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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal provide dedicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

ETHICS, REGULATION AND LEGAL ISSUE **REGARDING AI IN HEALTH CARE**

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ABSTRACT

We are currently living in an AI generation where these machines are intelligent like a human being; they are slowly replacing humans. Even in Health care also, they are replacing medical personnel. AI has a positive impact on diagnosis, where patient's time are reduced. By uploading earlier disease data, the people in the healthcare sector can speedily solve their problems. This paper also explains ethical concerns about the use of AI. There is a need to be concerned about the bias and patient voluntary choice. AI creates bias in health care, and uploading their data may be against their will. So, it is necessary to designed a transparent AI data that both patients and healthcare professionals can understand each other and be patient-centered and healthcare-centered. This Article also explains legal issues relating to AI. In India there are no specific laws which is dealt with AI in health care. Data privacy is covered under Article 21 of the Indian Constitution as a Right to privacy. Disha and Digital Information Security are the only legislation that cover some issues. So, there is a need for awareness and discussion regarding AI by stakeholders.

Keyword: Artificial Intelligence, Health care, Patient, Diagnosis.

1. Introduction

Artificial intelligence is a term which is applied to a machine or software and it has a capacity of simulating intelligent human behavior, rapid calculations, problem-solving and estimation of new data based on previously assessed data. In the health care or medical the safety and protection of patient is the biggest ethics. With the Scientific developed and new invention by human being now health care is shifted into a modern advantage technology and it became concern about ethical consideration.

2. AI-System in Health Care

Automated systems in healthcare are not a recent phenomenon in health but traced back to the 1950s when physicians made the first attempts to improve patient diagnoses using computer program. With the increasing availability of enormous amounts of digital data and the growing computational power of modern computers there are exponential upsurge of different AI-systems which includes machine learning systems, deep learning systems natural language processing systems in society. The AI-system are used by the radiology, pathology, dermatology, ophthalmology, cardiology, emergency triage and even mental health for researched.¹

The Ai system be used in healthcare as

2.1 Diagnosis

Ai system can positively impact diagnostics. Because of these systems capacity to analyze large amounts of data and find correlations between different data points, the use of these systems has the potential to reduce diagnosis time, catch diseases earlier, and better predict how diseases will develop over time, opening up a new area of preventive healthcare and reduced workloads. Fields that rely on medical imaging and radiology, such as oncology, dermatology, and pathology, gets benefit from such application.²

2.2 Clinical care

Analyzing a vast amount of digital data makes ai-systems beneficial for clinical practices. The fact that different sources of patient information such as electronic health records and doctor's notes could be integrated and streamlined increases the possibility to develop more robust treatment decisions, to avoid and catch clinical errors, and to improve clinical outcomes.³

2.3 Health care administration

Ai- systems can be useful for processing healthcare and medicinal administration. These systems can streamline administrative process and provide logistical support such as optimization of the medical supply chain, repetitive tasks or to support complex decision making, identifying and eliminating fraud or waste, scheduling patients,

¹ Tijis Vandemeulebroucke, *The Ethics of Artificial Intelligence Systems in Healthcare and Medicine: from a Local to a Global perspective, and back*, 477 Pflugers Archiv- European Journal of Physiology 591, 592 (2025).

² *Id.* at 593.

³ *Ibid.*

predicting which patients are unlikely to attend a scheduled appointment and assisting in identification of staffing requirements. These efficiency gains could lead to word reductions and possibly to coast savings.⁴

2.4 Health monitoring

Ai-systems can also be applied to monitor individual and public health through the use of wearables and monitoring devices. These systems can be used to develop insight into causes of poor health or disease outbreaks such as environmental degradation as well as social and environmental determinates of health.⁵

3. Ethical concerns in health care by Artificial Intelligence

Despite the potential benefits of AI in health care, its integration also raises important ethical concerns that must be addressed beforehand. One of the primary ethical concerns is the potential for bias. AI systems are only as objective as the data they are trained on and if the data are biased in any way, the AI system will also be biased. This can result in disparities in healthcare outcomes for different patient's populations, particularly for marginalized communities. For instance, an AI system trained on data primarily from white patients based on sociodemographic, cultural, and economic dimensions may not be as effective in diagnosing illnesses in patients of color, potentially leading to suboptimal patient care. Addressing this ethical concern is crucial to ensure that AI in healthcare is used in a fair and equitable manner for all patients. Another ethical concern regarding AI in health care is the potential loss of patient autonomy. As AI systems become more prevalent in health care, patients may feel as though they are no longer in control of their healthcare decision's, which can result in feelings of distrust and decreased patient satisfaction. Another related ethical concern is the potential for AI to undermine the physician-patient relationship. With the increasing use of AI systems in healthcare there is a risk that patients may view AI as their primary healthcare provider, rather than their human physician. This can lead to a breakdown in the trust and communication that is crucial to effective patient care.⁶

⁴ *Ibid.*

⁵ *Ibid.*

⁶ Sheikh Mohd Saleem & S. Muhammad Salim Khan, *The Ethics of Artificial Intelligence in Healthcare: Balancing innovation and Patient Autonomy*, 2 *Journal of Integrative Medicine and Public Health* 7, 8 (2023).

4. Regulation of AI for health care in India

In India, the regulation of AI health care involves several regulatory authority bodies, each addressing different aspects of AI technology health care, medical devices, data privacy and ethical considerations. The key regulatory bodies that play a significant role in regulating AI in healthcare are-

Regulatory body

In India, the regulations of AI in healthcare would involve several regulatory bodies, each addressing different aspects of AI technology, healthcare, medical devices, data privacy, and ethical considerations. The key regulatory bodies that play a significant role in regulating AI in health care are:

I. Central Drugs Standard Control Organization

The Central Drugs Standard Control Organization is the primary regulatory authority for medical devices and drugs in India. Since many AI applications in health care are integrated into medical device (e.g., diagnostic tools, imaging systems, decision support systems), CDSCO will play a central role in regulating AI- bases medical device.⁷

II. National Health Authority

The National Health Authority is responsible for overseeing and implementing Ayushman Bharat Digital Health Mission, which aims to create a digital health ecosystem. AI plays a significant role in this ecosystem for tasks like diagnostics, telemedicine and digital health record. NHA coordinates the implementation of national health programs, including those that may use AI technology in healthcare delivery.⁸

III. Indian Council of Medical Research

The Indian Council of Medical Research is the apex body for the formulation, coordination and promotion of biomedical research, and will play a significant role in regulating the clinical validation and ethics of AI based healthcare tools.⁹

IV. Ministry of Electronics and Information Technology

The Ministry of Electronics and Information Technology is involved in the broader governance of information technology and AI and will play a significant role in digital heath technologies including AI applications in healthcare.¹⁰

⁷ Nishith Desai Associates. REP. NO. 119795.2, at 11(2025).

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰ *Ibid.*

V. Central Consumer Protection Authority

As AI based healthcare tools become more consumer-facing, the central consumer protection Authority will play a role in regulating and protecting consumers from unsafe or misleading AI health care product.¹¹

5. Legal issues relating to AI

The law will need to catch up and keep pace with new innovations deploying AI, to fully exploit the potential of AI. This is particularly relevant in the healthcare arena. Several legal issues arise as no specific laws have been enacted to deal with AI. Existing regulations do not distinguish between cases where there is an error in diagnosis, malfunction of a technology or original use of inaccurate or inappropriate data for the training database. The software developer or the specific program design engineer are not liable. It is not clear how one determines the degree of accountability of a medical professional when the wrong diagnosis or treatment is due to the glitch in the system or an error in data entry. There is ongoing debate about who will be held liable when robots and AI, acting autonomously, harm patient's Current consensus states that the professionals are open to liability if he or she used the tool in a situation outside the scope of its regulatory approval, or misused it or applies it despite significant professional doubts of the validity of the evidence surrounding the tool, or with knowledge of the tool maker's obfuscating negative facts. In other cases, the liability falls back on the creators and the companies behind them. However, the interpretation of 'the law' could differ depending on so many viable. AI involves analysis of voluminous data to discern patterns which are then used to predict likelihood of future occurrences. These data set about individual's health can come from electronic health records, health insurance claims, purchasing records, income data, criminal records and even social media. Medical malpractice and product liability legal issues could arise with the use of 'black-box' algorithms, as users many not be able to provide a logical explanation of how the algorithm was arrived at initially. Appropriate legislation is necessary to allow the apportionment of damages consequent to actions of an AI enabled system.¹²

The Right to Privacy has been declared a fundamental right by the Supreme Court of India. The Srikrishna Committee constituted for recommendations on data privacy and its

¹¹ *Supra* note 10 at 12.

¹² k. Ganapathy, *Artificial Intelligence and Healthcare Regulatory and Legal Concerns*, 6 *Telehealth and Medicine Today* 1, 3 (2021).

management drafted a bill- The Personal Data Protection Bill, 2018. This is the first step towards India's Data privacy journey. The Ministry of Health and Family Planning, government of India is in the midst of enacting a sector-specific legislation called DISHA or Digital Information Security in Health care Act. All these are relevant to the growth and development of AI in health care in India.¹³

6. Conclusion

The Use of AI in health care sector is beneficial, but one of the disadvantages is that it raises ethical concerns. AI is a system-generated or trained machine learning model that follows the data which are already been trained or stored; sometimes, it becomes curious about bias it may also store biased trained program. Also, another concerning reason is the privacy of the patient. If all diseases have to be treated via AI, then we have to upload data of all treated patients. To provide, best potential AI in healthcare, the health care provider and scientists have to develop best practice AI. There is no single Law made by the policymakers regarding AI that will be responsible for if there is error in AI diagnosis. So, it become necessary globally to discuss who will be liable if misfortunate happens due to the use of an AI system in healthcare.

¹³ *Id* at 4.