International Journal of Medical Science and Clinical Research Studies

ISSN(print): 2767-8326, ISSN(online): 2767-8342

Volume 03 Issue 07 July 2023

Page No: 1350-1357

DOI: https://doi.org/10.47191/ijmscrs/v3-i7-23, Impact Factor: 6.597

Ethics and Regulation for Artificial Intelligence in Healthcare: Empowering Clinicians to Ensure Equitable and High-Quality Care

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ABSTRACT

As artificial intelligence (AI) technology becomes increasingly integrated into healthcare, it is crucial for clinicians to possess a comprehensive understanding of its capabilities, limitations, and ethical implications. This literature review explores the reasons why clinicians need to be better informed about artificial intelligence, emphasizes the potential benefits of artificial intelligence in healthcare, raises awareness regarding the risks and unintended consequences associated with its use, discusses the development of machine learning and artificial intelligence in healthcare, and underscores the need for ethical guidelines and regulation to harness the potential of artificial intelligence in a responsible manner.

KEYWORDS: Artificial intelligence, healthcare, ethical guideline.

ARTICLE DETAILS

Published On:
20 July 2023

Available on:
https://ijmscr.org/

INTRODUCTION

Artificial Intelligence (AI) is a phrase that inferred the use of a computer to model intelligent behavior with minimal human intervention. Artificial Intelligence in medicine consist of two main branches, virtual and physical. The virtual branch involves informatics approaches, including electronic health records and active guidance of physicians in their treatment decisions. Robots that used to assist the elderly patient or the attending surgeon is the example of physical branch artificial intelligence in medicine.[1] Artificial Intelligence can replace human tasks and activities. Artificial Intelligence can complete specific tasks and overcome some of the computationally intensive and intellectual limitations of humans.[2]

Recently, artificial intelligence make a big impact in healthcare. Artificial Intelligence can definitely help physicians to make better clinical decisions or even replace human judgement in certain functional areas of healthcare (eg, radiology). Applications of artificial intelligence increase the availability of healthcare data and give rapid developement of big data analytic methods. It shows the successfull applications of artificial intelligence in healthcare. Artificial intelligence techniques can solve clinically relevant information hidden in the massive amount of data led by relevant questions and help clinical decision making.[3]

Implementing artificial intelligence in medicine creates many ethical dilemmas that impact patient care, doctors' roles, and the roles of those involved in the field of medicine governments, regulators, insurers, payers, and other providers. Machine training ethics, machine accuracy ethics, patient-related ethics, physician ethics, and shared ethics are significant components to consider for the implementation of artificial intelligence in medicine. Optimal implementation of artificial intelligence in medicine need universal standardization for ethical and regulatory considerations.[4]

BENEFITS OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE

Artificial intelligence in healthcare gives advantages to people, organizations, and sector. Automated decision-making, patient monitoring particularly elderly patient monitoring, early diagnosis, and process simplification are the advantages of artificial intelligence for people. Workflow assistance, improvement of performance, reduction of cost, and fraud detection are the advantages for organizations. Saving time, reducing resource consumption, and providing professional training, data sharing, and data availability are the advantages for the sector.[5]

Artificial intelligence can enhanced decision making in several ways. Artificial intelligence can assist decision-makers in differentiating preoperative patients into risk

categories and stratifying the severity of ailments and health for non-operative patients. Artificial intelligence tools can replace traditional vital signs and laboratory values, then continuously monitoring and updating that components to give signal alarms for an acutely decompensating patient. Artificial intelligence may help overcome challenges with multiple outcome optimization limitations or sequential decision-making protocols that limit individualized patient care.[6]

Artificial intelligence in biomedicine have a big role in the diagnostics of diseases. Artificial intelligence allows health professionals to give earlier and more accurate diagnostics for many kinds of diseases. One major class of diagnosis is based on in vitro diagnostics using biosensors or biochips. Integrated Artificial intelligence can diagnose cardiovascular diseases in the early stage with biosensors and related point-of-care testing (POCT) systems. Artificial intelligence can help to predict the survival rates of cancer patients. Artificial intelligence also have role on medical imaging (two-dimensional) and signal (one-dimensional) processing for disease diagnostic.[7]

Artificial intelligence in healthcare influence patient outcomes. Artificial intelligence for drug discovery, artificial intelligence for clinical trials and patient care are some applications of medical artificial intelligence applications utilized in the healthcare industry. Clinical intelligence also analyzes patient's medical data and delivers insights to help them increase their quality of life. Maternal care, healthcare robotics, genetics artificial intelligence data-drive, artificial intelligence-powered stethoscope are significant clinical intelligence systems that improve patient care.[8]

Application of artificial intelligence and the analytics of big data in healthcare are considered as one of the important achievements for the intelligent healthcare system. Big data in the healthcare contains the medical images, clinical data of doctor, doctors' prescriptions and notes, computed tomography (CT) images, magnetic resonance imaging (MRI) scans, laboratory data, documents from the drugstore, files from the insurance electronic patient record data, and other data related to the administrative operations. Big data analytics is the process of scrutinizing huge volume of data from various kinds of sources of data. Various analytical methods such as data mining and artificial intelligence can be put in to examine the data. Approaches for big data analytics can be used to identify the abnormalities obtained as a result of combining large volume of data from different sources of data.[9]

Artificial intelligence is need to identify the risk of non-communicable disease, such as heart disease and diabetes. A non-communicable disease risk prediction closed-loop system can predict the risk of developing life-threatening disease (e.g. diabetes, thyroid, and stroke) at early stage then the public health of any community can be improved significantly, which can extend the life span of individuals as well. Recently, there has been growing interest to incorporate machine learning into cyber-physical systems, which can facilitate the disease classification, detection, monitoring, and prediction of several non-communicable diseases. The multistage conversion of heterogeneous internet of things sensor data into a meaningful dataset opens new door to predict the risk of non-communicable diseases from the low-level sensor data in human-cyber-physical systems. This has enabled the machine learning classification algorithms random forest and random tree to perform with 94% accuracy or more.[10]

In healthcare, traditional machine can predicting what treatment protocols are likely to succeed on a patient based on various patient attributes and the treatment context.[11] There is a very large amount of unstructured textual data consist of doctors' notes, test results, lab reports, medication orders, and discharge instructions in healthcare. Artificial intelligence can extract critical information about patients from such rich descriptive data, helping improve diagnoses and treatment recommendations. The capacity for machines to digest huge amounts of imagery and textual data quickly through machine learning and natural language processing will enable physicians to make timely diagnoses and treatment decisions, which can give advantage on health service delivery.[12]

RISK AND UNINTENDED CONSEQUENSES

Health care industry adopts artificial intelligence, machine learning, and other modeling techniques that give benefits to both patient outcomes and cost reduction. However, we have to aware and ensure the risk and the unintended consequenses. Other industries provide a framework for acknowledging and managing data, machine, and human biases to manage the risk while implementing artificial intelligence.[13]

Application of machine learning (ML) as the part of artificial intelligence developement is a great area of research. Rapid pace of change, diversity of different techniques and multiplicity of tuning parameters make it difficult to get a clear picture of how accurate these systems might be in clinical practice or how reproducible they are in different clinical contexts. Lack of consensus about how machine learning studies should report potential bias make the condition worse. Researchers need to consider how machine learning models, like scientific data sets, can be licensed and distributed to facilitate reproduction of research results in different settings.[14]

The lack of interpretability in artificial intelligence models is an obstacle to their widespread adoption in the healthcare domain. The absence of understandability and transparency frequently cause inadequate accountability and a consequent reduction in the quality of the predictive results of the models. On the other hand, the existence of interpretability in the predictions of artificial intelligence models will facilitate the

understanding and trust of the clinicians in these complex models. The data protection regulations worldwide emphasize the relevance of the plausibility and verifiability of artificial intelligence models' predictions.[15]

Many private entities own and controll artificial intelligence technologies. The nature of the implementation of artificial intelligence could mean such corporations, clinics and public bodies will have a greater than typical role in obtaining, utilizing and protecting patient health information. This raises privacy issues relating to implementation and data security. The first set of concerns includes access, use and control of patient data in private hands. Some recent public–private partnerships that implementing artificial intelligence have poor protection of privacy. Appropriate safeguards must be conducted to maintain privacy and patient agency. Another set of concerns is the external risk of privacy breaches through artificial intelligence-driven methods. Regulation should confirm patient agency and consent, and should encourage increasingly sophisticated methods of data anonymization and protection.[16]

Job displacement from automation and management of human-machine interactions is the anticipated implication of the use of artificial intelligence applications.[17] Artificial intelligence applications must be implemented with care regarding potential loss of jobs or professional reputation, highlighting the potential of artificial intelligence to remove the tedious aspects of work, improve job satisfaction and provide new skills. This must be coupled with careful attention to clinicians' training needs and career development.[18]

DEVELOPMENT OF MACHINE LEARNING AND AI IN HEALTHCARE

The history of artificial intelligence started in 1950 when Alan Turing and his proposed machine that can learn and capable of becoming artificial intelligence are brought into public eyes.[19] Since then, artificial intelligence has been developed and applied in many aspects of life including healthcare. There are two distinct major categories of artificial intelligence devices that we used. First category being machine learning techniques with capabilities to analyze structured data. In relation to healthcare use, machine learning can be used to classify patients condition and draw a probable outcomes of the patients condition. Machine learning was applied in processing radiology data, genetic research, and epidemiological studies.[3] Second category being natural language processing which extract information from unstructured data. Natural language processing produres capable of processing random data and texts to machine-readable structured data. After which, the data can be processed by machine learning techniques.[20]

Machine learning techniques comprised of two categories: unsupervised learning, which capable of feature extraction, and supervised learning which is used to predict relationship between patient condition (input) and patient prognosis or diagnosis (output).[3] Artificial intelligence developments in healthcare generally used supervised learning method which provide more relevant clinical results. Some analytical techniques that were used in conjunction to supervised learning machine learning were support vector machine, neural networks, and the most recent and advanced technique, deep learning.

Deep learning is superior to other machine learning techniques because it can overcome one of machine learning biggest weakness in analyzing data with high number of traits, which is very relevant in clinical settings. To give some example, one of deep learning's sub-technique, convolutional neural network was tested in clinical settings and reported over 90% diagnose accuracy in congenital cataract disease by analyzing ocular images.[21] Study also reported use of convolutional neural network with over 90% accuracy in identifying and differentiating benign and malignant skin cancer from images.[22] These results showed that convolutional neural network were comparable to experience physicians in accuracy to diagnose diseases in clinical settings.[3]

Natural Language Processing is no less important compared to machine learning techniques. Natural language processing function pivoting role to extract unstructured clinical data with wide variety of traits into a useful variables that machine learning techniques can analyze to infer the likely outcome of certain patient or condition.[23] Core components of natural language processing processes are text processing and classification. Keywords that significant in relation to certain diseases are selected and then processed with machine learning techniques.[24] Studies reported that use of natural language processing in clinical settings regarding laboratory-based adverse effects can be automated thanks to natural language processing algorithm.[25] Natural language processing also reported to have successfully identified 14 variables relating to brain aneurysm after it was given with clinical notes of patients with brain aneurysm.[26] This shows that natural language processing can be used in determining complex disease and variables related to it.

APPLICATIONS OF AI IN HEALTHCARE

Problems such as difficult and complex cases, increasing variables involved in pathogenesis of diseases in relation with modern life style, war on antibiotics resistancy, to name a few, are growing in number. Mass of misinformation, short-staffed and short-resourced environment are not uncommon. Artificial intelligence use acts as an alternative problem solving method in a wide aspects of healthcare system and as a tool to help healthcare provider to give better treatment to patient.[27]

In field of electronic health record, recent study stated that use of deep neural network, researchers has managed to produce artificial intelligence algorithm sith 90.5% to 92.8%

accuracy in predicting pneumonia cases following stroke based on previous clinical notes and relevant symptoms.[28] Another study have managed to show artificial intelligence model that predict mortality in paralytic ileus with 81.30% accuracy , and intensive care unit patients mortality rate based on previous electronic health records.[27,29] With documented prognosis of patient with specific condition, physician can decide the more likely treatment and outcome of that certain patient.

Artificial intelligence has also been shown to be capable to help identify specific-marker molecules in cancer and other genetic diseases. Study reported that support vector machine machine learning developed using various genomic data to match and classify cancer protein and drug targets were able to identify 53 new global cancer targets, 266 specific to breast cancers, 355 to ovarian cancers, and 462 targets in pancreatic cancers.[30] Another study managed to explain 46.9% of gene variance in height, and 32.7% gene variations in body mass index in patient with rheumatoid arthritis.[31] Recent study regarding coronavirus disease-19 proteomes shown that machine learning algorithm is able to predict antigens that require human leukocyte antigens-binding, processing, presentation to the cell surface, and it's potential to be recognized by T cells in immunotherapy targets.[27]

Studies reported that artificial intelligence have managed to do identification of melanoma based on clinical images with 91.3% accuracy, squamous cell carcinoma with 86.6% accuracy, and basal cell carcinoma with 87.6% accuracy. Same studies also reported classification of benign and malignant skin cancer with 89.5% accuracy, 85.1% sensitivity, and 89.2% specificity.[32] Other studies reported that histology-based convolutional neural network type of machine learning were capable of automatically grade prostate cancer, breast cancer, colon cancer, and lymphoma in par with experienced pathologist.[33] A study using support vector machine algorithm in early detection of unknown primary cancer shown that it is capable to predict the origins of metastatic adenoid cystic carcinoma, which is a rare cases that are likely to confuse physician.[34]

In radiology and imaging, artificial intelligence also shown great results and potential. Study using machine learning-based magnetic resonance imaging analysis reported it is capability to predict Alzheimer's disease progression with 91.6% accuracy, 90.59% sensitivity, and 92.96% specificity.[35] Another study about convolutional neural network capabilities in detecting irregularities and diagnose patients based on chest X-ray shown 81% accuracy, 2% higher than radiologist.[36] Convoluted neural network were also reported to help find microaneurism in diabetic retinopathy patient that may elude ophthalmologist examination.[37]

An artificial intelligence model developed by John Hopkins University, Smart Tissue Autonomous Robot (STAR) were reported to match and or outperform human surgeon in ex-vivo and in-vivo anastomosis of the bowl done with animal models.[38] Not limited to the surgery process itself, artificial intelligence can also be used in predicting post operative patient likely outcomes. Study reported that machine learning and natural language processing were capable of predicting with 92% accuracy, leakage of anastomosis in post operative patients.[39] This will help surgeon and postoperative team to decide what the next treatment will be.

Telemedicine, one of new frontier in healthcare service is also a potential field for artificial intelligence use. Increase in awareness during coronavirus disease-19 pandemic results in greater interest of artificial intelligence use in telemedicine. Studies regarding use of artificial intelligence in perioperative anesthesia telemedicine shown mixed results with potential to reduce disturbance on patient while also possesing potential weaknesses such as lack of related electronic health records and patient with unique and different clinical sign.[40] Another study proposed a telemedicine algorithm in eye diseases such as diabetic retinopathy and age-related macular disease. This new algorithm uses the advancements of internet to help data gathering from patients to then processed by artificial intelligence after which the results will be consulted on ophthalmologist. Though there were still lots of weaknesses to overcome before this algorithm is viable.[41]

THE NEED FOR ETHICAL GUIDELINES AND REGULATION

Ethical guidelines and regulations regarding artificial intellegence in healthcare play a crucial role in ensuring the responsible and safe use of these technologies. In the past five years, private companies, research institutions and public sector organizations have issued principles and guidelines for ethical artificial intelligence.[42] These guidelines provide a framework for addressing various ethical considerations and potential risks associated with artificial intellegence implementation.[43] According to a report by the World Health Organization (WHO) [44], ethical guidelines and regulations should focus on principles like beneficence, non-maleficence, justice, and respect for autonomy when integrating artificial intellegence into healthcare. These guidelines aim to uphold patient rights, minimize biases, promote accountability, and maintain the trustworthiness of artificial intellegence systems. According to a study by Mittelstadt et al.[45], robust ethical guidelines and regulations are essential to ensure the responsible and beneficial deployment of artificial intellegence in healthcare, fostering a balance between innovation and safeguarding human well-being. Also, artificial intellegence technologies can be used ethically, responsibly, and in the best interest of patients and society at large.

Addressing issues such as transparency, accountability, fairness, privacy, consent, and human oversight is crucial in the context of artificial intellegence 's healthcare applications. These aspects are essential for ensuring the ethical and

responsible use of artificial intelligence in healthcare systems. Transparency involves the opennes and clarity of making artificial intellegence algorithms, systems, and decision-making processes understandable and explainable to healthcare professionals, patients, and other stakeholders.[46] Accountability,is necessary to hold individuals, organizations, and systems responsible for the outcomes and actions facilitated by artificial intellegence technology.[47] One of the key accountability issues in artificial intellegence healthcare is the allocation of responsibility. As artificial intellegence systems become more integrated into healthcare processes, it becomes crucial to determine who is accountable for the decisions made by these systems. Healthcare providers, developers, regulatory bodies, and even artificial intellegence algorithms themselves may all have different levels of responsibility depending on their roles and contributions to the artificial intellegence technology. Fairness focuses on preventing biases and discrimination in artificial intellegence algorithms, ensuring equitable access to healthcare services for all individuals.[48] Privacy safeguards personal health information and ensures that artificial intellegence systems handle data securely and confidentially. Consent ensures that individuals have the right to make informed decisions about their involvement in artificial intellegence-driven healthcare interventions. Lastly, human oversight is critical to ensure that artificial intellegence is used as a tool to augment human decision-making rather than replacing human judgment altogether.

Clinicians play a vital role in shaping guidelines and ensuring the responsible use of artificial intelligence (AI) for the benefit of patients and the delivery of equitable, high-quality care. As the frontline providers of healthcare, clinicians bring invaluable expertise and insights into the development, implementation, and evaluation of artificial intellegence systems in clinical settings.[49] Their active involvement during the guideline development process helps formulate guidelines that are practical, effective, and aligned with ethical principles. Additionally, clinicians contribute to the responsible implementation of artificial intellegence technologies by assessing feasibility, providing feedback on user-friendliness, and optimizing artificial intellegence algorithms to enhance safety and effectiveness. As gatekeepers of patient-centered care, clinicians critically evaluate artificial intellegence outputs, exercise clinical judgment, and advocate for equitable access and ethical use of artificial intellegence in healthcare.[50] Their expertise and dedication are instrumental in ensuring that artificial intellegence technologies are integrated ethically, responsibly, and effectively into clinical practice, ultimately improving healthcare outcomes for patients.

EMPOWERING CLINICIANS

Clinicians play a crucial role in various stages of artificial intellegence development, implementation, and evaluation processes in healthcare. In the development phase, clinicians provide valuable insights into the specific clinical needs, workflows, and challenges faced in their respective specialties. Their expertise helps in identifying areas where artificial intellegence can be most beneficial and guiding the design of artificial intellegence algorithms and systems that align with clinical requirements. Clinicians can collaborate with artificial intellegence developers, providing feedback, testing prototypes, and ensuring that the technology is intuitive, user-friendly, and aligned with clinical practices.[51] During the implementation stage, clinicians actively participate in integrating artificial intellegence into their daily workflow and patient care processes. They work closely with technology teams to ensure seamless integration, evaluate the impact on workflow efficiency, and provide feedback on usability and practicality. Clinicians can also assist in training their peers on how to effectively use artificial intellegence systems and address any concerns or resistance that may arise during the implementation process.[52] Clinicians are instrumental in evaluating the effectiveness and safety of artificial intellegence systems. They can contribute to the monitoring and validation of artificial intellegence algorithms, assessing their accuracy, sensitivity, specificity, and performance in real-world clinical settings.[53] Clinicians also play a vital role in assessing the clinical outcomes and patient experiences associated with artificial intellegence implementation, helping to determine whether the technology achieves its intended goals and benefits patients. Continuous education and training programs should be established to enhance clinicians' artificial intellegence literacy, enabling them to critically assess artificial intellegence algorithms, challenge biases, and identify potential pitfalls.[54] By staying updated on artificial intellegence advancements and ethical considerations, clinicians can effectively navigate the complexities of artificial intellegence-driven healthcare and contribute to responsible and informed decision-making.

Clinicians' engagement in the development and implementation of artificial intelligence (AI) technologies will foster trust, promote responsible artificial intellegence use, and safeguard against undue reliance on technology. By actively participating in the design and evaluation of artificial intellegence systems, clinicians contribute their clinical expertise and contextual knowledge, ensuring that artificial intellegence is aligned with patient needs and the complexities of healthcare settings.[55] Clinicians' engagement helps establish transparency, explainability, and accountability in artificial intellegence systems, addressing concerns about the "black box" nature of algorithms. This active involvement also promotes a human-centered approach to artificial intellegence, where technology complements and augments the clinical decision-making process rather than replacing it.[56] By being actively engaged, clinicians can ensure that the benefits and limitations of artificial intellegence are appropriately communicated to

patients, fostering trust in the technology and avoiding unwarranted overreliance on artificial intellegence-driven recommendations.

CONCLUSION

Artificial intellegence make a big impact in healthcare. Artificial intellegence in healthcare gives advantages to people, organizations, and sector. However, we have to aware and ensure the risk and it's unintended consequenses.

Historic uses of artificial intellegence has been done in many fields including healthcare with promising yet not without weaknesses results. Applications of both type machine learning and natural language processing has shown great results for summaryzing complex clinical condition and generate great outcomes. Proved by many studies that reported high level of accuracy in diagnosis, making a prognosis, molecular prediction, and image processing comparable to or better than physician. Yet, weaknesses of artificial intellegence use still exists with and the use of it still needs heavy consideration by each physician and healthcare providers with different locations, patients, regulations, cultures, and different healthcare settings.

Ethical guidelines and regulations are essential for ensuring the responsible and safe use of artificial intellegence in healthcare, with a focus on principles such as beneficence, non-maleficence, justice, and respect for autonomy. Clinicians play a vital role in shaping these guidelines and ensuring the ethical and equitable implementation of artificial intellegence, fostering trust and improving healthcare outcomes for patients. Besides, clinicians' active engagement in artificial intellegence development and implementation fosters trust, promotes responsible use, and safeguards against undue reliance on technology, ensuring that artificial intellegence aligns with patient needs and the complexities of healthcare settings, while maintaining transparency and a human-centered approach.

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