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REVIEWING THE LEGAL AND ETHICAL DIMENSIONS OF AI IN THE INDIAN MEDICAL SECTOR

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Abstract

The growth of India as a hub of medical tourism and high-class healthcare facilities has increased the ever-growing demand for incorporating AI and digital systems in healthcare practices and related activities. The current government policies and schemes largely focus on transitioning the country into a 'Digital India' society. The medical sector is one of the primary areas where changes are being implemented for a technological revolution. AI is, therefore, being hailed for streamlining the otherwise overburdened and complex healthcare sector by easing communication with patients, collecting and computerizing medical data, providing early and personalized diagnosis and easy access to information, and even using robotics to aid surgical procedures. However, the goal of a digitally empowered medical sector lacks the infrastructural and regulatory means to achieve it effectively. India lacks regulatory mechanisms to address AI's potential ethical and legal violations, raising the question of identifying whom to hold accountable and liable. Growing dependency on AI overlooks the lack of a structural base that addresses AI governance and its issues in the healthcare industry. The current legal framework is insufficient and lacks the required guidelines to regulate AI in medical practices. Informed consent, protection of privacy, accountability and responsibility, data hacks and leaks, diagnosis and treatment errors, and patient confidentiality are some of the crucial issues that can challenge the constructive integration of digital mechanisms and AI in the medical sector for fruitful results. This paper will provide a descriptive analysis of AI as a tool and discuss the opportunities and benefits of AI and digital healthcare for patients and workers in the medical sector. It will also review the legal and ethical challenges and the underlying risks associated with the functioning of AI without any institutional limitations. Furthermore, the existing legal framework and policies

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relating to healthcare will be studied to understand how new policies and guidelines to incorporate AI can be formulated. The paper will, therefore, explore and highlight the need for making AI systems and mechanisms in healthcare accountable and responsible by understanding their benefits, challenges, and prospects.

Keywords: Artificial Intelligence, legal framework, data privacy, ethics, Indian healthcare.

Introduction

The progression of human history has demonstrated the gradual shift from manual labour to machinery and technology, leading to efficient working culture and enhanced lifestyle. The trend of advancing modernity has now reached the domain of Artificial Intelligence (AI) which has been reshaping and fostering the development of various sectors and industries by simplifying the workload and bringing about innovation. AI is not a new technology but has been developed and modified since the 1950s with the recent boost due to increasing computing power and capacity and the availability of large data to work upon, especially through the internet[2]. Artificial Intelligence can be understood as a technology that can simulate and imitate human intellect patterns and behaviors without human intervention. Hence it serves to mimic 'intelligent behavior' with the use of computer software.

AI permeates the basics of daily human needs such as online search recommendations, voice assistants, autocorrect features, chatbots to assist customers on various websites, facial and fingerprint recognition for passwords, spam filters and predictive replies on email, and many more. It has seamlessly integrated into the various domains of an individual's life, from a simple internet search to entertainment and even in the management of a healthy lifestyle. The use of AI in healthcare is not only restricted to robotics and Machine Learning in infrastructural and professional settings. Smartwatches with sensors to track biological activities, eHealth apps, chatbots, and virtual assistants serve to provide personalized healthcare services. Hence, remote healthcare clinical services, and wearable devices have diminished the constant need for physical checkups and improved the chances of early diagnosis. With its applications such as Machine Learning and Natural Language Processing, AI computerizes the ability to gather, arrange, synthesize, and analyse complex and unquantifiable data, therefore addressing the limitation of human abilities. It can effectively

[2] Hartmut Hirsch-Kreinsen, *Artificial intelligence: a "promising technology"*, AI & SOCIETY. (2023) https://doi.org/10.1007/s00146-023-01629-w

digitize the conventional practices of recording and organizing large amounts of patient data and medical records, and provide early diagnosis through symptom identification. The process can become more cost-efficient and speedier due to the replacement of slow manual labour with high-capability computers. A net outcome will be a preventive model of medical care where individuals will have more transparency and control over their overall health due to accessible medical devices and technologies providing early detection, general advice, and treatment recommendations[3].

The exponential benefits of AI require sharing private information and records in a large data pool prone to be hacked and misused. Certain ethical and legal considerations must be focused on to ensure patient safety, accountability, transparency, and fairness of medical procedures. India has also stepped into the digital health realm marked by the 'Digital Health Campaign' launch in 2015. The Ayushman Bharat Digital Health Mission, launched in 2021, aims to host a digital ecosystem for easing healthcare facilities and making them more simplified, inclusive, and affordable.[4] However, India still lacks a comprehensive Digital Health law that can address the concerns and govern the fair use of AI.

Application of AI in the Medical Sector

1. **Robotics Assisted Surgery**
   India's high deficiency of skilled surgeons, costly and time-consuming procedures result in patients facing severe repercussions due to a lack of immediate medical attention and surgeries. Robot surgery is a minimally invasive surgery that can assist - surgeons in speedier and high-precision operations, filter incidences of hand tremors, and allow quicker recovery periods due to smaller incisions and surgery areas. Deep learning will enable robots to carry out simple and repetitive surgical procedures, enabling doctors to perform more complex tasks[5]. The Apollo Institute of Robotic Surgery in India is the first medical institute in Asia-Pacific to use Renaissance Robotic Technology for minimally invasive spine surgery[6].

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[3] Omar Ali et al, *A systematic literature review of artificial intelligence in the healthcare sector: Benefits, challenges, methodologies, and functionalities*, *8*(1) JIK, (2022). https://doi.org/10.1016/j.jik.2023.100333

[4] National Portal of India, *Ayushman Bharat Digital Mission (ABDM)*. https://www.india.gov.in/spotlight/ayushman-bharat-digital-mission-abdm

[5] Kristen Clark, & Eliza Strickland, *Robot surgeons are taking over the operating room*, IEEE SPECTRUM. (May. 31, 2016). https://spectrum.ieee.org/robot-surgeons-are-taking-over-the-operating-room

[6] Apollo Hospitals, *Robotics*, (Jul. 3, 2016). https://www.apollohospitals.com/departments/robotics-surgery/

2. **Data Management and Administrative Workload**

   AI can improve and provide more accuracy in handling large amounts of data, along with reducing the workload in administrative tasks such as billing, registration, verifying documents, bed management, tallying medicines stocks, accounting, scheduling appointments, and tracking patient records. This reduces the margin of human errors, brings down operating costs, accelerates the long-time taken for paperwork, and brings about high precision and perfection in organising big data. The employees can be more productive with speedier processing of repetitive work[7]. The data is stored centrally and can be easily accessed by medical personnel, which serves to be helpful in cases of emergency. Machine Learning models of Optical Character Recognition can interpret prescriptions, which eliminates the errors of manual reading and even helps to integrate the prescribed data with electronic health records.

3. **Early Diagnosis and Detection**

   AI is becoming fundamental in early diagnostic analysis which can help detect diseases before acquiring a serious stage. It can accurately detect and classify cancer, even outperforming human diagnoses prone to mistakes and false detections[8]. Niramai is a Bangalore-based health tech company using Thermalytix, a diagnostic engine powered by AI for the early detection of breast cancer[9]. It is a less invasive process and minimises contact or use of radiation facilities. Hence, it requires fewer resources and is cost-effective in nature. X-rays, CT scans, and MRIs can be analysed with higher precision and provide accurate results[10]. Integrating pattern recognition with deep learning will enable AI systems to process large amounts of medical tests at enhanced speed, directing quicker treatments. Analysis of Electronic Health Records (EHRs) and medical histories can recognise high-risk patients and provide preventive measures. Further, the large database modelled on different sources like general

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[7] Indian Council of Medical Research, *Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare*, (2023). https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf

[8] Lukito M. Cahyo, & Santi D. Astuti, *Early Detection of Health Problems through Artificial Intelligence (Ai) Technology in Hospital Information Management: A Literature Review Study*, 4(3) JMHS, 37, 39 (2023). https://doi.org/10.32996/jmhs.2023.4.3.5

[9] Niramai Thermalytix, *Niramai*. https://www.niramai.com/about/thermalytix/

[10] Claire M. Parry & Urvashi Aneja, *Artificial Intelligence for Healthcare: Insights from India*, CHATHAM HOUSE, (2020). https://www.chathamhouse.org/sites/default/files/publications/research/2020-07-30-artificial-intelligence-for-healthcare-munoz-parry-aneja.pdf

medical knowledge and patient data can be utilised for identifying predictable patterns of symptoms which can result in future health complications.

4. **Monitoring Patients**

Chatbots and virtual assistants are backed by a huge medical database that enables them to provide personalized healthcare advice suited to the individual's problem. They are useful in managing schedules, reminders about medicines and appointments, providing basic medical details like symptoms and health history, and booking appointments[11]. The Digital Health Mission also introduces the concept of mHealth and makes health services available on smartphones and digital devices, removing the need for physical clinic visits regularly[12]. In the present age, nearly everyone uses mobile phones and it serves as the most accessible device for providing quality healthcare remotely and at lower costs. AI assistants in phones can solve patient queries about treatments and procedures, and provide references to specialists. Smartwatches and fitness bands have been equipped with electrocardiogram sensors where AI is used to monitor heart rate, blood pressure, oxygen saturation, and calories burnt which further recommends and alerts the individual on detecting irregularities[13].

5. **Drug Development**

Although still in the early stages, AI is the driving force behind accelerating and bringing in innovations in the pharmaceutical sector. It enhances and develops the processes of drug design, chemical synthesis, polypharmacology, screening, and repurposing[14]. Fast data collection and analysis of personal and biological data such as age, gender, and symptoms of large-scale demography can bring innovations in the field of vaccines for general treatments and personalised drugs for specific needs[15].

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[11] *Id*

[12] Nishith Desai Associates, *Digital Health in India,* (2023). https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Digital_Health_in_India.pdf

[13] Sumit Kumar & Arijita Banerjee, *Artificial Intelligence-Enabled Smartwatch Used for the Detection of Idiopathic Ventricular Tachycardia: A Case Report,* *15*(7) CUREUS, (2023). https://doi.org/10.7759/cureus.42054

[14] Debleena Paul et al, *Artificial intelligence in drug discovery and development,* 26(1) DRUG DISCOVERY TODAY, 80, 83 (2021). https://doi.org/10.1016/j.drudis.2020.10.010

[15] Indian Council of Medical Research, *Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare* (2023). https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf

Challenges of AI in the Medical Sector

The integration of AI in the Indian healthcare sector is fast-paced and ever-growing. As one of the biggest hubs of medical tourism, India now hosts several world-class medical facilities and hospitals that have actively adopted AI-based models in professional settings. However, there is a lacuna regarding comprehensive and binding rules, and regulations on the fair use of AI in the healthcare sector. Hence, the benefits of AI are often subdued by various illegal, immoral, and unethical practices which can become a barrier to its proper utilization.

1. Legal Challenges

1.1 Existing Regulatory Frameworks and its Shortcomings

Section 38 of the Clinical Establishments (Registration and Regulation) Act, 2010 provides that every state must maintain and supply the Centre with a digital register containing all information of the clinical establishments in the state, and update upon any addition or modification made to the register[16]. Rule 9(iv) of the Clinical Establishments Rules, 2012 prescribes that every clinical establishment must fulfil the condition of 'maintaining Electronic Medical Records or Electronic Health Records of every patient as determined by the Central or State Government' for the Grant of Registration and its continuation[17].

The Information Technology Act 2000 is the primary legislation that was passed for protection against cybercrimes, followed by the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011(Data Protection Rules). Section 43A of the IT Act [18]directs any 'body corporate to be liable to pay damages for the negligent implementation and maintenance of sensitive information resulting in wrongful loss or gain to a party. Rule 3 of the Data Protection

[16] The Clinical Establishments (Registration and Regulation) Act, 2010, §38, No. 23, Acts of Parliament, 2010 (India) https://www.indiacode.nic.in/bitstream/123456789/7798/1/201023_clinical_establishments_%28registration_and_regulation%29_act%2C_2010.pdf

[17] The Clinical Establishments (Central Government Rules, 2012, Gazette of India, Rule 9(iv) (May 23, 2012). http://clinicalestablishments.gov.in/WriteReadData/386.pdf

[18] The Information Technology Act, 2000, §43A, No. 21, Acts of Parliament, 2000 (India). https://www.indiacode.nic.in/bitstream/123456789/13116/1/it_act_2000_updated.pdf

Rules, 2011[19] provides for medical records or history, physical, physiological, and mental health conditions, sexual orientation, and biometric information to constitute sensitive personal data. Rule 4[20] mandates body corporates to provide privacy policies when handling sensitive personal data while Rule 5[21] makes it a requirement for the body corporate to obtain the consent of the provider of the sensitive personal data. In medical settings, the healthcare institution or medical practitioner becomes bound by law to obtain the permission of the patient and provide details on why their personal sensitive information is being collected[22]. The Rules additionally ensure that consent of the provider is taken before disclosure of the information to any third party[23] and such transfer must ensure that the receiving body or party provides adequate security measures[24]. These legal frameworks do face certain shortcomings given that much of the Indian population still avail the unorganized and unprofessional medical services due to poverty. People are not aware of their privacy rights and the requirement for consent[25]. Even though the IT Act and Rules have been implemented over decades, there have been still numerous incidences of data breaches and hacks in medical institutions and therefore there is an urgent need for stricter legislation.

The Digital Personal Data Protection Act, 2023 is the latest Act passed for governing digital data protection in India and replacing Sec 43A of the IT Act, 2000. Notably, the Act does not provide as to what constitutes sensitive personal information. This lack of clarity and absence of proper definition provides a loophole for data leaks and privacy breaches as there is no yardstick to differentiate between sensitive information and other data. Despite the requirement of consent from the data principals for the processing

[19] The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, Gazette of India. Rule 3 (Apr. 11, 2011). https://upload.indiacode.nic.in/showfile?actid=AC_CEN_45_76_00001_200021_1517807324077&type=rule&filename=GSR313E_10511(1)_0.pdf
[20] *Id.*, rul.4
[21] *Id.*, rul.5
[22] Nishith Desai Associates, *Digital Health in India*, (2023). https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Digital_Health_in_India.pdf
[23] *Supra* at note 18., rul. 6
[24] *Id.*, rul. 7
[25] Paarth Naithani, *Protecting healthcare privacy: Analysis of data protection developments in India*, 9(2) IJME, 149 (2024). https://ijme.in/wp-content/uploads/2023/12/Protecting-healtcare_149.pdf

of personal information, there can still be a breach of privacy through using the shared data for commercial purposes and sharing it with third parties[26]. The Act also fails to incorporate any provisions to regulate the use of AI systems in the digitization of personal information and to prevent its misuse.

Some other legislations and frameworks regulating the Indian medical sector include the Health Data Management Policy 2022, the Drugs and Cosmetics Act, 1940, the Medical Devices Rules, 2017, and the Telemedicine Practice Guidelines.

1.2 Data Security Concerns

Artificial Intelligence and Machine Learning thrive upon sourcing knowledge and inputs from various digital sources to improve and broaden their databases. Electronic Health Records, clinical research data, biobanks, hospital management data, pharmacy records, and mobile health apps provide the vital information needed by AI systems to optimise and train their algorithms. Such access to private and sensitive information of patients, and by extension, their families, can pose a huge security risk of data breaches, hacking, and cybercrimes. With the growing amount of personal information being submitted on online websites and health apps, and digital records stored in hospital and clinic management systems, patient information can become easily accessible by cybercriminals and hackers. Patients' health and related non-health data like contact details, credit card information, occupation, address, family details, Aadhar, PAN, insurance details, etc., can be shared by the medical centres with banks, companies, and interested institutions which can use those to contact the patients, offering services and for promotional purposes. Weak digital security and encryption increase the vulnerability of data breaches used to create fake medical records, phishing emails, and ransomware attacks with the help of Generative AI[27]. This can put a high risk on the elderly and technologically handicapped individuals who lack the security awareness to verify the legitimacy and authenticity of such scams. AI

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[26] *Id.*

[27] Steve Alder, *Editorial: Why AI Will Increase Healthcare Data Breaches*, THE HIPAA JOURNAL, (Oct 12, 2023).https://www.hipaajournal.com/editorial-why-ai-will-increase-healthcare-data-breaches/

chatbots like ChatGPT provide easy access to formats for convincing emails to secure personal information and coding malware software to hack into databases containing sensitive records[28]. The Indian government is encouraging data localisation to prevent the cross-border thefts and selling of medical data that can lead to further hacks and privacy violations[29].

Cyberattacks on health data are frequent and rampant in the present days when digital security measures are not adequate. India saw one of its largest cases of data leaks with the information of 815 million patients being leaked on the dark web on October 2023 due to a breach at the Indian Council of Medical Research(ICMR). It was first noticed by US-based cybersecurity firm Resecurity which flagged a broker selling Aadhar and Passport information of 815 million Indians, accessed from the COVID-19 details registered with the ICMR[30].

1.3 Responsibility and Accountability

The advancing development of Machine Learning is progressing towards a reality where AI will have the capability to function and operate at the levels of trained medical practitioners instead of just aiding them in surgical procedures. However, the existing laws are still inefficient in allocating liability in situations of negligence and medical wrongs that AI-powered mechanics can commit due to the prevailing question of whether such offences would fall under human or product liability[31]. Determining the bearer of responsibility and accountability becomes even more difficult, given that AI cannot be regarded as a legal person or entity that can be punished for its

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[28] Jingquan Li, *Security Implications of AI Chatbots in Health Care*, 25 JMIR, (2023). https://doi.org/10.2196/47551

[29] Dr. Sheikh Inam Ul Mansoor, *The Legal Implications of Artificial Intelligence and Machine Learning in Indian Healthcare*, 1(1) USLR, 157, 163 (2024). https://www.researchgate.net/publication/381009921_The_Legal_Implications_of_Artificial_Intelligence_and_Machine_Learning_in_Indian_Healthcare

[30] HT News Desk, *Aadhaar details of 81.5 cr people leaked in India's 'biggest' data breach*, HINDUSTAN TIMES (Oct. 31, 2023). https://www.hindustantimes.com/technology/in-indias-biggest-data-breach-personal-information-of-81-5-crore-people-leaked-101698719306335.html

[31] Ricardo Costa Macedo et al, *Obstacles to healthcare AI: legal issues relating to the increasing use of AI in healthcare and medical technologies*, INTERNATIONAL BAR ASSOCIATION, (Nov 2, 2023). https://www.ibanet.org/Obstacles-healthcare-ai#_edn1

mistakes and errors, even though its intelligence mimics that of a human being. Wrong data input, and mechanical breakdowns, possess unpredictable risks and AI might lack the knowledge required to make quick decisions in unprecedented and new situations it has not been programmed to face. Independent functioning of AI-based systems without proper human surveillance can result in loss of resources, harm to patients, and costly errors that cannot be managed or prevented before the damage is caused.

Human healthcare professionals are liable for their actions and decisions resulting in misdiagnosis, gross medical negligence, surgical errors, wrong medications, lack of informed consent, and medical malpractices. Civil suits or complaints to consumer forums can be filed against the medical practitioner, service provider, or medical institution vicariously for the tort of negligence and the victim can claim compensation for the harm caused. The landmark judgment of Indian Medical Association v. V.P Shanta[32] brought the medical profession under the Consumer Protection Act, 1986 as it falls under the ambit of 'service' defined in Section 2(1)(o) of the Act. Criminal proceedings can be constituted under Sec 304A, 336, 337, and 338 of the Indian Penal Code 1980.

Gluyas and Day (2018) lists that '*there are many parties involved in an AI system (data provider, designer, manufacturer, programmer, developer, user and AI system itself)… and there are many factors to be taken into consideration'* making it difficult to ascertain liability[33]. There can be a dual perspective on determining the liability- human liability and product liability[34]. Similar to the principle of vicarious liability that governs the employer-employee between hospitals and the medical professionals and staff, the doctor and the hospital can be held liable for the mishaps committed by the AI medical devices. The degree of liability can be tested on the standard due care taken by the doctor and healthcare institution in selecting, maintaining,

[32] (1995) 6 SCC 651

[33] Lee Gluyas & Stefanie Day, *Who Is Liable When AI Fails To Perform?*, CMS LAW TAX (2018). https://cms.law/en/media/local/cms-cmno/files/publications/publications/artificial-intelligence-who-is-liable-when-ai-fails-to-perform?v=1

[34] *Supra* at note 30

and properly administering the specific technology[35]. However unpredictable and unavoidable AI-based errors, even when the standards of duty of care have been taken, present a perplexity that no present statute or law can be referred to.

Attributing product liability requires fixing liability on the manufacturer or developer of the AI device or mechanism. However, there is a lack of clarity on whether AI algorithms or software can be categorized as a 'product,' given it functions more as a technology that is providing 'service'[36]. Moreover, the formation of AI software includes many players such as the designer, the manufacturer, the developer, and the data provider which further adds to the ambiguity of fixing responsibility.

2. Ethical Challenges

2.1 Privacy and Informed Consent

In the landmark judgment of K.S Puttaswamy v. Union of India[37] in 2017, the right to privacy was recognised as a fundamental right under Article 21 and every human has the right to live with dignity. The medical sector thrives on its inherent values and morals of maintaining patient confidentiality and privacy of sensitive information. The dependency on AI for storing patient information exposes it to the risk of being hacked and leaked. With digital access to a patient's personal and sensitive information such as biometrics, medical history, credit details, age, gender, etc., an individual loses the power of complete autonomy over their private details and it becomes prone to being misused and circulated without consent. Failures and mismanagement of stored data in AI-run systems can pose eminent risks of data losses and hacks. Privacy failures endanger groups having highly intimate medical data and sensitive information such as women who had abortions, HIV-positive individuals, and transgenders[38]. Integrating AI into digital accounts containing

[35] World Health Organisation, *Ethics and governance of artificial intelligence for health: WHO guidance*, (2021). https://iris.who.int/bitstream/handle/10665/341996/9789240029200-eng.pdf?sequence=1

[36] *Id*

[37] (2017) 10 SCC 1

[38] Dipika Jain, *Regulation of Digital Healthcare in India: Ethical and Legal Challenges*, 11(6) MDPI, (2023). https://doi.org/10.3390/healthcare11060911

personal information can lead to further incidences of unauthorized access to passwords, emails, Aadhar, and phone numbers which can be used to connect to other accounts such as bank accounts, and digital lockers.

Informed consent is one of the cornerstones of ethics in the medical sector and profession. The patient and the doctor share a contractual relationship and the former retains full autonomy over the personal information they share, and the right to know how and to what extent it is to be used. No decisions or actions can be taken without the full conscious and voluntary consent of the patient[39]. The medical practitioners and institutions have a non-negotiable duty to provide full disclosure of all treatments, procedures, potential risks, medical fees, and such relevant information to the patients and their guardians. The introduction of technology and complex AI tools in medical procedures brings new challenges regarding acquiring consent as patients need to be rightfully made aware and knowledgeable about the technicalities and the extent to which AI is being used for surgeries and treatment, the personal data being processed by AI systems and the possible risks and benefits. Without any proper framework and guidelines, it becomes difficult to determine how much information is to be shared with the patients which may lead to procedures, treatments, and data accesses that the patient has not consented to.

2.2 Fairness and Biases

The Machine Learning model is developed by the collection and analysis of information from the general population which serves as a training dataset to develop the algorithm. AI is prone to prediction errors and discriminative programming as it fails to classify subgroups and minorities due to sampling bias in data collection[40]. The data collection method can contribute to social biases[41] if the data sampling and analysis are homogeneous and lack adequate representation, resulting in racial biases. A narrow patient demography will make AI predictions non-inclusive, leading to wrong diagnoses. When the

[39] *Id.*

[40] Kerstin N. Vokinger et al, *Mitigating bias in machine learning for medicine*, 25 COMMUN MED, (2021). https://doi.org/10.1038/s43856-021-00028-w

[41] Nithesh Naik et al, *Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility?*, 9 FRONT. SURG, (2022). https://doi.org/10.3389/fsurg.2022.862322

input data is limited to a certain age, gender, sexual orientation, race, or biological characteristics that reflect the majority section of the general population, the output data tends to leave out the marginalised and minority groups. Social, cultural, and economic backgrounds influence an individual's exposure to digital and technological platforms[42]. The populations of underprivileged sections and underdeveloped locations will lack digital exposure and their data will be excluded as training samples for AI software. The AI models further exacerbate the societal inequalities marginalising the underrepresented patient groups because of the absence of a diverse database. The ICMR has published ethical guidelines which suggest that the researchers must preserve data quality and ensure that the data accurately represents the population where the algorithm is being used[43].

Conclusion

Human beings unquestioningly depend on AI which has brought a recourse in the contemporary lifestyle. An AI-integrated medical sector will serve as a great boost in the efficiency and productivity of the overall healthcare scenario in India. However, the prevailing gaps and challenges must be urgently addressed to ensure a safe, equitable, high-quality, and accessible healthcare space. Robust and comprehensive legal frameworks and policies need to be introduced for assigning liability, protecting patient rights, and providing redressal forums to file complaints. Quality control, strong security for data protection, consent, and protection of privacy, transparency, and inclusivity are some of the key aspects that need to be addressed by future legislation. The ICMR has already taken a stepping stone by releasing ‘Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare’. Medical professionals and staff need to be properly educated and trained in utilizing AI devices and technologies.

As India cements itself as a medical hotspot, the traditional model of medical guidelines and practices needs to evolve to integrate AI advancements while also addressing the ethical and legal challenges that can potentially harm patient and societal interests.

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[42] Trishan Panch et al, *Artificial intelligence and algorithmic bias: implications for health systems*, 9(2) J GLOB. HEALTH, (2019). https://doi.org/10.7189/jogh.09.020318

[43] Indian Council of Medical Research, *Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare*, (2023). https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf