Laying the Foundations for Artificial Intelligence in Healthcare: Ethico-Legal Perspectives

Prof. Dr. Jyoti Bhakare*[1], Ms. Vipasha Chirmule[2]
[1.] *Professor, Department of Law, Savitribai Phule Pune University, Pune*
[2.] *Savitribai Phule Pune University, Pune*

Abstract: **Digital technology has made rapid advances in the fields of education, business and healthcare, in particular during the Covid-19 pandemic. As an emerging arena in India, Artificial Intelligence ('AI') can add machine intelligence to software applications. It also has the ability to contribute to the healthcare system in India. AI can benefit the healthcare field by mining medical records, designing treatment plans, managing medication, predicting health events, assisting in clinical decision making, and drug creation. As is the case with all forms of technologies, it also raises certain ethical and social concerns with regard to clinical safety, privacy, liability and equitable access. If these concerns are addressed, then the benefits of AI can be harnessed by reducing its risks.**

Considering the socio-ethical implications which AI raises for the healthcare system and its stakeholders, the authors felt it necessary to analyse the potential legal risks of the AI technologies being utilized in healthcare. The paper attempts to provide an overview of the emerging ethico-legal issues in implementation of AI in healthcare, which will be useful to strengthen its responsible deployment in the healthcare system in India.

Keywords: AI, ethics, legal, healthcare, technologies

I. INTRODUCTION

Artificial Intelligence (AI) includes computer or machine systems that can simulate human cognitive functions such as learning and problem-solving, which can be carried out with or without any human supervision.

Technology algorithms in AI can process a massive amount of data and identify patterns. AI systems can analyse healthcare data and learn to understand human conditions and disease patterns. The World Economic Forum report (2022) predicts that AI expenditure in India may reach $11.78 billion by 2025. Studies have also predicted that 90% of hospitals across the world may use AI applications for diagnosis and remote monitoring by 2025.

AI has great potential to provide a detailed understanding of human health. 'Intelligent medicine' as a new model of healthcare combines the human element and machine or technology element. AI can rapidly revolutionize healthcare systems, by prioritizing prevention and public health by augmenting system capabilities and tools. In medical settings, AI has been showing progress in using patient data for delivering diagnosis, recommending treatment plans and preventive care.

Recent reports suggest that the AI in healthcare may grow to 102.7 billion dollars by 2028. At present, AI is being integrated into diagnostic algorithms to screen for cancer, diabetic retinopathy, and cardiovascular disease.

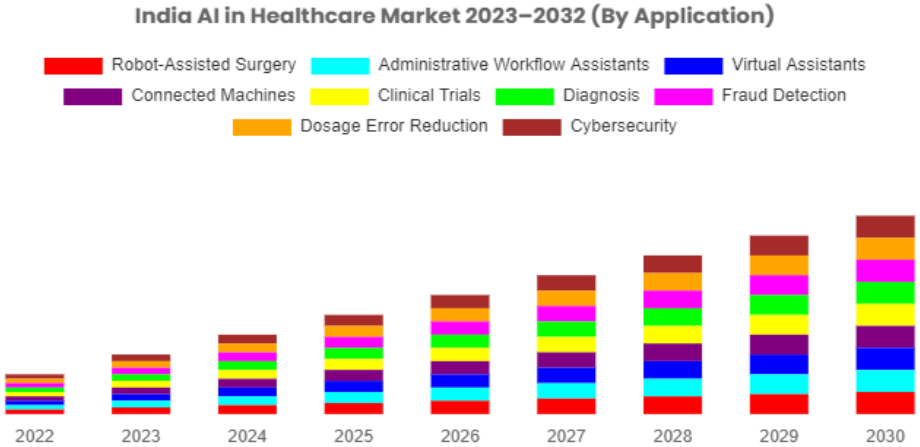

Fig 1. Increase in growth rate of the AI healthcare market in India[1]

NITI Aayog (Government of India) has been testing the application of AI for early detection of diabetes complications. In its National Strategy for Artificial Intelligence report (2018), the NITI
Aayog has highlighted how AI in healthcare can help India improve accessibility and availability of health care. Recently, the Indian Government has asked technology companies to seek its approval before they release artificial intelligence (AI) tools that are "unreliable" or under trial to the public.
Researchers have raised important issues in this field, including assessment of risks and benefits of AI technologies and establishing accountability, in order to frame a regulatory setup. Nations across the world are preparing policy planning documents and strategies for coordinating the ethical deployment of AI in healthcare. In the present time, it is important to understand how

[1] Avi Gaikwad, *India AI in Healthcare Market Size, Forecast, Analysis & Share Surpass US$ 35 Bn By 2030, At 30% CAGR*, LinkedIn (June 6 2023), https://www.linkedin.com/pulse/latest-india-ai-healthcare-market-size-forecast-analysis-avi-gaikwad

healthcare professionals, technologists, and policymakers have begun to analyse and recommend directions to regulate AI applications in healthcare.

II. APPLICATIONS OF AI IN HEALTHCARE

1. Physician and machine interaction:

a. Robotics and simulation:

Robots can be programmed to perform predefined tasks such as delivering supplies or in automation. In India, robotic assistants can work alongside surgeons in spine surgery. Comrade robots can gather medical data and clinical findings about a patient using its sensors, while surgical robots have enhanced capacity for precise surgical procedures.
Digital twins are personalized simulation models that are now being used in healthcare. These digital biomedical models of patients could be examined to test the efficacy of new treatments or interventions, in the digital environment.

b. Clinical decision support:

Machine learning (‘ML’) as a method of AI, enables machines to learn and make predictions by recognising patterns. It identifies patterns in the data by automating data analysis using algorithms. Machines can train themselves to read images or data and analyse them to diagnose conditions and plan treatments. In primary care, AI can be used for clinical decision making such as assessing symptoms, image recognition and to predict patients with undiagnosed conditions.

c. Diagnosis and precision healthcare:

Predictive analytics can identify persons at high risk for diabetes, cardiovascular disorders, and cancer. Advanced algorithms analyze datasets, by factoring in genetic, clinical and lifestyle information to provide personalized treatment plans. The market for AI in precision medicine is expected to grow to 14.5 billion dollars by 2030. Precision healthcare or personalized healthcare can customize and enhance the diagnosis, treatment and prevention of diseases of a patient based on ML datasets which take into consideration unique biological differences, such as genetic traits and lifestyle factors. This can help in tracking disease progression, gene therapy and specialized drug treatments.

d. Patient engagement applications:

Remote monitoring devices use AI algorithms to track patients' vital signs and warn of potential health issues. Mobile sensors can help physicians to monitor, interpret and analyse biomedical data collected remotely from the patient. This information collected from biosensors, watches, smartphones, softwares can help to tailor recommendations by comparing other treatments.
Assistance of chatbots can help patients to schedule and track appointments, bill payments, results, follow-ups. Natural Language Processing systems can analyse clinical notes, prepare reports, transcribe patient interactions and carry out conversations with patients.

2. Pharmaceutical research and drug development:

Machine learning models can analyze molecular structures and can predict potential drug candidates. Studies have shown that AI is helping pharmaceutical companies save up to 60% in drug discovery costs. With ongoing research for precision medicine, disease processes, targeted therapeutics could be better analysed by improving clinical trial design processes. Robotics or models of genetic targets, organs, drugs, diseases can be used for drug discovery.

III. IMPACT ON THE MEDICAL FIELD

1. Recent developments:

At present, AI systems are being adopted by healthcare providers to automate repetitive clinical tasks. The Tata Medical Center and the Indian Institute of Technology recently launched the Comprehensive Archive of Imaging, which uses AI-based tools to improve outcomes for cancer research. Microsoft's AI Network for Healthcare and Apollo Hospitals are developing an AI model to predict heart attack risk.

For accessing data, electronic medical records are present in 15 percent of cancer hospitals in India, while other hospitals do not have the infrastructure to digitise radiology or pathology data. In radiology, AI is being used to interpret and analyze information and send big data in a format such as colour codes, to track whether the treatment is working. Reports can be typed by AI and relayed to the treating doctors.

2. Anticipated developments:

It is anticipated that healthcare practitioners will be co-innovators with technology developers to develop AI systems for healthcare. If physicians become over reliant on AI technologies for clinical processes, diagnosis and treatments, it may result in physician deskilling in the form of deteriorated examination skills or clinical knowledge, or the ability to make informed decisions regarding diagnosis and treatment. The requirements of end users may not always be met by AI solutions, which may affect integration of such AI solutions and the workflows, or standards of clinical practice.

IV. ETHICO-LEGAL CONCERNS

1. Safety and transparency in operations:

AI based devices require approval by the appropriate regulators, which is provided on the basis of meticulous testing and clinical studies. AI based medical devices have now shifted from the traditional softwares to learning models, which may have the capacity to continually update themselves and may not be standardized. Adequate validation of AI technologies through scientific research is required before it is deployed for the healthcare sector.

Recently, there is considerable increase in developer companies investing in healthcare mergers, which may result in increased regulatory scrutiny, considering the potential conflicts of interest. Transparency in AI requires the developers to provide information about the algorithm model, that is, its training, validation, use, benefits and harms.

2. Accountability for inaccuracy and errors:

AI deployment in healthcare requires meaningful human control, by avoiding over reliance on AI based tools. With the implementation of novel technologies, there are concerns about the ability of doctors to operate the smart devices and platforms, or the concern that such technologies may even replace doctors. This is because such machines can self-educate and improve their output or performance. Physicians should be able to provide feedback on proposed AI models to enable a continuous learning loop. To ensure the safety of AI, developers must ensure that the datasets are valid, and that the system issues regarding cybersecurity are revealed. For autonomy, patients have the right to get information about treatments and be aware of who should be held responsible for medical errors.

The lack of openness in the algorithms' decision-making processes has been a demerit for use of AI, especially in medical education. Explainability in AI could increase trust and determine liability for AI errors, that is, a technical explanation. This means that persons affected by the outcome of AI technologies should be able to challenge the factors and logic that led to that outcome. They should be able to get a reasonable explanation of how or what features of the algorithm have contributed to a decision. Due to the lack of autonomy and sentience in AI, moral agency is a human attribute. Accountability may be studied by examining the physician's interactions with sensors and software.

The accuracy of AI's outputs depends on its training data (lab results, imaging studies, and medical records), and errors could lead to risks for patients. Due to the complexity of AI algorithms, there may be lack of trust or resistance considering the risks for harm. Where AI models are supporting healthcare services on their own, responsibility could be difficult to attribute. Also, proving causation in negligence may be difficult as the algorithm itself influences its output. If decision-support system results are accepted, judges may base their decisions based on risk assessments which can turn out to be inaccurate. If a healthcare provider cannot justify the output of the AI software which he is using, then he may not be able to appropriately justify its actions.

3. Patient-provider relationship:

As an important principle of patient autonomy,

informed consent requires patients to be aware how their data might be used for training of AI models and what factors influenced a decision by a physician. For example, the physician may have to disclose to the patient that a medical decision was taken using AI, or they may have a duty to explain the complexities of such an AI algorithm to the patient. In the absence of explainability, physicians may not be able to educate the patient about the data inputs, potential biases and forms of ML in the algorithm. Consultation empathy which is provided by healthcare professionals in the form of expertise, intuition, and compassion may be replaced by automated chatbots or applications. Physicians should recognize clinical evidence of a patient's disorder when they interact with AItechnologies, by focusing on the patient's history and clinical examination. Here, physicians must be able to exercise professional autonomy or discretion in dealing with complex diseases. Although AI systems can direct a patient to a particular care centre according to its diagnosis, it may not consider the patient's economic restrictions or other individual requirements. Confidentiality of patient data may be impacted by the intermediaries involved in patient-physician interactions, especially in telemedicine and administrative clinical applications.

4. Data access and privacy:

Healthcare data is considered to be sensitive because it contains personal and intimate information about an individual, which makes it difficult for people to consent to its use. This data may have value only when AI algorithms decode the information in such data. For persons who sign the user agreements during frequent updates of the software, the ethical responsibility of a user agreement must include the way in which information from patient applications is used for clinical decision making.

Prediction models can find new ways to detect and treat chronic illnesses by utilizing data found in tracking devices or sensors. Lack of informed consent may result in the non availability of sufficient open-access training representative datasets for diseases occuring in the Indian population, which may affect the development of accurate AI algorithms for diagnosing those specific diseases. ML algorithms may be misused to create methods that compromise the security and safety of data, without revealing the real-time usage and collection of data.

5. Social gaps and justice:

Biases can occur with regard to population features such as age, ethnicity or disabilities, which depends on how AI systems analyze the data. The software may not give accurate recommendations for populations which the training data did not represent.

Due to the growth of technologies and high-quality medical service, the traditional healthcare model which tried to provide infrastructure to ensure access for the population to services has become overburdened. AI algorithm models may learn the biases hidden in their training datasets and display such discrimination in their output without explaining the same, which could affect disadvantaged groups whose data has not been represented in the training data sets. The effectiveness of AI platforms depends on the integrity of the stakeholders involved in the digital health market, such as technological companies, healthcare providers and the government.

V. REGULATORY MECHANISM

1. United States:

Under the Federal Food, Drug, and Cosmetic Act 1938, a healthcare provider could be held liable for any erroneous outcome as the AI based clinical based support system would be considered as a tool in the hands of the healthcare provider. Courts have been reluctant to impose product liability on healthcare software developers for their software, since it is basically considered to be a a tool. Recently, in California, a class action suit has been filed against Cigna Healthcare, alleging that its AI system rejected 300,000 pre-approved insurance claims.

2. European Union:

In its resolution, the European Parliament pointed out that its Council Directives on liability for defective products may not cover robotics, and provided two approaches for either establishing strict liability or for responsibility for risk management. The General Data Protection Regulation regulates use of personal data related to the health of a person, where data controllers have to provide them with information about automated decision making along with the consequences of such data processing.

The European Union's Artificial Intelligence Act (expected to be approved by the end of 2024)

classifies AI systems according to their risk levels and bans specific high-risk applications, such as social scoring and emotion recognition, that pose a threat to personal safety, civil liberties, and democratic governance. It stresses the importance of transparency and explainability, so that users can access information about AI-generated decisions.

3. India:

Last year, the Indian Council of Medical Research released 'Ethical Guidelines for Application of AI in Biomedical Research and Healthcare'. They emphasize the importance of responsible AI by ensuring autonomy of the patient to choose or reject AI technologies; safety and risk minimization by benefit-risk assessment; trustworthiness through reliability and validity of the software; data privacy through consent for data access and safety measures; accountability and liability attributed through continuous supervision; and accessibility and inclusivity by improving access to technology to vulnerable populations and removing language barriers. The document also provides guidelines for clinical validation and approval of AI solutions, and the responsibilities of various stakeholders such as developers, healthcare providers and ethical reviewers in deploying AI solutions.

VI. CONCLUSION

Digital technologies have had a great impact on healthcare systems worldwide. National governments are taking action to support the integration of AI into health care which would require substantial improvements. AI health applications have had a significant impact on the nature of interactions between healthcare professionals and patients. However, AI systems today cannot still use the human reason or clinical intuition which physicians have.

It has been recognised that there are significant issues in the adoption of AI technologies in healthcare. The EU legislation offers a good starting point for a global discussion on how not to use AI. There has to be integration between technology innovators, healthcare industry and investors to ensure effective clinical relevance of AI clinical products. Public reception of the benefits and risks of AI in healthcare is a critical factor in deployment of AI, because it is affected by patient-physician trust and comfort for complex or sensitive health-related issues. At present, ensuring diverse data programming systems and contiuous audits of the algorithms are requirements.

The Organisation for Economic Cooperation and Development has provided five principles for operationalization of AI in healthcare:

1. 'Accountability', which would govern the transparent reporting of AI incidents;
2. 'Human centred values and fairness', which would enable healthcare providers to improve outcomes for patients;
3. 'Inclusive growth, sustainable development, and well-being', which would enable health solutions to be accessible to the public;
4. 'Transparency and explainability', which would enable AI solutions to be clear and understandable for patients; and
5. 'Robustness, security, and safety', which would enable the responsible and safe use of sensitive health data.

Recently, the World Health Organization has released a guidance document on ethical principles for the deployment of AI in healthcare. It encourages governments to create regulatory frameworks by ensuring that AI systems are transparent, and aligned with sustainability and human rights.

A multidisciplinary approach through collaboration between technology innovators and healthcare providers is necessary to recognise the best ethical practices to implement AI technologies for equitable and effective use.

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