Navigating AI in Healthcare: Examining Medical Liability and the Imperative of Informed Consent in Addressing AI-Driven Prescription Errors

Suyambulingam S[1], Sumathi S[2], Maheswari S[3]

[1,2]5th Year B. Com (LL. B) Student, Sastra Deemed to be University, Tanjore, Tamil Nadu
[3]2nd Year B. A (LL. B) Student, Sastra Deemed to be University, Tanjore, Tamil Nadu

ABSTRACT:

With the advent of information technology and Artificial Intelligence the world started to walk towards the technological civilisation. AI has marked an integral place in almost all sectors throughout the world including medical sector. The issue lies in determining the liability for AI generated medical treatments which results in causing harm to the life of the patients. AI driven medical decisions may result in serious injury or error. This paper tries to analyse the challenges on attributing liability i.e. upon AI developers and hospitals employing AI in their treatments. There is no legislation as to medical or tortuous liability on part of AI. But there are numerous cases where the medical professionals sought the help of Artificial Intelligence for medical ambiguities. Some doctors were worried about in trusting AI generated solutions for which it may lead to severe liability and prosecution threats. Technological advancement is essential which facilitates country's development in every sector. This paper highlights the importance of AI in healthcare and need to impose different levels of liability on these players. It also analyse compensatory liability when fault has occurred. We analyse existing legal frameworks, ethical guidelines, different cases and highlighting the need for a comprehensive approach to AI liability in health care. This research explores the regulatory approaches to medical AI liability across different jurisdictions identifying best practices and areas of improving patient's safety. At the end this paper seeks to ensure that AI in healthcare is developed and deployed responsibly, prioritizing patient's safety and well-being while fostering innovation.

KEYWORDS: Artificial Intelligence, Legal liability, Informed consent, Product liability, misdiagnoses, Negligence

BACKGROUND OF THE STUDY:

The transformative wave of Artificial Intelligence in India can be traced back to twentieth century where the research and development is in a budding stage. It was only in 21st century with the advancements of technology worldwide AI became cornerstone in almost all sectors including healthcare. Artificial intelligence (AI) is being used in telemedicine and home healthcare services by start-ups like Practo and

Portea Medical[1]. The medicines were prescribed by the doctors by making prognosis and diagnosis on a patient's body physically. Now it becomes a practice where the physicians give symptoms in AI tool which prescribes medicine for illness only based on that symptoms. There is a high chance of generating incorrect prescriptions as the AI is ignorant of the patient's physical condition like whether the patient's body is adoptable to the prescribed medicine, after consequences and the quantity of medicine to be administered in the patient's body. The legal liability for incorrect prescriptions generated by AI is a complex and evolving areas of concern. As it becomes more prevalent there raises a issue as to who should be held liable for incorrect or harmful prescriptions. This paper deals with imposing of liability on three players ie., AI developers, healthcare professionals and hospitals. It is under the following assumptions. Manufacturers and developers of AI may be held responsible for errors and flaws in their algorithms and programmes. Physicians who rely on AI generated prescriptions may be liable for negligence or failure to exercise proper oversight. Institutions and hospital management can be held accountable for implementing AI systems without proper safeguards or training. Current regulations and laws in healthcare are often unclear and inadequate. This sets the base for exploring the complex legal liability issues surrounding AI generated prescriptions.

LITERATURE REVIEW:

Artificial Intelligence in medical sector found a significant place in developed countries like USA. (Jessica S. Allain, 2013) Dr. Watson a medical super computer with borderline AI in US medical field provides quality services in prescribing suggestions to physicians within 3 seconds which the physicians understand in weeks. Developing a simplified liability for artificial liability systems will promote their adoption by making potential liabilities clearer. By merging aspects from medical malpractice, vicarious liability, products liability and enterprise liability, the legal system can establish a consistent method for AI systems thus removing any disparities that could occur when courts use different theories to interpret liability[2].

Different aspects of medical AI makes it difficult to apply doctrine applicable to torts with regard to medical malpractice making these principles less effective in encouraging the proper and safe use of AI. (W Nicholson Price II & I. Glenn Cohen, 2024) the paper proposes an alternative approach instead of enterprise liability by holding hospitals accountable for any negligent harm within their facilities but with a caveat: hospitals need to have the necessary data for adjusting and overseeing the use of medical AI. The paper recommends if the data is not available, then the liability move from hospitals to the creators of AI who are withholding information[3]. (Bajpai, Nirupam , 2021)It is crucial to provide AI training to the workforce before implementing AI-based healthcare so they can handle confidential patient data with care, prevent data theft, and operate AI systems efficiently. Furthermore, it is essential that any healthcare decisions made with AI technologies make rationale and can be explained[4]. (Glenn Cohen, 2020), while there is some flexibility in the legal principles the current legal framework suggests that, on the whole, responsibility for not informing patients about the application of medical AI/ML in treatment recommendation formulation is unlikely to create liability. However, there are certain

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[1] Rahul rk, The rise and roar of AI in India: A transformative journey, (oct 09, 2023), indiaai.gov.in

[2] Jessica S. Allain, From Jeopardy to Jaundice: The Medical Liability Implications of Dr. Watson and Other Artificial Intelligence Systems, 73 LA. L. REV. 1049 (2013).

[3] W. Nicholson II Price & I. Glenn Cohen, Locating Liability for Medical AI, 73 DEPAUL L. REV. 339 (2024).

[4] Bajpai, Nirupam; Wadhwa, Manisha (2021) : Artificial Intelligence and Healthcare in India, ICT India Working Paper, No. 43, Columbia University, Earth Institute, Center for Sustainable Development (CSD), New York, NY

scenarios where the legal principles might be more expansive, which I aim to illustrate (for example, when patients ask about the role of AI/ML, when the AI/ML is less transparent, when it plays a significant part in the decision-making process, or when it is utilized to cut costs instead of enhancing patient well-being), although extending these exceptions is not guaranteed[5].

The integration of AI into clinical practice has sparked considerable debate over medical liability, particularly regarding accountability when AI systems generate incorrect prescriptions. In the article "AI and Liability in Medicine," Rimkutė (2023) emphasizes the complexity of defining liability, especially under European law, where the EU has introduced frameworks for AI-related liability. The literature suggests the need to address organizational negligence, medical malpractice, and product liability in cases involving AI in medicine, stressing the importance of informed consent as a protective measure against potential harms and uncertainties.[6]

RESEARCH PROBLEM:

The integration of AI in clinical practice raises critical issues regarding medical liability, particularly concerning inaccurate prescriptions generated by these systems. There is ambiguity about accountability when AI outputs lead to patient harm, complicating traditional product liability frameworks. Additionally the implications for informed consent are unclear as patients may not fully understand the role of AI in their treatment. Addressing these issues is essential to ensure patient safety and clarify responsibilities in an evolving healthcare landscape.

OBJECTIVES:

This paper tries to examine the role of AI in medical malpractice claims and litigations by determining the liability of healthcare providers and AI creators when using AI generated medical suggestions. It also analyse the impact of AI suggestions on patient's rights and informed consent. Finally it suggests certain recommendations for policymakers and healthcare organizations to address legal concerns.

RESEARCH QUESTIONS:

1. Whether AI systems are capable of committing negligent acts so as to be made liable?
2. Whether the use of AI generated medical suggestions increase liability for healthcare providers?
3. Whether existing tort law frameworks are sufficient to address AI related medical errors?
4. Whether patients are sufficiently informed about AI generated medical prescriptions.

RESEARCH METHODOLOGY:

This study adopts a doctrinal research approach, which involves a systematic examination of legal doctrines, statutes, case law, and scholarly literature relevant to medical liability and informed consent in the context of AI-driven prescription errors in healthcare.

AI AND MEDICAL MISDIAGNOSES:

Misdiagnoses refers to a situation where the medical professionals or Artificial intelligence incorrectly

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[5] Glenn Cohen, Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?, 108 GEO. L.J. 1425 (May 2020).

[6] Baltic Journal of Law & Politics 16:2 (2023): 64–81 https://content.sciendo.com/view/journals/bjlp/ bjlp-overview.xml

identifies a patient's condition or disease. It may be due to negligence or lack of proper disclosure of symptoms by the patient or even delay caused by patient in approaching the doctors. By adopting AI in medicare there are both pros and cons in prescribing treatment. AI has the ability to examine enormous volumes of medical data, such as imaging scans, lab findings, and patient histories, to find patterns that human physicians fail to detect. Particularly in radiology, AI systems can occasionally outperform human radiologists in identifying abnormalities in imaging studies (such as MRIs or X-rays).

According to IMA chief Dr. R V Asokan, artificial intelligence can help medical professionals but cannot take the position of doctors. He claimed that although the medical field has always been the first to adopt technology, the relationship between a patient and a physician cannot be replaced by it[7]. This is because countries like India which involves medical paternalism and where people treat doctors as supreme they don't want to rely on AI technologies when it comes to their life. Since AI has many complications like AI systems may produce inaccurate or skewed diagnostic results if their training data is biased or lacking. Clinicians run the risk of depending too much on AI suggestions and maybe missing crucial patient history or clinical subtleties. Now the issue is who is liable for wrongful misdiagnoses of AI.

Under product liability laws, the creators or makers of the AI software could be held accountable if the system itself is flawed or gives false information. This may rely on whether there were insufficient warnings or if the software was poorly made or planned. Insurance laws are to be amended to state that insurance coverage may need to change to cover liabilities associated with AI-driven diagnostics as the technology becomes more widely used. However these are some possible issues related to AI misdiagnoses where possible litigations may flew upon.

PRODUCT LIABILITY:

Product liability in the context of AI in the healthcare sector refers to the legal responsibility of manufacturers, developers, and providers for any harm caused by their AI products or systems. Given the increasing reliance on AI technologies in healthcare such as diagnostic tools, treatment recommendations, and patient monitoring systems ,understanding product liability is crucial.

AI products can be considered "products" under the Consumer Protection Act, 2019[8], in India. The Act defines a product as any goods or services that are made available for sale, which includes both physical items and digital services.

Section 2(33) of the Consumer Protection defines the term product as, "product" means any article or goods or substance or raw material or any extended cycle of such product, which may be in gaseous, liquid, or solid state possessing intrinsic value which is capable of delivery either as wholly assembled or as a component part and is produced for introduction to trade or commerce, but does not include human tissues, blood, blood products and organs.

An AI product is a software or hardware solution that incorporates artificial intelligence technologies to perform tasks, solve problems, or enhance user experiences.[9] These products often use machine learning, natural language processing, computer vision, or other AI techniques to automate processes, provide insights, personalize interactions, or facilitate decision-making. Examples: Amazon Alexa, Google

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[7] https://www.deccanherald.com/india/artificial-intelligence-cannot-replace-doctors-says-indian-medical-association-chief-asokan-3003071

[8] https://www.indiacode.nic.in/bitstream/123456789/15256/1/a2019-35.pdf

[9] https://medium.com/@neriasebastien/is-ai-a-feature-a-product-or-both-b5227204d43f

Home, and Apple HomePod , Tempus One, Curie, etc. Hence it will come under the definition of the act as a Product.

Section 2(34) of the Consumer Protection defines the term product liability as "product liability" means the responsibility of a product manufacturer or product seller, of any product or service, to compensate for any harm caused to a consumer by such defective product manufactured or sold or by deficiency in services relating thereto;

In the case of AI products[10], for defect in the products, the manufacturer will be held liable for any problems. But if the product is not used as per the manuals then the service provider ie, the doctor will be held liable for mistreatment of the patient. It is the duty of the hospital to maintain all its equipments in their hospital, if it fails then they will be held liable for non maintenance.

AI as a feature refers to the integration of artificial intelligence capabilities into an existing product or service to enhance its functionality. Instead of being a standalone product, AI features augment traditional systems by providing smart functionalities. Examples : Siri, Google Assistant, Bixby , etc.

Section 2(38) of the Consumer Protection defines the term product service provider "product service provider", in relation to a product, means a person who provides any service in respect of such product;

In the case of AI as a feature, then the service provider will be held liable as the service is provided by him with the help of AI. The doctors use this AI just for the reference purposes only. They have to treat the patients based on his expertise and not based on AI. If they totally depends on it, then also they will be held liable.

In both criteria, the AI developer, the doctor and the hospital will be held liable in certain situations and will be punished with fine or cancellation of licences. Finally, AI can be considered as a product and if there is any defect in the product, then the manufacturer will be held liable and in healthcare sector the hospital and the doctors will be held liable for non maintenance and non proper use of the AI as a product or as a feature.

HEALTHCARE PROFESSIONAL LIABILITY:

Health care professionals must strike a balance between trusting AI- generated prescriptions and maintaining a healthy skepticism. They must first acknowledge the possibility of biases or faults in AI systems before recommending a medication. They have to apply professional judgment and expertise to AI generated prescriptions and review and update them regularly to ensure safety and accuracy. The over reliance on AI by the medical practitioners without proper knowledge of the same may lead to extremely harmful consequences leading to depriving a person of his right to life and health which is granted to every citizen by the constitution. According to the latest study 2019-2020 conducted by Indian Council of Medical Research, 45% of doctors are writing incomplete prescriptions to their patient. It introduced a concept that "Prescriptions having deviations" which refers to prescriptions that do not follow the established treatment criteria or that are not comprehensive in terms of formulation, dose, duration, or frequency. An unacceptably high deviation was one that raised the risk of medication interactions, non reaction, cost increases, avoidable adverse drug reactions (ADRs), and/or antibiotic resistance[11]. AI generated prescriptions may or may not fall under prescriptions having deviations. The

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[10] https://enterprisersproject.com/article/2022/4/artificial-intelligence-what-ai-product

[11] Service, E.N. (no date) *45% doctors at top institutes give faulty prescriptions to patients, says ICMR*, *The New Indian Express*. Available at: https://www.newindianexpress.com/cities/delhi/2024/Apr/14/45-doctors-at-top-institutes-give-faulty-prescriptions-to-patients-says-icmr

reason is because there is a chance of correctness and irregularities within the same. It is the duty of the healthcare professionals to assess the information through his medical expertise and finally prescribe to the patients. Since there is no specific law as of today regarding AI liability the doctors is often made liable for blindly applying the incorrect prescriptions generated by AI.

Health care professionals may be held liable under torts for negligence if they fail to properly review AI-generated prescriptions without verifying the patient information and medical histories by his professional judgment and expertise. The Bolam test is the test that is being applied by the Indian courts for determining medical liability cases. The test is whether the doctor exercise standard of care while treating his patients. But the standard of care for health care professionals using AI generated prescriptions is still evolving. Similarly health care institutions and hospitals can be held vicariously liable for the actions of their employees including those who rely on AI prescriptions and damages can be claimed by making them jointly liable. To establish negligence, the following essentials must be proved., duty of care, breach of duty, damage, causation. By attributing AI to negligence the first two essentials can't be satisfied because AI has no capacity of understanding duty in strict sense as that of humans.

INFORMED CONSENT vs. REAL CONSENT:

Consent is of two types real and informed. The former is of narrow sense which states that patient must give their consent voluntarily and minimum nature of treatment to be administered to him by the doctors must be disclosed to the patients before obtaining consent. The latter is of very wide perspective where the doctors have to disclose each and every minutes of treatment like the nature and scope of the proposed treatment, the risk, the alternatives available to that treatment, the expected outcome and what should be done if the treatment becomes unsuccessful or harmful. India and England follows real consent whereas USA follows informed consent. Indian courts through its judgments try to evolve the nature into informed consent but it is still evolving. The question is whether the patients consent is to be obtained for AI generated prescriptions since every patient has a right to body autonomy which means right to make decisions about his body. Informed consent states that patient should be made informed about every aspects of treatment which includes education of the patients in AI limitations and potential risks. When a doctor neglects to provide a patient with all pertinent information regarding a course of treatment, especially the risks involved, the patient may be subject to medical malpractice claims based on a lack of informed consent. The idea that a doctor touched a patient without permission constituted a battery is where modern medical malpractice claims originated. a doctor is obligated to disclose to a patient."Alternatives to the proposed treatment or diagnosis and the reasonably foreseeable risks and benefits involved as would permit the patient to make an informed evaluation,"In order to adhere to this requirement, doctors could be required to tell patients that they are employing Watson and get their consent before doing so.

For the countries like India following real consent there comes the issue as to patient right to be informed about AI prescriptions. The doctors can't be made liable in such a case because law does not require them to disclose the same. But it becomes a necessity that patients should be fully informed about the use of AI in generating their prescriptions, including the potential benefits and risks. Patients should understand how AI-Generated prescriptions work and the role of healthcare professionals in reviewing and verifying them. They should be informed about potential red flags and errors in AI

prescriptions and what to do if they suspect an issue. Patients have the right to refuse AI prescriptions and their decisions to be respected.

JUDICIAL INTERPRETATIONS:

The Indian judiciary imposes two kinds of liability on doctors ie., tortuous and penal liability mostly in medical negligence cases. Medical negligence means improper or unfair treating of patients without exercising due care and caution. However doctor can't be made liable for error of judgment if he proves the court that it is done in good faith. Error of judgment may be of two kinds. They are error of judgment and error of judgment due to negligence. The former implies that merely because the doctor's decision is found to be wrong we can't make him liable for medical negligence and does not amount to breach of duty. The latter implies that it would be regarded as error of judgement due to negligence if all the considerations were taken into account before making a choice for which doctors are made liable and amounts to breach of duty.

In State of Haryana v. Smt. Santra[12], The Supreme Court ruled that every doctor has a responsibility to act with a reasonable level of care. Since no one is flawless and even experts make mistakes, a doctor can only be held accountable for failing to exercise the same level of reasonable caution that any other doctor with average training would be able to.

In Bhalchandra Alias Bapu & Another v. State of Maharashtra[13], the Supreme Court held that criminal negligence refers to the gross failure to exercise reasonable care and precaution to protect both an individual and the public, whereas negligence is defined as failing to do something that a reasonable man would do or doing a thing which a reasonable man would never do. So the AI generated prescriptions relied by the doctors cannot be entirely make them liable unless they exercise due care and caution provided it must prove to the satisfaction the court that there is no negligence on the part of the doctors.

In a US decision of Gilbert v.Sycamore Mun. Hosp[14]it was held that hospital is made liable for the negligent acts of an emergency room physician, who was not a employee of the hospital, because the public could reasonably assume that the physician was acting as an agent of the hospital. By applying this dictum AI can be placed in the position of an agent which though acting for the hospital cannot be brought under the definition of employee as there is no control element between hospital and AI.

In Crowston v. Goodyear Tire & Rubber Co ,521 N.W.2d 401 (N.D. 1994), stating that manufacturers have a continuing duty to warn consumers about the dangers, duty to warn the treating physician and hospital of the product's potential dangers. Ethical considerations and professional guidelines highlight the need for development and deployment of AI generated prescriptions. Some ethical considerations are autonomy which means respect for patient autonomy and decision making capacity, Non- malficence to avoid harm or injury to patients and justice which involves fairness and equity in access to AI generated prescriptions. Similarly guidelines for AI developers to ensure transparency, accountability and safety should be made in order to impose liability on them. Guidelines for healthcare professionals on the appropriate use and interpretation of AI generated prescriptions should be framed.

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[12] State of Haryana v. Smt. Santra, AIR 2000 SC 1888.
[13] Bhalchandra Alias Bapu & Another v. State of Maharashtra, 1968 SCR (3) 766.
[14] Gilbert v. Sycamore Mun. Hosp., 622 N.E.2d 788, 793-94 (Ill. 1993)

FINDINGS:

Under Indian law AI systems are not liable for negligent acts due to lack of legal personhood, intent and direct causation since AI acts on programming and algorithms not human like intent. It can't be suited within the legal definition of negligence as it has no duty of care as that of doctors and hence not liable for the results of misdiagnoses. AI developers and deployers are to be made strictly liable for harm regardless of intent. AI systems are not infallible. If a healthcare provider follows an AI-generated suggestion that leads to a negative outcome, the user might face liability if the AI's recommendations were inaccurate or if the provider failed to validate the suggestions against established medical knowledge.

Physicians must ensure that patients understand the role of AI in their care. Failure to properly communicate this could lead to issues of informed consent which is a part of right to life and personal liberty under article 21 of the Indian constitution, potentially increasing liability. But in India which attach to medical paternalism trust the doctors and they give consent to everything they prescribe in order to save their loved one. They don't want the treatment to be delayed because of explaining complicated medical terms and AI functioning which lead to giving consent impliedly. This is the reason why law of informed consent can't be adopted in India to its fullest sense. Similarly, Proper documentation of the AI's input and the doctor's decision-making is crucial. Lack of clear records can lead to difficulties in defending against malpractice claims. If an AI system malfunctions or produces erroneous results, product liability claims might be applicable. However, these cases can be complicated by issues such as proving design defects or whether the product was used as intended. The lack of comprehensive regulation for AI in healthcare can lead to gaps in accountability. Existing tort laws may not sufficiently cover the nuances of AI, necessitating new developments in the law.

RECOMMENDATIONS:

For Doctors

- Clearly explain AI-based diagnostic or treatment tools to patients, including potential risks and limitations, to ensure informed decision-making.
- Use AI as a supportive tool while retaining final decision-making authority to avoid over-reliance on AI recommendations, especially in critical cases.
- Regularly participate in training on new AI systems, including understanding the strengths and limitations of algorithms used in patient care.
- Work closely with AI specialists and engineers to better understand the operational aspects of AI tools and provide feedback on their clinical relevance.
- Document and report any AI-generated errors or malfunctions to help improve system reliability and support institutional accountability.

For Hospitals

- Develop policies on the scope and limitations of AI in clinical decision-making to ensure safe and responsible AI deployment.
- Provide ongoing training for medical staff on the use and ethical implications of AI tools, enhancing their ability to use AI responsibly.
- Ensure robust data protection measures are in place, especially given the sensitive nature of patient data used in AI applications.

- Regularly review AI system performance and safety, involving multidisciplinary teams to assess AI's impact on patient outcomes.
- Facilitate structured feedback channels for clinicians to report AI tool issues directly to developers, supporting continuous improvement.

For AI Developers

- Engage with healthcare professionals to understand the clinical context and workflow, ensuring AI systems align with practical medical needs.
- Design algorithms with transparent decision-making processes to allow clinicians to understand and verify AI-generated recommendations.
- Given the diversity in patient demographics in India, ensure AI systems are trained on locally relevant data to improve accuracy and reduce bias.
- Conduct continuous safety audits of AI models, particularly for high-risk applications, to address errors or potential risks promptly.
- Inform end-users about the limitations and appropriate use cases of AI tools, including areas where AI is less reliable or requires human oversight.

CONCLUSION:

The incorporation of artificial intelligence in the medical field brings about major progress but also brings up serious ethical issues, especially about who is responsible for wrong diagnoses and the need for patients to give their informed consent. As artificial intelligence technology becomes more common in the process of diagnosing illnesses, it's crucial to set up clear guidelines that explain who is at fault when mistakes happen. This involves outlining the responsibilities of medical staff, those who create AI systems, and the hospitals involved in protecting the well-being of patients. Furthermore, the concept of informed consent needs to adapt to the new challenges posed by artificial intelligence. Patients must be properly educated about how these AI technologies work, the possible dangers they carry, and the consequences of using them in making decisions about diagnosis and treatment. By focusing on openness and involving patients in their care, the medical field can build trust and achieve better results. In the end, tackling these problems demands a joint effort from tech experts, medical staff, and government officials. By making sure there's accountability and sticking to the values of informed consent, we can take advantage of the advantages that artificial intelligence brings to healthcare while protecting the rights of patients and improving the standard of care.

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