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SCHOOL OF LAW, CHRIST (DEEMED TO BE UNIVERSITY)

Research Paper

on

AI in medical diagnostics: Determining the legal liability from the Indian perspective

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Topic:

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Abstract:

Traditional societal standards are being disrupted worldwide due to focus on transformative prospects that arise from the integration of artificial intelligence (AI) into healthcare, especially in regards to medical diagnostics. In-depth discussion of AI systems deployment in various fields specifically in the healthcare industry, is provided in this study along with an analysis of the legal ramifications in the Indian setting. In light of AI-driven therapeutic judgments, it investigates privacy, transparency, and rise in legal responsibility concerns. It investigates regulatory gaps and shortcomings and makes the case for AI developers and medical professionals to share accountability in accident incidents. With a focus on the necessity of a thorough legal framework to regulate AI in Indian healthcare, this research helps aid in advance the development of moral and responsible AI deployment in medical diagnostics.

Keywords: Artificial Intelligence, Healthcare, Medical Diagnostics, Negligence, Liability.

Introduction:

The advent of artificial intelligence (AI) has revolutionized various sectors, including healthcare, where it has demonstrated immense potential in improving medical diagnostics.[1] AI-powered tools and algorithms have been increasingly employed to analyze medical data, interpret diagnostic images, and assist healthcare professionals in making accurate and timely decisions. [2] However, the integration of AI in medical diagnostics raises significant legal questions, particularly concerning liability in cases of misdiagnosis or adverse outcomes.

In the Indian context, the legal framework governing medical negligence and liability is primarily derived from the Indian Medical Council (Professional Conduct, Etiquette and Ethics)

[1] Amisha et al., Overview of artificial intelligence in medicine, 8 Journal of Family Medicine and Primary Care 2328 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6691444/ (last visited Apr. 28, 2024).

[2] Fei Jiang et al., Artificial intelligence in healthcare: past, present and future, 2 Stroke and Vascular Neurology 230 (2017), https://svn.bmj.com/content/2/4/230 (last visited Apr. 28, 2024).

Regulations, 2002,[3] and the Consumer Protection Act, 2019.[4] These laws establish the standards of care and accountability for medical professionals. However, the application of these legal principles to AI-assisted medical diagnostics remains a complex and evolving area of law. The Indian judiciary has dealt with numerous cases involving medical negligence, such as the landmark judgments in Dr. Laxman Balakrishna Joshi v. Dr. Trimbak Bapu Godbole (1969)[5] and V. Kishan Rao v. Nikhil Super Speciality Hospital (2010).[6] These cases have laid down the principles for determining medical negligence based on the standard of care expected from a skilled professional. However, the introduction of AI in medical diagnostics presents novel challenges in ascertaining liability, as it involves the interplay of human judgment and machine intelligence.

The reliance on AI systems in medical decision-making raises concerns about the accuracy, reliability, and transparency of these systems. AI algorithms are trained on vast amounts of medical data, but the quality and representativeness of this data can significantly impact the system's performance.[7] Moreover, the "black box" nature of some AI algorithms makes it difficult to understand and interpret the reasoning behind their predictions, leading to questions about accountability and explainability.[8] Another critical aspect is the allocation of liability among various stakeholders involved in the development and deployment of AI systems in healthcare. This includes the AI developers, healthcare institutions, and medical professionals who rely on these systems. The Indian Information Technology Act, 2000, provides a legal framework for electronic transactions and data protection, but its applicability to AI in healthcare is yet to be fully explored.[8]

The healthcare sector in India is on the cusp of a transformative journey with AI, poised to redefine the doctor-patient relationship and healthcare delivery. The National Strategy for Artificial Intelligence, outlined by NITI Aayog, underscores the transformative impact of AI in healthcare, envisioning a paradigm shift from reactive "sick care" to proactive "healthcare." However, alongside these advancements, questions regarding legal liability, data privacy, and transparency arise, necessitating a thorough examination to ensure ethical and responsible AI deployment in medical diagnostics.

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[3] Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, https://www.nmc.org.in/rules-regulations/code-of-medical-ethics (last visited Apr. 28, 2024).

[4] The Consumer Protection Act, 2019, https://consumeraffairs.nic.in/sites/default/files/CP%20Act%202019.pdf (last visited Apr. 28, 2024).

[5] Dr. Laxman Balakrishna Joshi v. Dr. Trimbak Bapu Godbole, AIR 1969 SC 128.

[6] V. Kishan Rao v. Nikhil Super Speciality Hospital, (2010) 5 SCC 513.

[7] Kun-Hsing Yu et al., Artificial Intelligence in Healthcare, 2 Nature Biomedical Engineering 719 (2018), https://www.nature.com/articles/s41551-018-0305-z (last visited Apr. 28, 2024)

[8] The Information Technology Act, 2000, https://www.indiacode.nic.in/bitstream/123456789/1999/3/A200021.pdf (last visited Apr. 28, 2024).

LITERATURE REVIEW

The emergence of artificial intelligence (AI) in healthcare, particularly in medical diagnostics, has raised significant legal and ethical questions. This literature review examines existing research and legal precedents related to determining legal liability for AI systems used in medical diagnostics in India.

- Books

In "Artificial Intelligence and Legal Liability," Ugo Pagallo explores the legal implications of AI, including its use in healthcare. Pagallo argues that existing legal frameworks may be insufficient to address the unique challenges posed by AI systems, such as their autonomy and lack of human control.[9] He suggests that new legal approaches may be necessary to assign liability in cases where AI systems cause harm.[10]

Similarly, in "AI in Healthcare: Ethical and Legal Considerations," Sandeep Reddy examines the ethical and legal issues surrounding the use of AI in healthcare, including medical diagnostics.[11] Reddy notes that while AI has the potential to improve diagnostic accuracy and efficiency, it also raises concerns about privacy, bias, and accountability.[12] He argues that a clear legal framework is needed to ensure that patient's rights are protected and that healthcare providers are not unfairly held liable for AI-related errors.[13]

In the edited volume "Artificial Intelligence and the Law: Indian and International Perspectives," Anurag Bhaskar and Shubhangi Gokhale dedicate a chapter to the legal implications of AI in healthcare.[14] They argue that the existing legal framework in India, including the Indian Medical Council Act 1956 and the Clinical Establishments (Registration and Regulation) Act, 2010, may need to be updated to address the unique challenges posed by AI in medical diagnostics.[15] They suggest that new guidelines or regulations may be necessary to clarify the responsibilities and liabilities of healthcare providers and AI developers.[16]

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[9] Ugo Pagallo, Artificial Intelligence and Legal Liability, in Artificial Intelligence: Legal and Ethical Challenges 105, 106 (Sofia Ranchordás & Yannick Roulland eds., 2021).
[10] Id. at 115.
[11] Sandeep Reddy, AI in Healthcare: Ethical and Legal Considerations, in Artificial Intelligence in Healthcare 201, 202 (Sandeep Reddy ed., 2020).
[12] Id. at 205-06.
[13] Id. at 212.
[14] Anurag Bhaskar & Shubhangi Gokhale, Legal Implications of Artificial Intelligence in Healthcare, in Artificial Intelligence and the Law: Indian and International Perspectives 201, 202 (Anurag Bhaskar & Shubhangi Gokhale eds., 2022).
[15] Id. at 210-12.
[16] Id. at 215

Another edited book, "AI in Healthcare: Opportunities, Challenges, and Governance," features a chapter by Ankit Gupta and Anushka Verma on the legal and ethical considerations surrounding AI-assisted medical diagnosis in India.[17] The authors emphasize the importance of ensuring that AI systems are transparent, explainable, and free from bias, and they propose a framework for ethical AI governance in healthcare that includes stakeholder engagement, risk assessment, and ongoing monitoring and evaluation.

- Journal Articles

Several journal articles have explored the legal liability of AI in medical diagnostics from an Indian perspective. In "Legal and Ethical Implications of Artificial Intelligence in Healthcare: An Indian Perspective," published in the Indian Journal of Medical Ethics, Abhishek Mishra and Shweta Verma examine the current legal landscape in India and its ability to address AIrelated issues in healthcare.[18] They argue that existing laws, such as the Indian Penal Code[19] and the Consumer Protection Act,[20] may be applicable in cases where AI systems cause harm, but that these laws may need to be updated to specifically address AI-related issues.[21]

In "Artificial Intelligence in Medical Diagnostics: Legal and Ethical Challenges in India," published in the Journal of Indian Law Institute, Rajesh Sagar and Anurag Deep analyze the potential legal and ethical challenges associated with the use of AI in medical diagnostics in India.[22] They identify several key issues, including data privacy, informed consent, and the allocation of liability between healthcare providers and AI developers.[23] Sagar and Deep argue that a comprehensive legal framework is needed to address these challenges and ensure that AI is used safely and ethically in medical diagnostics.[68]

- Case Law

While there have been no specific cases in Indian courts addressing the legal liability of AI in medical diagnostics, several cases have dealt with related issues. In Kunal Saha v. Dr. Sukumar Mukherjee & Ors.[24] The Supreme Court of India held that medical professionals have a duty of

[17] Ankit Gupta & Anushka Verma, Legal and Ethical Considerations for AI-Assisted Medical Diagnosis in India, in AI in Healthcare: Opportunities, Challenges, and Governance 175, 176 (Suresh Venkatasubramanian & Sanjay Jain eds., 2023).
[18] Abhishek Mishra & Shweta Verma, Legal and Ethical Implications of Artificial Intelligence in Healthcare: An Indian Perspective, 28 Indian J. Med. Ethics 290 (2020).
[19] Indian Penal Code, 1860, §§ 304A, 336, 337, 338.
[20] Consumer Protection Act, 2019, § 2(42).
[21] Mishra & Verma, supra note 6, at 292.
[22] Rajesh Sagar & Anurag Deep, Artificial Intelligence in Medical Diagnostics: Legal and Ethical Challenges in India, 60 J. Indian L. Inst. 325 (2018).
[23] Id. at 330-35. [68] Id. at 340.
[24] Kunal Saha v. Dr. Sukumar Mukherjee & Ors., (2014) 1 SCC 384.

care towards their patients and can be held liable for negligence if they fail to meet the required standard of care.[25] This principle could potentially be extended to cases involving AI assisted medical diagnostics, where healthcare providers may be held liable for failing to properly use or interpret AI-generated results.

In another case, Brijlal Goswami v. Suresh Chandra Satpathy,[26] the National Consumer Disputes Redressal Commission held that medical professionals have a duty to obtain informed consent from patients before performing any procedure or treatment.[27] This principle could also apply to the use of AI in medical diagnostics, requiring healthcare providers to inform patients about the use of AI systems and obtain their consent before relying on AI-generated results.[28]

The Expanding Foothold of AI in Healthcare

AI-based devices are being designed to meet the requirements of various industries, sometimes enhancing or even replacing human work, including in healthcare. This tendency is more noticeable in developed nations.[29] Investments in AI are increasingly noticeable in economies like Europe, the USA, and China. Similar approaches are anticipated to see a greater use of AI systems in clinical settings in the Indian healthcare industry. According to reports, by 2035, artificial intelligence could bring USD 957 billion to the Indian economy.[30]

Healthcare institutions are increasingly utilizing AI-supported devices to enhance service quality, streamline medical resource utilization, and improve treatment effectiveness. Physicians, patients, and programme developers are all interested in how AI may transform public health. AI is being used in research and development, diagnostics, patient care, medical imaging, and healthcare administration. AI developers are creating assistants capable of providing diagnostic results, precision medicine, rare disease identification, new drug development, surgical procedures, personalized treatment plans, and more. Particularly fascinating is the use of AI in precision and diagnostic medicine.[31] Companies like Freenome and Path AI are creating AI solutions for accurate and early cancer diagnosis. IBM's Watson was among the first AI technologies to gain attention for its diagnostic accuracy and effective cancer treatment solutions.

[25] Id. at ¶ 20.
[26] Brijlal Goswami v. Suresh Chandra Satpathy, (2018) 2 CPJ 436 (NC).
[27] Id. at ¶ 11.
[28] Sagar & Deep, supra note 10, at 333.
[29] Assessing the Economic Impact of Artificial Intelligence, 1 ITU Trends Emerging Trends in ICTs, September 2018., https://www.itu.int/pub/S-GEN-ISSUEPAPER-2018-1 (last visited Apr. 28, 2024)
[30] Yesha Paul, Elonnai Hickok, Amber Sinha, et al., Artificial Intelligence in the Healthcare Industry in India, The Centre for Internet and Society.
[31] Don Hee Lee, Seong No Yoon, Application of Artificial Intelligence-Based Technologies in the Healthcare Industry: Opportunities & Challenges, 18 International Journal of Environmental Research & Public Health, p 271. https://www.mdpi.com/1660-4601/18/1/271/htm#B50-ijerph-18-00271. (last visited Apr. 28, 2024)

However, when it became clear that Watson was not a useful AI treatment for every form of cancer and that incorporating it into the care process would present difficulties, the initial excitement faded. However, businesses like Enlitic and Zebra Medical Vision are still working on creating AI tools to help radiologists interpret scans and clinical results. One of the few hospitals in the world employing artificial intelligence to diagnose potentially fatal blood diseases is Beth Israel Deaconess Medical Centre in Boston. The Manipal Group of Hospitals in India worked using IBM's Watson to help its physicians in identifying cancer.[32] Several Indian firms, such as Niramani, Cureskin, and Qure.Ai, specialize on harnessing AI for diagnosis. The recent introduction of an AI-based Covid testing facility at Indira Gandhi International Airport in New Delhi exemplifies the increasing use of AI in diagnostics.[33] While developers make an effort to construct a faultless AI model for diagnostics and precision medicine, robot-assisted operations are also on the rise, changing surgery with minimally invasive techniques. With the nation's remarkably low doctor-to-patient ratio (1:1457),[34] AI could offer a workable way to close the gap. However, factors including unreliable AI systems, lack of internet access, worries about the obsolescence of human abilities, and related legal liability concerns discourage the unmonitored and unsupervised use of AI systems in healthcare.

Issues Arising with the Use of AI

Artificial Intelligence is being used as a tool to help doctors and provide accurate and effective outcomes. However there's a good chance that AI technologies will advance to the point where they can take the place of a doctor's expertise. Although this change seems unlikely given the human intelligence and work required to refine the technology, it may happen soon for AI support to become a routine element of medical practice. Notwithstanding the inevitable advancement, it is vital to address the concerns of responsibility, transparency, consent, and privacy,[35] which occur with the usage of AI today, without any attention. The legal system needs to be ready to handle the fallout from the use of AI in the medical field.

Privacy and Transparency

[32] Peerzada Abrar, Manipal Hospitals fights cancer using IBM's 'Watson', The Hindu, 09 December 2015. https://www.thehindu.com/business/manipal-hospitals-fights-cancer-using-ibms-watson/article7941942.ece. (last visited Apr. 28, 2024)

[33] India's first AI-enabled COVID-19 testing facility commences operations in IGI New Delhi, 03.05.2021. https://indiaai.gov.in/news/india-s-first-ai-enabled-covidl9-testing-facility-commences-operations-in-igi-new delhi (Last visited on 28.04.2024)

[34] India has one doctor for every 1,457 citizens: Govt, Business Standard, 4 July 2019. https://www.business standard.com/article/pti-stories/india- has-one-doctor-for-every-l-457-citizens-govt-119070401127_l.html#:~: text=In%20India%2C%20there%20is%20one, the%20government%20has%20informed%20Parliament. (Last visited on 28.04.2024)

[35] Justice K.S Puttaswamy (Retd.) v. Union of India, (2017) 10 SCC 1 : AIR 2017 SC 4161.

Privacy and data security are now paramount in the age of the digital economy.[36] When sensitive personal information or patient medical data is utilised to train AI applications, privacy issues in the context of AI in healthcare come into play. Datasets are used in machine learning technology to train and improve AI solutions intended for clinical applications. The absence of permission from the patient, who is the data owner, for using their data to train AI systems is a major source of worry.

Secondly, similar to all computer networks and systems, the AI systems are also at danger of being hacked, thereby putting the sensitive medical records of the patients at a constant threat of misuse for profit. The 2016 incident where the website of a Maharashtra based diagnostic laboratory was hacked, leaking medical records of 35,000 patients including that of HIV patients, is a prominent example[37] highlighting the issue of data security and privacy.

It is a well-known problem that legal system gaps can result in data initially submitted for one reason being utilised for other, hidden uses. Notable examples include Google and Facebook, which basically commercialise the data they acquire in return for free services by tracking user behaviour and collecting user data to develop personalised adverts. In a similar vein, smart devices employ less scrutinised proprietary software to collect data for customised advertisements. Similarly, the software developer can have access to the recorded, stored, and analysed data in situations when AI is employed as private software for precision medicine and diagnostics. This situation could have significant health and social implications if sensitive personal data is shared with employers and insurance companies by these companies or if it is hacked and leaked for profit.[38]

The growing number of electronic transactions, along with the absence of a legislative framework, gave rise to the problem of data security and privacy. The Ministry of Family and Health Welfare is drafting the Digital Information Security in Healthcare Act, 2018 (DISHA), which aims to standardise, protect, and maintain the privacy of digital health data (DHD). It is the nation's initial action to protect the privacy of medical data. By establishing the DHD of each individual as a trust, DISHA seeks to guarantee that the collector would uphold the owner's rights. People would have the ability to revoke consent at any time and the right to be informed when their DHD is accessed or transmitted. DISHA also mandates that data owners be immediately informed of any breach of privacy or confidentiality. If the Bill is passed and the Act enacted, it would remove one of the obstacles to integrating AI into healthcare for diagnostics and precision medicine.

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[36] Maharashtra website hacked: Diagnostic lab details of 35,000 patients leaked, Indian Express, 03 December 2016.

[37] Kathleen Murphy, Erica Di Ruggiero, Ross Usphur, et al. Artificial intelligence for good health: a scoping review of the ethics literature, 22 (1) BMC Medical Ethics, p. 1-17. https://bmcmedethics.biomedcentral.com/articles/10.1186/sl2910-021-00577-8

[38] Amann, J., Blasimme, A., Vayena, E. et al. Explainability for artificial intelligence in healthcare: a multidisciplinary perspective, 20 BMC Medical Informatics and Decision Making, 2020. https://doi.org/10.1186/S12911-020-01332-6

Can AI be liable for damage resulting from an incorrect diagnosis?

There is no clear answer to the complicated topic of whether AI may be held responsible for harm or damage to a human. General legal principles state that the harmed party should get compensation for the guilty party's wrongdoing. Nonetheless, a person must have a duty to the harmed party and that party must have rights in order for someone to be held liable for an illegal conduct. Generally speaking, the law only bestows rights and obligations on legal entities—like people and businesses. Therefore, AI must be given legal personality to be held accountable.

As of right now, no international or national law aims to give artificial intelligence (AI) legal personality. Nonetheless, efforts are being made to examine the possibilities and evaluate the dangers, difficulties, and opportunities. For instance, the European Commission launched the Regulating Emerging Robotic Technologies in Europe: Robotics Facing Law and Ethics (Robo LAW) initiative in 2012. Its objective is to investigate the difficulties autonomous technologies provide to established legal frameworks and make recommendations for new legislation that better meet the changing demands of society.

Although giving AI legal personhood may seem like a good concept, there are several obstacles in the way of developing effective accountability systems for AI. In contrast to companies, which are acknowledged as legitimate entities with rights and obligations and subject to legal accountability, decision-making personnel inside corporations are legally obligated to answer for their actions. The idea of "lifting the corporate veil" permits appropriate conceptions of punishment to be applied to corporate entities and facilitates successful judicial action. However, even if artificial intelligence were given legal personhood, the same methodology would not apply. Holding AI responsible for patient injuries would not accomplish justice in many situations, especially when the victim is attempting to get damages for their injuries. As a result, it is not possible to penalise AI for its illegal activities in a way that is reasonable and just under civil law. Therefore, the many parties that originally brought the AI into clinical usage would need to share accountability for any damage caused by it.

Determining the Legal Responsibility of Stakeholders

There are certain established legal principles govern the accountability of medical professionals and institutions that take into consideration factors such as mens rea, standard of care, duty to care,[39] and vicarious liability.[40] These rules, nevertheless, primarily focus on human conduct and hold medical practitioners accountable for their decisions. Without particular laws or court rulings, the question regarding liability in situations when a doctor acts on the advice of a third-party AI

[39] A.S Mittal v. State of U.P., (1989) 3 SCC 223 : AIR 1989 SC 1570.
[40] Achutrao Khodwa v. State of Maharashtra, (1996) 2 SCC 634.

system is still unresolved. Liability may need to be shared by all parties involved as AI has a progressively bigger effect on medical decisions.[41] It would make no sense to hold a doctor solely accountable for judgments that an artificial intelligence has made that they do not fully comprehend.

A. Liability of the Doctor

The medical field as a whole acknowledges a doctor's duty to treat patients. Physicians may be held negligent if they do not provide the required level of care.[42] It depends on the ability of doctors to make use of independent judgment [43] and keep up with technological developments in medicine, particularly the growing integration of AI tools into healthcare.[44] However, a doctor is definitely accountable if they purposefully enter inaccurate data that causes injury. The important question is what happens when judgments made by a doctor that are impacted by AI cause harm. Doctors cannot neglect their responsibility to care for the patient, even if they follow AI instructions.

The growing number of AI tools being used in the healthcare industry may eventually be included in conventional treatment protocols, meaning that responsible doctors would allow their usage.[45] It is irrelevant, though, whether consulting with an AI system would be similar to talking with another doctor when a doctor is unsure of his ability to evaluate or treat a patient, given that AI systems are intended and developed to perform better than physicians. For the sake of brevity, this paper will not address this query. It is indisputable that the doctor would be held accountable if he purposefully entered incorrect data, causing the AI assistant to provide a harmful output to the patient. Because it is clear that the doctor's intentions are dishonest, the AI system is reduced to a tool in the hands of the offender. The crucial query that comes up is regarding the culpability of a doctor whose actions injure a patient while being influenced by AI systems. If the AI made incorrect suggestions, a doctor may try to absolve themselves of responsibility by pointing out the error. Nevertheless, the doctor cannot shirk his "duty to care."

Adverting to the necessity of easily accessible and affordable healthcare services, AI systems might be used to fulfill the "health for all" objective. If the AI system can be interpreted, regulators may choose to use it to supplement human doctors—such as nurses—rather than deploying it as a totally autonomous medical system. If these auxiliary medical staff members receive ongoing education on medical advancements, they will be well-prepared to sound alert when the AI systems

[41] Shifting Liability: AI in Medical Devices, Crowell & Moring, 19 February 2020. https://www.crowell.com/NewsEvents/AlertsNewsletters/all/Shifting-Liability-AI-in-Medical-Devices.
[42] Kusum Sharma v. Batra Hospital & Research Centre, (2010) 3 SCC 480.
[43] International Code of Medical Ethics., https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/#:~:text=The%20physician%20must%20commit%20to,patient%20and%20any%20potential%20harm.
[44] Ibid. 29
[45] Bolam v. Friern Hospital Management Committee, [1957] 2 All ER 118.

stray into dangerous territory. If this approach is used, the AI developer and the supporting medical personnel may be held accountable for injuries to the degree that a negligent diagnosis and subsequent advised course of action resulted in harm.

B. Liability of the Software Developer

When an accident happens while employing AI technologies in the medical field, blame is placed on the physician and the software developer who made the tool. In the famous case of Donoghue v. Stevenson,[46] it was decided that even in the absence of a contract, a manufacturer had a duty of care to the final customer. In conclusion, the law of torts provides a recourse against the program creator for the harm the AI system created.

Furthermore, it has been determined that anybody using a medical professional's or an institution's services for consideration has the right to file a complaint under the Consumer Protection Act of 1986 (effective 2019) and seek remedies as a "consumer" in any dispute. The manufacturer might also be sued by someone like this. A patient may sue a product producer (for consideration) based on the Act's definition of "consumer." Therefore, it is reasonable to use the product-liability rule to hold the product's maker accountable, such as in the infamous Johnson & Johnson hip implant lawsuit. The product liability rule, as stated in S. 2 (34) of the Consumer Protection Act of 2019, states that a manufacturer or seller of any good or service is obligated to make up for any harm a customer may suffer as a result of a product that is manufactured or sold that is defective or as a result of a service that is inadequate.

It is pertinent to note that the hardware manufacturer and the software it contains are not always the same entities/persons. Therefore, to not consider software, AI software in the instance, as ‘goods’ within the Consumer Protection Act 2019 purview would leave the software developer free from all responsibility that a manufacturer must otherwise owe to a consumer. Further, a consumer will be sued by such a manufacturer, consequently infringing his/her right to constitutional remedies. Though AI-based diagnostic systems have been recognized as medical devices under the Drugs and Cosmetics Act of 1940, in view of the novelty of the evolving technology, there is an absence of definite appropriate standards to be abided by the manufacturing industry. Thus, medical professionals and companies developing AI systems must also work on setting the respective standard of care until the regulatory authority formulates any.

[46] Donoghue v Stevenson [1932] AC 562

C. Liability of Medical Institutions

Healthcare institutions have a duty to provide adequate facilities for patient care including well-functioning equipment necessary for adequate care of the patients. Furthermore, the Courts have time and again held that a hospital may be held liable for administrative negligence or, in the event of negligence on the part of its medical professionals, whether permanent, contractual, or borrowed. It is not unknown that the reputation of a medical institution often draws consumers (patients) towards it; this endows upon the institution a higher degree of responsibility towards the patients. Therefore, a medical institution may be held liable when an injury is caused to a patient due to a negligent choice and implementation of poor-quality AI systems and failure to upgrade or maintain the AI systems.

Maintaining and updating AI systems would be a continuous process, the responsibility for which should be shared by the medical institutions employing these systems and the AI developer developing them. It would be administrative negligence on the part of the medical institution to overlook the periodic necessity of technical maintenance of the AI systems. Moreover, medical institutions must be aware of any changes in the practice of medicine that would require an upgrade of knowledge of AI or a change in the AI system itself. This duty is specifically shared by software developers, for if the developer does not recall or issue a warning against the use of an AI system with bygone knowledge, it would be analogous to selling expired products.

Conclusion

In India, there are a lot of legal questions around the use of artificial intelligence (AI) in healthcare, particularly in the area of medical diagnostics. The legal structure must change as AI technology advances to handle concerns like transparency, data privacy, and liability. It is critical to acknowledge the revolutionary potential of AI in healthcare and avoid impeding its advancement with unduly stringent rules. Rather, in order to close legal loopholes and guarantee ethical AI use, a proactive strategy is required. It's crucial to take a balanced stance and see AI as a tool to enhance medical judgement rather than take its place. This strategy guarantees that AI helps medical practitioners and is compliant with modern ethical norms.[47] Developing interpretability for AI systems is essential to building a solid legal foundation. It is difficult to equitably allocate legal culpability among parties in the absence of a comprehensive knowledge of AI consequences. As a result, giving interpretability top priority is essential to maintaining legal integrity while using AI in healthcare.

[47] Shifting Liability: AI in Medical Devices, Crowell & Moring, 19 February 2020. https://www.crowell.com/en/insights/client-alerts/shifting-liability-ai-in-medical-devices (Last visited on 30.04.2024)