. (42) The reporting standard presents a barrier to implementing AI research in practical settings. Many reviews have noted that studies creating prediction models for clinical use often lack transparent descriptions. This lack of transparency can lead to a lack of trust among patients and clinicians and may limit the use and replication of these findings. (43)

Healthcare organizations that lack AI-compatible technologies might bridge the technology gap by upgrading their existing systems to meet the integration criteria. The lack of technical knowledge hold back the use of AI in healthcare due to the gap among health professionals and the absence of requisite training. (44) It is important to understand the precise function of AI to reduce health professionals' reluctance to adapt. (45) Data management and security are critical components of AI integration, besides technological and human challenges. (46) Enabling AI in healthcare necessitates the availability of substantial amounts of medical data. Nevertheless, healthcare administration has the potential to address the privacy and security of medical data . (47) It is difficult for decision-makers to ensure the utmost level of protection while sharing medical data with AI developers and tech experts. The economic implications are another obstacle that health organizations face. Particularly in the public sector, healthcare organizations frequently endure

burdensome financial obligations. The costs of AI integration are significant and may include talent acquisition, technology infrastructure upgrades, software procurement, and training program implementation. This presents a substantial barrier to the incorporate AI in the healthcare sector. (10)

The development of laws and protocols helps AI researchers to effectively present their work. TRIPOD-AI and PROBAST-AI, are a couple of examples which provide guidelines and tools to minimize research waste. (48) It is important to design AI applications with clinical needs in mind to prevent research waste and align with clinicians' requirements, even when predicting multiple outcomes simultaneously. (43)

In a Japanese study conducted by Changhee Han (49) et al., their research team showed the clinically-relevant findings from their workshop by addressing three gaps between AI and Healthcare Sides. Their responses are presented below:

- *GAP 1: AI, including Deep Learning, provides unclear decision criteria, does it make physicians reluctant to use it for diagnosis in a clinical environment?*
- *Response on Healthcare side: "AI can aid in diagnosis but should not replace physicians. It can provide a second opinion by analyzing clinical data. However, its minimal explanation to persuade physicians and patients makes it difficult. Physician intervention is necessary for an intuitive explanation. Pursuing explainable AI may decrease diagnostic accuracy, so physicians should still be involved in making the final decision. Autonomous AI-based diagnosis without a physician is not the norm"*

- *Response on AI side:* "Deep Learning's explanations are not particularly poor compared to other systems or physicians. We might be setting excessively high standards for AI, promoting unnecessary anxiety. Verifying the reliability of AI's diagnoses against physicians could make an intuitive explanation optional"
- *GAP 2 :_ Are there any Benefits to Actually Introducing Medical AI?*
- *Response on Healthcare side:* "AI's high accuracy and convenience are commercially beneficial, especially in small clinics lacking CT or MR scanners, where physicians are desperately needed."
- *Response on AI side:* "Medical AI's commercial deployment is linked to diagnostic accuracy, making it profitable in upcoming years if it achieves outstanding accuracy"

➤ *GAP 3: Is medical AI's Diagnostic Accuracy Reliable?*

- *Response on Healthcare side:* "Assessing AI's diagnostic performance involves evaluating sensitivity, specificity, and inter-scanner variability, as well as assessing its suitability for clinical use"
- *Response on AI side:* "Research on medical AI is actively focusing on robust datasets to reduce the risk of overlooking diagnoses, prioritizing sensitivity over specificity unless imbalance is disrupted"

C. Barriers for Implementing AI in Healthcare

Additionally, the objective of this paper is also to identify and address the barriers that inhibit the healthcare sector from implementing artificial intelligence (AI). The expanding body of literature underscores the significance of investigating these challenges and offering scientifically based recommendations to facilitate the decision-making process. We reviewed many of the included studies focussing on various challenges associated with the deployment of AI in healthcare. Implementing AI effectively presents significant challenges, including ethical, technological, safety, regulatory, workforce, social, and economic barriers. (2,10) (Figure 2)

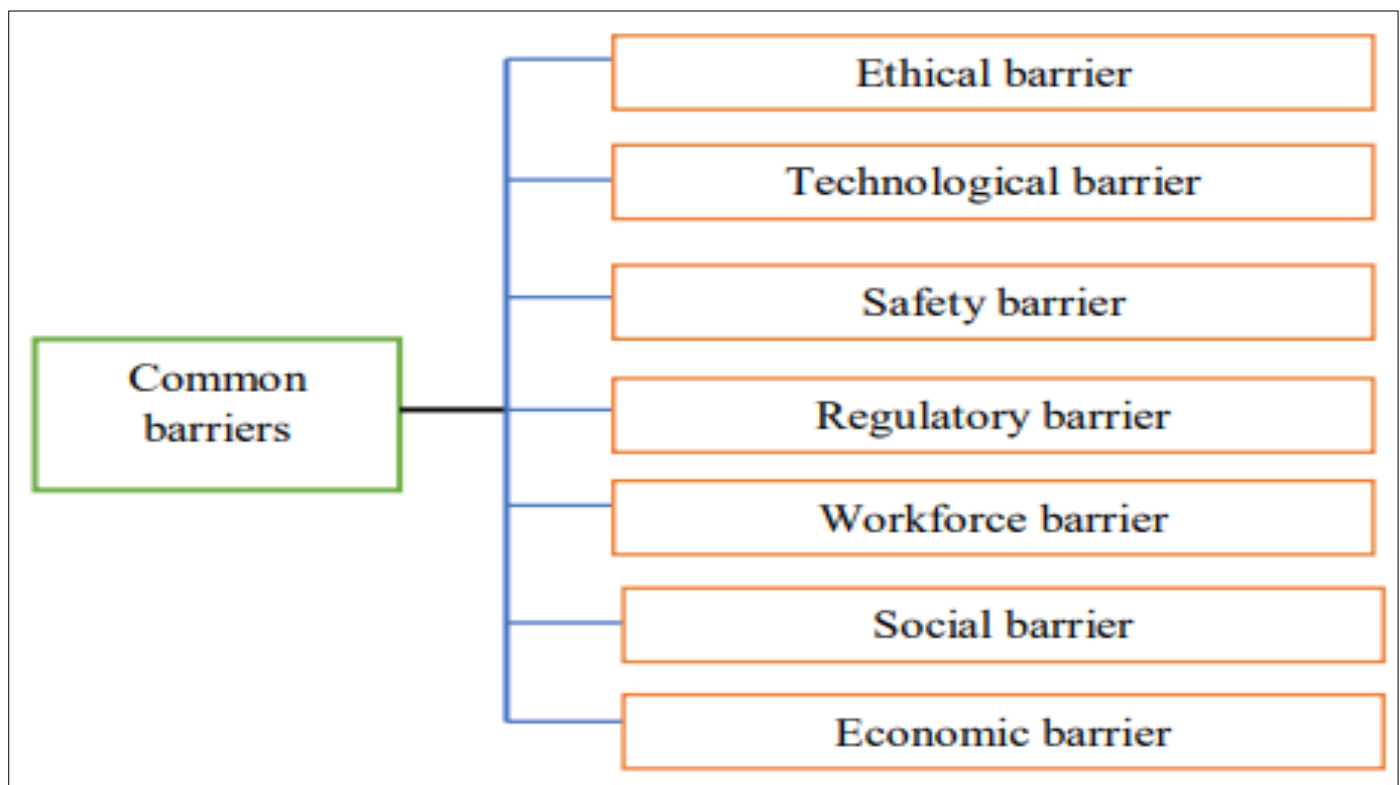


Fig 2 Common Barriers for Implementing AI in Healthcare

➤ *Ethical Barrier:*

Confidentiality, trust, consent, and conflicts of interest fall into the sub-units of ethical barrier. Developers need enormous datasets for training to create accurate AI systems, and there is a reasonable concern that this may violate patient confidentiality. (50) AI developers must inform patients about the fate of their data and obtain their consent for its use. Patients need to understand who can access their data, the

storage, and the security measures in place to protect their privacy. (51,52) He et al. recommended redefining patient confidentiality and data privacy terms as data sharing increases. (53) Healthcare AI implementation needs explicit governance that defines all stakeholders' data ownership. (44) Marcu et al. emphasized the necessity of data privacy regulations for secure data storage, usage, and sharing to protect confidential information. (54)

➤ *Technological Barriers:*

Integrating data in terms of accuracy, quality, and storage poses a big challenge. It is difficult to acquire and integrate large, diversified, high-quality data sets. (55). Health organizations can address some of such challenges internally, giving them control over the causes. For instance, IT infrastructure constraints, which are significant in developing nations, influence AI integration. (17) Upgrades to meet integration requirements can help healthcare businesses without AI-compatible systems to close this technology gap. (10)

➤ *Safety Barrier:*

We must carefully evaluate concerns about the impact on patient safety throughout clinical AI implementation. (56) Failure to address these safety concerns might severely impact AI implementation, causing patients and staff to lose trust. Patient safety must remain at the heart of AI for patient management and if any safety issues arise, especially for high-profile candidates, would immediately affect confidence in the technology and could inhibit its success. (2)

➤ *Regulatory Barrier:*

Whether regulations are in place or not, they can affect the implementation of AI in healthcare by both users and developers. Systems regulators must understand and trust the AIs used in their field to regulate effectively. Unfortunately, most current technologies lack transparency. (57) This major obstacle affects whether consumers and regulatory bodies are ready to trust an AI in clinical practice. The GDPR guidelines, which became effective in May 2018, define a comprehensive set of regulations for the governance of personal information. These regulations have a wide range of implications for AI implementation. (58)

➤ *Workforce Barriers:*

The healthcare workforce's education and training significantly impede AI adoption. The medical community's understanding of the potential and functionality of AI is still rudimentary, necessitating a significant measure for AI education and training. (59) We must address the challenges of differing levels of technical literacy, and comprehension of existing technologies before the workforce can become settled and competent in clinical practice. (60) However, the difficulties could intensify as physicians strive to integrate AI platforms while battling with current healthcare technologies. (47) Healthcare providers should specifically design training programs for physicians using AI systems and tailor these programs to address various concerns that arise when using unfamiliar technology. (61)

➤ *Social Barrier:*

Healthcare bias, which involves treating patients differently based on race, age, gender, or other factors, has the potential to exacerbate this gap. Therefore, any new technology must not contribute to social inequality but instead minimize healthcare system bias. Inequalities and biases in healthcare can limit AI implementation. Studies showed that social acceptance of AI models hinders deployment. Singh et al. argued that AI implementation identifies important performance indices and tracks return on investment to make healthcare more economical and efficient. (47) However, the 'black box' nature of AI limits its social acceptance, and it is unclear whether patients will accept a diagnosis from a computer instead of a clinician, especially if it is perceived to save time and money without clear evidence that quality has not been compromised. (2)

➤ *Economic Barrier:*

"Minimal funds. (Morris et al., 2023; Owoyemi et al., 2020), Unclear Return and Investment in funds (ROI). (Wolff et al., 2020), Development and maintenance charges. (Alnasser, 2023), and service-based reimbursements. (Alami et al., 2020)" can be counted as some of the economic barriers for implementing AI in healthcare. (10)

The success, elevated accuracy, and promise that AI is yielding in research are undeniable, despite its barriers. For this advancement to be most beneficial in the field of healthcare, it is essential to dismantle the barriers between AI research and clinical care. We can achieve this by implementing the discussed solutions and developing new ones. (43)

IV. CONCLUSION

The evolving theories, models, and frameworks in implementation science hold significant promise in advancing our grasp of AI implementation. This integrated approach, which harmonizes AI and implementation science, transcends the conventional limitations of each field. The fusion of these distinct yet complementary disciplines is indispensable for gaining valuable insights into the bridging the gap for implementation of AI in healthcare. This paper, while focusing on a general literature review, contributes to the literature on bridging the gap between research and implementation of AI in healthcare. However, further broadened research in this area could explore more extensive implementation of AI in healthcare.

ABBREVIATIONS

AI	Artificial Intelligence
ML	Machine Learning
CHADS-VASC	Congestive heart failure, Hypertension, Age, Diabetes mellitus, prior Stroke or TIA or thromboembolism - Vascular disease, Age, Sex category
ChatGPT	Chat Generative Pre-Trained Transformer
DL	Deep Learning
FDA	Food and Drug Administration

GDPR	General Data Protection regulation
IoT	Internet of Things
IT	Information Technology
NLP	Natural Language Processing
CNN	Convolutional Neural Networks
DCNN	Deep Convolutional Neural Networks
DNN	Deep Neural Networks
EHR	Electronic Health Records
BEHRT	Bidirectional Health Encoder Representations Transformer
TRIPOD-AI	Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis-Artificial Intelligence
PROBAST-AI	Prediction model Risk Of Bias ASsessment Tool – Artificial Intelligence

REFERENCES

- [1]. Prakash P. Artificial intelligence in healthcare: Bridging the gap between boon and bane. *IP Annals of Prosthodontics and Restorative Dentistry*. 2024;2(10):90–2.
- [2]. Ahmed MI, Spooner B, Isherwood J, Lane M, Orrock E, Dennison A. A Systematic Review of the Barriers to the Implementation of Artificial Intelligence in Healthcare. *Cureus* [Internet]. 2023 Oct 4 [cited 2024 Jul 16]; Available from: <https://www.cureus.com/articles/170025-a-systematic-review-of-the-barriers-to-the-implementation-of-artificial-intelligence-in-healthcare>
- [3]. Ismail L, Materwala H, Karduck AP, Adem A. Requirements of Health Data Management Systems for Biomedical Care and Research: Scoping Review. *J Med Internet Res*. 2020 Jul 7;22(7):e17508.
- [4]. Ismail L, Materwala H, Tayefi M, Ngo P, Karduck AP. Type 2 Diabetes with Artificial Intelligence Machine Learning: Methods and Evaluation. *Arch Computat Methods Eng*. 2022 Jan;29(1):313–33.
- [5]. Chomutare T, Tejedor M, Svenning TO, Marco-Ruiz L, Tayefi M, Lind K, et al. Artificial Intelligence Implementation in Healthcare: A Theory-Based Scoping Review of Barriers and Facilitators. *IJERPH*. 2022 Dec 6;19(23):16359.
- [6]. McCarthy J, Minsky ML, Rochester N, Shannon CE. A Proposal for the Dartmouth Summer Research Project on Artificial Intelligence, August 31, 1955. *AI Magazine*. 2006 Dec 15;27(4):12–12.
- [7]. Temsah MH, Altamimi I, Jamal A, Alhasan K, Al-Eyadhy A. ChatGPT Surpasses 1000 Publications on PubMed: Envisioning the Road Ahead. *Cureus* [Internet]. 2023 Sep 6 [cited 2024 Jul 16]; Available from: <https://www.cureus.com/articles/186004-chatgpt-surpasses-1000-publications-on-pubmed-envisioning-the-road-ahead>
- [8]. Amjad A, Kordel P, Fernandes G. A Review on Innovation in Healthcare Sector (Telehealth) through Artificial Intelligence. *Sustainability*. 2023 Apr 14;15(8):6655.
- [9]. Pacis DMM, Subido EDC, Bugtai NT. Trends in telemedicine utilizing artificial intelligence. In *Bali, Indonesia*; 2018 [cited 2024 Jul 16]. p. 040009. Available from: <https://pubs.aip.org/aip/acp/article/791769>
- [10]. Aldwean A, Tenney D. Artificial Intelligence in Healthcare Sector: A Literature Review of the Adoption Challenges. *OJBM*. 2024;12(01):129–47.
- [11]. Trinkley KE, An R, Maw AM, Glasgow RE, Brownson RC. Leveraging artificial intelligence to advance implementation science: potential opportunities and cautions. *Implementation Sci*. 2024 Feb 21;19(1):17.
- [12]. Stone P, Brooks R, Brynjolfsson E, Calo R, Etzioni O, Hager G, et al. Artificial Intelligence and Life in 2030: The One Hundred Year Study on Artificial Intelligence [Internet]. *arXiv*; 2022 [cited 2024 Jul 16]. Available from: <https://arxiv.org/abs/2211.06318>
- [13]. MacKay C, Klement W, Vanberkel P, Lamond N, Urquhart R, Rigby M. A framework for implementing machine learning in healthcare based on the concepts of preconditions and postconditions. *Healthcare Analytics*. 2023 Nov;3:100155.
- [14]. Yu KH, Beam AL, Kohane IS. Artificial intelligence in healthcare. *Nat Biomed Eng*. 2018 Oct 10;2(10):719–31.
- [15]. Seneviratne MG, Shah NH, Chu L. Bridging the implementation gap of machine learning in healthcare. *BMJ Innov*. 2020 Apr;6(2):45–7.
- [16]. Ali O, Abdelbaki W, Shrestha A, Elbasi E, Alryalat MAA, Dwivedi YK. A systematic literature review of artificial intelligence in the healthcare sector: Benefits, challenges, methodologies, and functionalities. *Journal of Innovation & Knowledge*. 2023 Jan;8(1):100333.
- [17]. Petersson L, Larsson I, Nygren JM, Nilsen P, Neher M, Reed JE, et al. Challenges to implementing artificial intelligence in healthcare: a qualitative interview study with healthcare leaders in Sweden. *BMC Health Serv Res*. 2022 Dec;22(1):850.
- [18]. Secinaro S, Calandra D, Secinaro A, Muthurangu V, Biancone P. The role of artificial intelligence in healthcare: a structured literature review. *BMC Med Inform Decis Mak*. 2021 Dec;21(1):125.
- [19]. Victor Mugabe K. Barriers and facilitators to the adoption of artificial intelligence in radiation oncology: A New Zealand study. *Tech Innov Patient Support Radiat Oncol*. 2021 Jun;18:16–21.

- [20]. Strohm L, Hehakaya C, Ranschaert ER, Boon WPC, Moors EHM. Implementation of artificial intelligence (AI) applications in radiology: hindering and facilitating factors. *Eur Radiol*. 2020 Oct;30(10):5525–32.
- [21]. Morrison K. Artificial intelligence and the NHS: a qualitative exploration of the factors influencing adoption. *Future Healthc J*. 2021 Nov;8(3):e648–54.
- [22]. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. 2015 Apr 21;10:53.
- [23]. Amarasingham R, Patzer RE, Huesch M, Nguyen NQ, Xie B. Implementing Electronic Health Care Predictive Analytics: Considerations And Challenges. *Health Affairs*. 2014 Jul;33(7):1148–54.
- [24]. Smith J. Setting the agenda: an informatics-led policy framework for adaptive CDS. *Journal of the American Medical Informatics Association*. 2020 Dec 9;27(12):1831–3.
- [25]. Jenkins DA, Martin GP, Sperrin M, Riley RD, Debray TPA, Collins GS, et al. Continual updating and monitoring of clinical prediction models: time for dynamic prediction systems? *Diagn Progn Res*. 2021 Dec;5(1):1.
- [26]. Petersen C, Smith J, Freimuth RR, Goodman KW, Jackson GP, Kannry J, et al. Recommendations for the safe, effective use of adaptive CDS in the US healthcare system: an AMIA position paper. *Journal of the American Medical Informatics Association*. 2021 Mar 18;28(4):677–84.
- [27]. Finlayson SG, Subbaswamy A, Singh K, Bowers J, Kupke A, Zittrain J, et al. The Clinician and Dataset Shift in Artificial Intelligence. *N Engl J Med*. 2021 Jul 15;385(3):283–6.
- [28]. Hickey GL, Grant SW, Murphy GJ, Bhabra M, Pagano D, McAllister K, et al. Dynamic trends in cardiac surgery: why the logistic EuroSCORE is no longer suitable for contemporary cardiac surgery and implications for future risk models. *European Journal of Cardio-Thoracic Surgery*. 2013 Jun 1;43(6):1146–52.
- [29]. Davis SE, Lasko TA, Chen G, Siew ED, Matheny ME. Calibration drift in regression and machine learning models for acute kidney injury. *Journal of the American Medical Informatics Association*. 2017 Nov 1;24(6):1052–61.
- [30]. Wong A, Cao J, Lyons PG, Dutta S, Major VJ, Ötleş E, et al. Quantification of Sepsis Model Alerts in 24 US Hospitals Before and During the COVID-19 Pandemic. *JAMA Netw Open*. 2021 Nov 19;4(11):e2135286.
- [31]. Jiang X, Osl M, Kim J, Ohno-Machado L. Calibrating predictive model estimates to support personalized medicine. *J Am Med Inform Assoc*. 2012 Mar;19(2):263–74.
- [32]. Van Calster B, Vickers AJ. Calibration of Risk Prediction Models: Impact on Decision-Analytic Performance. *Med Decis Making*. 2015 Feb;35(2):162–9.
- [33]. Davis SE, Lasko TA, Chen G, Matheny ME. Calibration Drift Among Regression and Machine Learning Models for Hospital Mortality. *AMIA Annu Symp Proc*. 2017;2017:625–34.
- [34]. Ötleş E. [PDF] Mind the Performance Gap: Examining Dataset Shift During Prospective Validation | Semantic Scholar [Internet]. 2021 [cited 2024 Jul 16]. Available from: <https://www.semanticscholar.org/paper/Mind-the-Performance-Gap%3A-Examining-Dataset-Shift-%C3%96tle%C5%9F-Oh/bd6d24be7320d7d456e610827b89639f3249a6ab>
- [35]. Davis SE, Walsh CG, Matheny ME. Open questions and research gaps for monitoring and updating AI-enabled tools in clinical settings. *Front Digit Health*. 2022 Sep 2;4:958284.
- [36]. De Fauw J, Ledsam JR, Romera-Paredes B, Nikolov S, Tomasev N, Blackwell S, et al. Clinically applicable deep learning for diagnosis and referral in retinal disease. *Nat Med*. 2018 Sep;24(9):1342–50.
- [37]. Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. *Qual Saf Health Care*. 2010 Oct;19 Suppl 3(Suppl 3):i68-74.
- [38]. Knight W. The Dark Secret at the Heart of AI [Internet]. 2017. Available from: <https://www.technologyreview.com/2017/04/11/5113/the-dark-secret-at-the-heart-of-ai/>
- [39]. Keane PA, Topol EJ. With an eye to AI and autonomous diagnosis. *npj Digital Med*. 2018 Aug 28;1(1):40, s41746-018-0048-y.
- [40]. Banda JM, Sarraju A, Abbasi F, Parizo J, Pariani M, Ison H, et al. Finding missed cases of familial hypercholesterolemia in health systems using machine learning. *npj Digit Med*. 2019 Apr 11;2(1):23.
- [41]. Qayyum S, Habib A, Kechyn S, Auger D, Damani N, Griguer A, et al. P01 Heartflow: experience of a high-volume district general hospital. In: Scientific poster abstracts [Internet]. BMJ Publishing Group Ltd and British Cardiovascular Society; 2020 [cited 2024 Jul 16]. p. A5.3-A5. Available from: <https://heart.bmj.com/lookup/doi/10.1136/heartjnl-2020-BSCI.14>
- [42]. Artificial Intelligence and Machine Learning in Software as a Medical Device | FDA [Internet]. [cited 2024 Jul 16]. Available from: <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>
- [43]. Shipley E, Joddrell M, Lip GY, Zheng Y. Bridging the Gap Between Artificial Intelligence Research and Clinical Practice in Cardiovascular Science: What the Clinician Needs to Know. *Arrhythm Electrophysiol Rev* [Internet]. 2022 Apr 14 [cited 2024 Jul 16];11. Available from: <https://www.aerjournal.com/articleindex/aer.2022.07>
- [44]. Reddy S, Allan S, Coghlan S, Cooper P. A governance model for the application of AI in health care. *Journal of the American Medical Informatics Association*. 2020 Mar 1;27(3):491–7.

- [45]. Weinert L, Müller J, Svensson L, Heinze O. Perspective of Information Technology Decision Makers on Factors Influencing Adoption and Implementation of Artificial Intelligence Technologies in 40 German Hospitals: Descriptive Analysis. *JMIR Med Inform.* 2022 Jun 15;10(6):e34678.
- [46]. Firouzi F, Farahani B, Barzegari M, Daneshmand M. AI-Driven Data Monetization: The Other Face of Data in IoT-Based Smart and Connected Health. *IEEE Internet Things J.* 2022 Apr 15;9(8):5581–99.
- [47]. Singh RP, Hom GL, Abramoff MD, Campbell JP, Chiang MF, on behalf of the AAO Task Force on Artificial Intelligence. Current Challenges and Barriers to Real-World Artificial Intelligence Adoption for the Healthcare System, Provider, and the Patient. *Trans Vis Sci Tech.* 2020 Aug 11;9(2):45.
- [48]. Collins GS, Dhiman P, Andaur Navarro CL, Ma J, Hooft L, Reitsma JB, et al. Protocol for development of a reporting guideline (TRIPOD-AI) and risk of bias tool (PROBAST-AI) for diagnostic and prognostic prediction model studies based on artificial intelligence. *BMJ Open.* 2021 Jul;11(7):e048008.
- [49]. Han C, Rundo L, Murao K, Nemoto T, Nakayama H. Bridging the Gap Between AI and Healthcare Sides: Towards Developing Clinically Relevant AI-Powered Diagnosis Systems. In: Maglogiannis I, Iliadis L, Pimenidis E, editors. *Artificial Intelligence Applications and Innovations* [Internet]. Cham: Springer International Publishing; 2020 [cited 2024 Jul 16]. p. 320–33. (IFIP Advances in Information and Communication Technology; vol. 584). Available from: https://link.springer.com/10.1007/978-3-030-49186-4_27
- [50]. Grant K, McParland A, Mehta S, Ackery AD. Artificial Intelligence in Emergency Medicine: Surmountable Barriers With Revolutionary Potential. *Annals of Emergency Medicine.* 2020 Jun;75(6):721–6.
- [51]. Brady AP, Neri E. Artificial Intelligence in Radiology—Ethical Considerations. *Diagnostics.* 2020 Apr 17;10(4):231.
- [52]. Kelly CJ, Karthikesalingam A, Suleyman M, Corrado G, King D. Key challenges for delivering clinical impact with artificial intelligence. *BMC Med.* 2019 Dec;17(1):195.
- [53]. He K, Gan C, Li Z, Rekik I, Yin Z, Ji W, et al. Transformers in medical image analysis. *Intelligent Medicine.* 2023 Feb;3(1):59–78.
- [54]. Marcu LG, Boyd C, Bezak E. Current issues regarding artificial intelligence in cancer and health care. Implications for medical physicists and biomedical engineers. *Health Technol.* 2019 Aug;9(4):375–81.
- [55]. Ben-Israel D, Jacobs WB, Casha S, Lang S, Ryu WHA, De Lotbiniere-Bassett M, et al. The impact of machine learning on patient care: A systematic review. *Artificial Intelligence in Medicine.* 2020 Mar;103:101785.
- [56]. Challen R, Denny J, Pitt M, Gompels L, Edwards T, Tsaneva-Atanasova K. Artificial intelligence, bias and clinical safety. *BMJ Qual Saf.* 2019 Mar;28(3):231–7.
- [57]. Lai MC, Brian M, Mamzer MF. Perceptions of artificial intelligence in healthcare: findings from a qualitative survey study among actors in France. *J Transl Med.* 2020 Dec;18(1):14.
- [58]. UK GDPR guidance and resources | ICO [Internet]. [cited 2024 Jul 16]. Available from: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/>
- [59]. Paranjape K, Schinkel M, Hammer RD, Schouten B, Nannan Panday RS, Elbers PWG, et al. The Value of Artificial Intelligence in Laboratory Medicine. *American Journal of Clinical Pathology.* 2021 May 18;155(6):823–31.
- [60]. Panch T, Mattie H, Celi LA. The “inconvenient truth” about AI in healthcare. *npj Digit Med.* 2019 Aug 16;2(1):77.
- [61]. Scarpazza C, Ha M, Baecker L, Garcia-Dias R, Pinaya WHL, Vieira S, et al. Translating research findings into clinical practice: a systematic and critical review of neuroimaging-based clinical tools for brain disorders. *Transl Psychiatry.* 2020 Apr 20;10(1):107.