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Editorial

Artificial Intelligence in Healthcare and Biomedical Research - Ethical Aspects

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1. Introduction

Artificial intelligence (AI) is a scientific field which involves creating advanced machines/computers to learn, reason, and act in a such way which requires human intelligence. It is a system's ability to achieve specific goal or task by interpreting external data in correct sense with flexible adaption.[1]

It can perform various simple to complex and repetitive to cognitive tasks using complex computer algorithms emulating human cognition. It has many applications in healthcare sector and biomedical research. The AI-based tools and techniques are expected to improve healthcare delivery system leading to improvement in affordable and accessible quality healthcare to needy. But, the integration of AI in these fields has raised many ethical concerns. Hence, AI technology development and its application should be governed by an ethically sound policy framework.

The conventional or AI-based health and biomedical research should adhere with the basic ethical principles of autonomy, beneficence, non-malfeasance and distributive justice. This will ensure the protection of dignity, rights, safety and well-being of Human community. There is huge risk of mistakes in patient diagnosis using AI and there may be difficulty in establishing accountability for it.

AI-based machine learning system in healthcare may subject to algorithmic bias based on gender, race, etc.[2] There is need from Governmental regulatory bodies and healthcare institutions to establish a structure to monitor the key issues and provide for governance mechanism to overcome its negative implications.[3,4]

Indian Council of Medical Research (ICMR) Artificial Intelligence Cell issued its document named 'Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare' in 2023 to ensure ethical conduct in Biomedical research and Healthcare by addressing the key emerging ethical challenges due to application of AI. These guidelines provide needed ethical framework guiding decision-making towards AI application in development, deployment and adoption of AI-based healthcare solutions. These guidelines provide the basic ethical framework for all stakeholders involved research on Artificial intelligence in healthcare and biomedical research.[5]

These guidelines applicable to the AI-based tools involved in biomedical and healthcare research and the concerned stakeholders. AI in healthcare applied to various purposes and scientific fields such as diagnostics and screening of diseases, therapeutic, drug discovery and development purposes, clinical care, epidemiology

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and disease prevention, behavioural and mental healthcare, forensic medicine, health management system. These guidelines include various sections related to ethical principles, guiding principles for stakeholders, an ethics review process, AI use governance and informed consent.

AI-based healthcare solutions mostly dependant on the data from human subjects. It involves additional concerns of autonomy, interpretation, data handling, human personal biases, data sharing, professional competence and data privacy. An informed, collaborative and multidisciplinary approach on safe, secure, fair, transparent, ethical and responsible AI deployment will facilitate to assure equality in prediction judgements addressing the explicit and implicit biases in the system.

1. Ethical principles for AI in healthcare and Biomedical Research[5]

The AI technology development and application in health sector is being guided by the values and core principles of ethics. As it directly affects to the human lives and may result in grave consequences endangering human life, there is need of cautious, non-obstructive and ethical approach in development and deployment of AI in healthcare and Biomedical research. The ethical principles are as follows-

1.1 Autonomy

Using AI technologies may undermine human autonomy and there is possibility of independent functioning of the AI system. The decision-making powers may be fully transferred in the hands of machine. To avoid this, humans need to have complete control on AI-based healthcare solutions and healthcare decision making. At any circumstances, the AI technology should not interfere with patient's autonomy. More emphasis should be given to formulate the policies and guidelines which facilitate the strengthening of autonomy of the participants.

1.2 Safety and risk minimization

Before starting use of AI-based solutions in healthcare there is need of affirmation about system's safety, consistent performance and reliability towards protecting participants rights, dignity, well-being and safety. It should have a robust set of control mechanism to prevent its deliberate or unintended misuse.

1.3 Data privacy

The AI-based solutions need to ensure privacy, confidentiality and personal data protection at all stages of its implementation in healthcare. Use of surplus data from participants should not be used without proper consent.

1.4 Optimization of Data Quality

As the AI is data driven technology, the outcome is based on data used in training and testing and data bias is considered as the greatest threat. Hence, training data should be free from known biases. It needs to represent the large section of target population. Sampling bias should be avoided.

1.5 Trustworthiness

For effective use of AI in healthcare, healthcare providers and researchers should provide simple, systemic and trustworthy way to test its validity and reliability. A trustworthy AI solution should provide lawful, ethical, reliable, transparent, explainable and valid, technically sound and quality results.

1.6 Accountability and liability

An individual researcher or organization obliged to account for its activities. They need to accept responsibility for their actions. They owe responsibility of disclosing the results in a transparent manner. There is mandatory need of regular internal and external audits of AI technologies for ensuring optimum functioning. The concept of 'Human in The Loop' (HITL)[6] is going to place human beings in a supervisory role for healthcare purposes to ensure an individualized patient-centric decision making by the health professionals. In case there is a harm due to AI-technology, the legal liability and the relative role of stakeholders in damage should be identified based on appropriate mechanism ethical norms.

1.7 Accessibility, equity and inclusiveness

The digital divide is existent in almost all countries. It is more prominent in low- and middle-income countries (LMICs). The dependence on technology may affect its

wide application to such states. Stakeholders need to provide fair and equitable opportunities to access the AI based healthcare solutions to different users. The potential end user groups such as underprivileged, poor, etc. should be encouraged to access the AI technologies through Government schemes. AI developers and stakeholders should be determinant on providing the accessibility of AI technologies to economically and socially disadvantaged classes.

1.8 Non-discrimination and fairness principles
Bias-free and accurate data collection from representative population will ensure quality. AI-tool developers need to promote and protect equality of individuals ensuring individual rights, dignity equality and justice. AI solutions should be designed for universal use and free from any discrimination based on race, age, caste, religion or social status.

1.9 Collaboration
As the field is data driven, a well-curated large datasets collection is needed for development of any meaningful AI for health which can be achieved by fostering collaboration amongst various stakeholders at every level encouraging inter-disciplinary collaborations.

1.10 Validity
Before applying the AI technology in healthcare on patients/participants, it must be subjected to rigorous clinical and field validation to ensure safety and efficacy.

2. Guiding principles for stakeholders

AI-based solutions development, validation/ testing and its utilization in healthcare is a multistep process involving partners and collaborators from various fields. Each step needs to follow standard practices for making AI-based solutions ethically appropriate and technically sound with application to larger part of society with fairness and equity. The stakeholders need to follow the guiding principles to make the AI-based solutions more acceptable and useful to beneficiaries.

Public engagement is essential to improve acceptability and help to build public trust. Stakeholders have important role in various processes such as conceptual framework, designing, development, implementation, training, monitoring, feedback, ongoing education, improvements, accountability and advocacy.

3. Ethical review process in Medical AI

Ethical committee (EC) has a great role in assessing the scientific proposal with ethical considerations. It is responsible to ensure that the scientific proposal is sound and benefits population at large. EC need to check the proposals for data sources, methodology, anonymity, data safety and security, privacy and confidentiality, sound selection process, data quality, subject protection, compensation and possibility of stigmatization, etc.

4. Informed Consent

In the AI-based bio-medical research, researcher should obtain a written informed consent from study participants. Full information should be disclosed to the participants informing them risks, benefits, complications and subject have right to refuse to participate. The researcher should ensure voluntariness for participation in the research. With advancement of technology and science, there are various avenues in forensic medicine with use of AI technology.[7-9]

5. Use of AI technology in healthcare and biomedical research governance

The Indian Government is keen on streamlining the AI technologies in all sectors including healthcare. To leverage Digital health Technologies, the National Health Policy (2017) have made focused efforts to integrate digital health establishing National Digital Health Authority.[10] Further, National Digital Health Blueprint (NDHB 2019) facilitates the development of a system of electronic health records based on international standards integrating principles of data anonymity and de-identification.

The Government of India Ministry of Health & Family welfare (MOHFW) proposed the Digital Information Security in Healthcare Act (DISHA) 2018 provides for electronic health data privacy, Security, safety, confidentiality and standardization, it also provide for establishment of National Data Health Authority and Health Information Exchanges.[11]

Definition of medical device is expanded with inclusion of any software or an accessory intended

to be used for a medical purpose as per the Medical Device Rules, 2017 and its amendments in 2020.[12]

The incorporation of AI-based solutions and technology is expected to improve healthcare delivery to underprivileged and needy. It aims to make healthcare accessible and affordable to all.

It is improving the quality care of healthcare services provided to large sections of the society. Following ethical guidelines in development and deployment of AI based solutions in healthcare will facilitate appropriate implementation of AI in healthcare and biomedical research.

We can harness AI's potential to improve healthcare and biomedical research by acknowledging and addressing these ethical considerations, with ensuring responsible and beneficial innovation.

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