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Artificial Intelligence, medical advice and Patient Harm: A Comparative Analysis in Relation to legal liability and Gaps in India and the UK.

Surumi Y

Ramaiah university of applied science bengaluru

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ARTICLE DETAILS

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Author: Surumi Y

Institution: Ramaiah university of applied science bengaluru

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Artificial Intelligence, medical advice and Patient Harm: A Comparative Analysis in Relation to legal liability and Gaps in India and the UK.

Surumi Y

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1. Abstract

Artificial intelligence is increasingly being utilised within healthcare and many patients seek medical advice from AI chatbots and health apps. Whilst this can help improve access to healthcare, there is a risk that incorrect, incomplete or misleading advice can cause harm. A key issue raised here is who can be held accountable for this harm, whether it be the developer, company providing the tool, doctor providing the advice or nobody. This paper will look into the issues faced by medical advice provided by AI and Legal Liability. The main focus will be on India with the UK used as a comparator to help identify some key learnings. Within India this would be governed by general laws such as medical negligence, the Consumer Protection Act 2019 and Bharatiya Nyaya Sanhita 2023. It will also be governed by guidelines such as the Telemedicine Practice Guidelines 2020 and ICMR guidelines for the use of AI in healthcare. None of these were intended for use with AI and currently there is no specific law relating to this in India. Conversely, the UK has a more established system in place with the MHRA governing medical software, Consumer Protection Act 1987 and Bolam and Montgomery principles. However, there are still issues with AI such as 'black box', proving causation and general chatbots. This paper will look at the issues faced by both countries and whether traditional principles of liability are enough to protect patients. Some recommendations will be made on how the system can be improved in India including risk-based classification of medical AI, clear liability and increased protection for patients.

Keywords: Artificial Intelligence, medical negligence, Patient Harm, Legal Liability, Gaps.

2. Hypothesis

The current laws relating to medical negligence, Consumer Protection and Medical Devices in India have been created with human doctors and items in mind. Therefore, they cannot be used to establish liability when a patient has been harmed by AI-generated medical advice. This gap is larger in India due to there being no specific laws or regulation for AI. Therefore, India needs a risk-based liability system.

3. Research Problem

AI tools provide advice directly to patients. However, this area has not been updated in law within India. There is no specific legislation available relating to AI within healthcare. This would therefore be covered by traditional medical negligence principles (V.P. Shantha and Jacob Mathew). This is based on the idea that a human doctor will provide any advice and therefore can be held accountable. However, AI cannot be considered a doctor. The Telemedicine Practice Guidelines 2020 state that AI cannot advise patients however, this is just guidance. It would be

very difficult to enforce this with chatbots and apps especially from overseas. The Medical Devices Rules 2017 do not cover all medical software and general chatbots will typically not be covered. The Consumer Protection Act 2019 does include product liability. However, it is unclear whether AI software can be considered a product. There is also a large issue with proving causation due to the AI being a 'black box'. The UK does have a more established system with the MHRA covering software as a medical device and the Montgomery case providing protection for patient consent. However, the Consumer Protection Act 1987 is an old statute and it is unclear whether software will be covered. General chatbots will not be covered if they are not intended to provide medical advice. There is no specific statute for AI and therefore there will still be uncertainty around liability. This paper looks at the gaps and suggests what new laws or amendments India should implement.

4. Research Questions

1. Are current laws relating to medical negligence and Consumer Protection sufficient to establish liability?
2. What are the main gaps in the current regime in India relating to general chatbots and the black box issue? How does the UK handle this?
3. Using the UK as an example, what reforms should be implemented in India to establish liability between developers, deployers and doctors?

5. Research Objectives

- To understand how AI-generated medical advice works and what risks are involved.
- To research current laws and guidelines in India relating to AI in healthcare.
- To research the legal and regulatory regime in the UK.
- To compare both regimes to identify the gaps. Mainly focusing on India.
- To identify whether traditional principles of negligence, causation and product liability would be relevant.
- To suggest changes/amendments to protect patients and establish liability.

6. Research Method

This research will be doctrinal as it looks at various statutes, case law, guidelines and reports. It will also be comparative as it compares India and the UK on an issue-by-issue basis.

7. Current Legal Position

Currently there is no legislation within India relating to AI-generated medical advice. This would therefore be mainly governed by general laws. Medical Negligence is covered by case law (Jacob Mathew v. State of Punjab (2005) and Indian Medical Association v. V.P. Shantha (1995)). Therefore, medical services will be covered by consumer law. The Consumer Protection Act 2019 provides protection for poor service and product liability. Section 106 of the Bharatiya Nyaya Sanhita 2023 provides protection for death caused by negligence. The Telemedicine Practice Guidelines 2020 state that only registered medical practitioners can give advice and AI cannot

advise or prescribe. The ICMR Ethical Guidelines for AI in Biomedical Research and Healthcare 2023 provide ethical principles but are not binding. Medical software may be covered by the Medical Devices Rules 2017 and Drugs and Cosmetics Act 1940. General chatbots will not typically be covered. Liability for third parties is covered by the Information Technology Act 2000. The Digital Personal Data Protection Act 2023 protects patient data however does not provide protection for incorrect advice. NITI Aayog has also published reports on responsible AI however these are just policy documents. Within the UK the main regime is the Consumer Protection Act 1987, Medical Devices Regulations 2002 (MHRA covers software as a medical device). UK GDPR apply. It is suggested that India needs a specific AI regime with risk-based categorisation, clear liability, human oversight and appropriate regulator.

Introduction

In today's society, AI is commonly used in medical practice. Both patients with symptoms such as headaches or rashes, and medical professionals may use AI. However, in countries such as India, where there is unequal access to medical professionals, this may create a significant legal issue. It is uncertain as to who can be held liable in a situation where a patient has suffered as a result of inappropriate advice from medical AI. Within the UK, it is believed that medical professionals owe a duty of care to patients if they are not in line with 'responsible medical opinion',[1] and must give material risk information.[2] Within Indian courts, similar principles apply. In V.P. Shantha, medical services were included within consumer protection law.[3] Within Jacob Mathew, gross negligence by medical professionals was set to be a very high level.[4] Within both countries, it is assumed that decisions are made by humans and can therefore be justified. As chatbots are not medical professionals, and in many cases it is unclear how decisions have been made, it is extremely difficult to prove negligence and causation.[5]

Within India, there is no specific regulation governing AI in medical practice. If a patient suffers damage as a result of medical AI, general rules may apply. This may be either product/service provision under the Consumer Protection Act, 2019[6] or criminal negligence resulting in death under the Bharatiya Nyaya Sanhita, 2023.[7] Guidance has been given through the Telemedicine Practice Guidelines;[8] however, only registered medical practitioners may give advice or

[1] Bolam v. Friern Hosp. Mgmt. Comm., [1957] 1 W.L.R. 582 (Q.B.) (Eng.).

[2] Montgomery v. Lanarkshire Health Bd., [2015] UKSC 11, [2015] A.C. 1430 (appeal taken from Scot.).

[3] Indian Med. Ass'n v. V.P. Shantha, (1995) 6 S.C.C. 651 (India).

[4] Jacob Mathew v. State of Punjab, (2005) 6 S.C.C. 1 (India).

[5] W. Nicholson Price II, *Medical Malpractice and Black-Box Medicine*, *in* Big Data, Health Law, and Bioethics 295 (I. Glenn Cohen et al. eds., 2018).

[6] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019 (India).

[7] Bharatiya Nyaya Sanhita, 2023, No. 45, Acts of Parliament, 2023, § 106 (India).

[8] Ministry of Health & Family Welfare & NITI Aayog, Telemedicine Practice Guidelines (2020) (India).

prescriptions. Ethical guidance has been given regarding AI by the ICMR.[9] However, this guidance is not legally binding and difficult to enforce, particularly in relation to foreign applications. Only certain medical software is regulated within the Medical Devices Rules, 2017.[10] General medical chatbots are largely unregulated. In contrast, within the UK, medical software is regulated as medical devices under the Medical Devices Regulations 2002, controlled by the MHRA.[11] Product liability is covered by the Consumer Protection Act 1987.[12] However, it is unclear whether medical software would be classed as products. General medical chatbots, which are not intended to be medical, are largely unregulated. Within this paper, the liability of AI providing medical advice in India will be considered. Comparisons will be made with regulation in the UK to identify what lessons can be taken from this country. Gaps in regulation will be identified in both countries. Recommendations will be made for changes in regulation within India.

Are current medical negligence and consumer protection laws in India sufficient to clearly allocate liability for harm caused to patients by AI providing medical advice?

Medical negligence in India was created to be applied to human medical professionals. Medical professionals will be liable if they fail to act with the skill of a 'competent' medical professional. The Bolam Test from England has been accepted within India.[13] Within criminal cases, it was decided in Jacob Mathew that medical professionals can only be found grossly negligent/reckless, not simply in error.[14] It was also decided that if treatment of a patient was unsuccessful, the medical professional cannot be blamed. Usually expert medical evidence will be required to show that the medical professional has breached their duty.[15] However, as this law assumes a medical professional is responsible for giving medical advice, issues may occur with AI. As chatbots are not registered medical professionals and do not have legal personhood, they cannot owe a duty of care and therefore cannot be sued. Within the Telemedicine Practice Guidelines it is stated that AI cannot give advice or prescriptions, only registered medical professionals can do so.[16] Therefore, if inappropriate advice is given by AI and the patient is harmed, it is unclear who can be held liable. The developer, the company running the application, or the medical professional using it

[9] Indian Council of Medical Research, Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare (2023) (India).

[10] Medical Devices Rules, 2017, G.S.R. 78(E) (India).

[11] Medical Devices Regulations 2002, SI 2002/618 (UK).

[12] Consumer Protection Act 1987, c. 43 (UK).

[13] Jacob Mathew v. State of Punjab, (2005) 6 S.C.C. 1 (India) (adopting Bolam v. Friern Hosp. Mgmt. Comm., [1957] 1 W.L.R. 582 (Q.B.) (Eng.)).

[14] Jacob Mathew v. State of Punjab, (2005) 6 S.C.C. 1 (India) (holding that criminal liability of a doctor requires gross negligence or recklessness).

[15] Martin F. D'Souza v. Mohd. Ishfaq, (2009) 3 S.C.C. 1 (India).

[16] Ministry of Health & Family Welfare & NITI Aayog, Telemedicine Practice Guidelines (2020) (India).

may be liable. However, this does not fit well with a negligence framework. It is difficult to decide what 'competent' standard a medical professional may be expected to meet from a technology provider.

Whilst consumer protection law may seem like the best route for patients to be compensated, there are gaps in the law. Following V.P. Shantha, medical services may be classed as 'service' therefore patients may be able to be compensated for poor service.[17] However, within the Consumer Protection Act, 2019, unpaid services are not classed as 'service'[18] As many popular AI chatbots are free, it may not be possible for patients to be classed as consumers if they have suffered as a result of the application. Within the Consumer Protection Act, 2019, there is a section on product liability. It states that producers, service providers for products and sellers must be liable for damage caused by faulty products.[19] However, a clear definition of what a 'product' is has not been given to include software/AI.[20] Therefore it may be argued that it could include software/AI, however this has not yet been decided by courts. It is also unclear whether inappropriate advice from AI would constitute a faulty product. Medical software may be regulated as medical devices within the Medical Devices Rules, 2017.[21] However, only medical software with medical purposes (diagnosis/treatment) are regulated. General chatbots are largely unregulated. Platforms may attempt to be protected by safe harbours in the Information Technology Act, 2000.[22]

If a claim is to be made, there may be issues proving it within India. In general, negligence and causation must be proved.[23] As AI decisions are often unclear even to developers (the black box problem), it is extremely difficult for claimants to prove where the error may have occurred.[24] Scholars have commented that traditional ideas of intention and causation in AI systems may not be appropriate.[25] Issues also occur within criminal law. Although there is a provision for death by negligence, this was created in reference to actions by humans.[26] It is difficult to attribute a patient's death to decisions made by an AI by a developer. Therefore, although laws may be manipulated to fit situations (if a doctor blindly follows AI advice), it is not clear who can be held liable if a patient has suffered direct harm as a result of a chatbot. As such, current legislation in this area is inadequate. Therefore dedicated regulation within India may be required.

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[17] Indian Med. Ass'n v. V.P. Shantha, (1995) 6 S.C.C. 651 (India).

[18] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019, § 2(42) (India).

[19] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019, §§ 82–87 (India).

[20] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019, § 2(33) (India).

[21] Medical Devices Rules, 2017, G.S.R. 78(E) (India).

[22] Information Technology Act, 2000, No. 21, Acts of Parliament, 2000, § 79 (India).

[23] Kusum Sharma v. Batra Hosp. & Med. Rsch. Ctr., (2010) 3 S.C.C. 480 (India).

[24] W. Nicholson Price II, *Medical Malpractice and Black-Box Medicine, in* Big Data, Health Law, and Bioethics 295 (I. Glenn Cohen et al. eds., 2018).

[25] Yavar Bathaee, *The Artificial Intelligence Black Box and the Failure of Intent and Causation*, 31 Harv. J.L. & Tech. 889 (2018).

[26] Bharatiya Nyaya Sanhita, 2023, No. 45, Acts of Parliament, 2023, § 106 (India).

What are the main gaps in regulation in India (particularly for general chatbots and the black box issue)? How is regulation in the UK?

A major gap in regulation within India in relation to medical advice given by AI is that there is no specific regulation. There is no specific legislation relating to AI within medical practice. Regulation currently relies on existing laws and voluntary guidance.[27] Although guidance exists within the Telemedicine Practice Guidelines[28] and ethical guidance from the ICMR,[29] these are not legally binding. Furthermore, neither specify any penalties. Another gap is that general chatbots are not well regulated. As general chatbots provide health advice, but do not claim to be medical in purpose, they are not regulated under the Medical Devices Rules (2017).[30] The Consumer Protection Act (2019) does not protect consumers from free services.[31] Therefore as most chatbots are free, it may be impossible for patients to qualify as 'consumer.' if they have suffered as a result of the chatbot. Platforms may attempt to be protected by safe harbours for intermediaries within the Information Technology Act, 2000.[32] Although patient data is protected under the Digital Personal Data Protection Act, 2023,[33] it does not specify whether the advice given was appropriate. Finally, the black box issue is a major issue. As the claimant must prove negligence and causation[34] and the reasons for the decision may be unclear to even developers, it may be difficult for the patient to prove this.[35] Within Indian law, there is no requirement for developers to record information, or justify why an answer may have been made.

Some of these issues are better addressed in the UK. Within the Medical Devices Regulations 2002, software is regulated depending on its purpose.[36] If symptom checking software claims to help with diagnosis or treatment, it must be safe and must have a conformity mark from the UK before it can be sold. The MHRA has also begun a change programme to better regulate AI as medical devices (Software and AI as a Medical Device Change Programme).[37] AI medical

[27] Ministry of Elecs. & Info. Tech., India AI Governance Guidelines (2025) (India).

[28] Ministry of Health & Family Welfare & NITI Aayog, Telemedicine Practice Guidelines (2020) (India).

[29] Indian Council of Medical Research, Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare (2023) (India).

[30] Medical Devices Rules, 2017, G.S.R. 78(E) (India).

[31] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019, § 2(42) (India).

[32] Information Technology Act, 2000, No. 21, Acts of Parliament, 2000, § 79 (India).

[33] Digital Personal Data Protection Act, 2023, No. 22, Acts of Parliament, 2023 (India).

[34] Kusum Sharma v. Batra Hosp. & Med. Rsch. Ctr., (2010) 3 S.C.C. 480 (India).

[35] Yavar Bathaee, *The Artificial Intelligence Black Box and the Failure of Intent and Causation*, 31 Harv. J.L. & Tech. 889 (2018).

[36] Medical Devices Regulations 2002, SI 2002/618 (UK).

[37] Medicines & Healthcare Prods. Regul. Agency, Software and AI as a Medical Device Change Programme (2022) (UK).

products may be tested in a supervised sandbox (AI Airlock).[38] These systems are not present in Indian law. Negligence is also better regulated. As per Montgomery, medical professionals must inform patients of material risk.[39] This may include using an AI tool. If expert opinion lacks logical justification, it may be disregarded (Bolitho).[40] Therefore, medical professionals cannot claim that they blindly followed AI advice as many other medical professionals do. With respect to the black box issue, within article 22 of the UK GDPR, individuals have a right not to be subject to important decisions made solely by automated processes.[41] Individuals may be able to request a human to review the decision. Also, the General Medical Council make it clear that medical professionals remain responsible for decisions made, even if using technology.[42]

However, issues still exist within the UK system. Many of these are similar to the issues in India. Within the Consumer Protection Act 1987, damage to goods must be proved. It is still unclear whether software can be classed as goods.[43] The Court of Appeal briefly considered this in St Albans.[44] If a defect in the product could not be discovered at the time of production, producers may not be liable.[45] This is concerning within AI, as it is constantly evolving. General non medical chatbots are also unregulated as medical devices, in the same way as within India. There is no specific legislation on AI within the UK. A light touch, encouraging innovation approach has been taken, with individual regulators within sectors deciding how to regulate AI within their sector.[46] The Law Commission recognise that it is difficult to prove fault and causation in AI due to the black box issue and changes to the law may be required.[47] Whilst regulation of products within the UK prior to reaching patients is stronger than within India, it is unclear how compensation may be provided once harm has occurred. Within comparison to the UK, there are greater gaps in regulation within India. As there is no regulator and clear rules on liability, there are three lessons to be taken from regulation within the UK. Firstly, medical AI should be regulated within India depending on its purpose. General chatbots should be regulated in the same way. Secondly, a specific regulatory body should be created with a testing sandbox. Finally, important decisions made by AI should be reviewed by humans.

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[38] Medicines & Healthcare Prods. Regul. Agency, AI Airlock: The MHRA's Regulatory Sandbox for AI as a Medical Device (2024) (UK).

[39] Montgomery v. Lanarkshire Health Bd., [2015] UKSC 11, [2015] A.C. 1430 (appeal taken from Scot.).

[40] Bolitho v. City & Hackney Health Auth., [1998] A.C. 232 (H.L.) (appeal taken from Eng.).

[41] Regulation 2016/679, art. 22, 2016 O.J. (L 119) 1 (as retained in UK law as the UK GDPR).

[42] Gen. Med. Council, Good Medical Practice (2024) (UK).

[43] Consumer Protection Act 1987, c. 43, § 1(2) (UK).

[44] St. Albans City & Dist. Council v. Int'l Computers Ltd., [1996] 4 All E.R. 481 (C.A.) (Eng.).

[45] Consumer Protection Act 1987, c. 43, § 4(1)(e) (UK).

[46] Dep't for Sci., Innovation & Tech., A Pro-Innovation Approach to AI Regulation, CP 815 (2023) (UK).

[47] Law Comm'n, Artificial Intelligence and the Law: A Discussion Paper (2025) (UK).

What changes could be made to law in India (in comparison to the UK) to clearly allocate liability between developers, deployers and doctors?

As this issue has a direct effect on patient safety in India, guidelines alone should not be relied upon. Firstly, risk based regulation should be applied to health focussed AI. This can be done through creating new legislation, or amending existing legislation. AI tools should be categorised into low, medium or high risk.[48] Low risk AI provides general well-being information. Medium risk AI includes symptom checkers. High risk AI includes diagnosis, treatment advice and prescriptions. The higher risk AI is, the stricter regulation should be. This may include testing, registration, and monitoring after release. Although risk based regulation is used in the UK[49] (software is regulated depending on purpose),[50] improvements can be made. General chatbots are not regulated under the Medical Devices Rules (2017) as they do not seem to be medical.[51] However, within India, functional based regulation should be applied. If the chatbot regularly provides health related advice, regardless of what the company claims, it should be classed as health AI. Currently medical devices are regulated by the Central Drugs Standard Control Organisation under the Drugs and Cosmetics Act, 1940.[52] To improve regulation, a specific section for AI could be created within this organisation, rather than creating an entirely new body. A testing sandbox similar to that within the UK could also be created.[53] AI products can be tested within a supervised environment prior to mass sale. Additionally, the Telemedicine Practice Guidelines, which state that only registered doctors can give advice/prescription should be made legally binding so that they can be enforced against apps/chatbots.[54]

Secondly, clear allocation of liability between developers, deployers and doctors should be created. Developers should make sure that the system is appropriately designed, tested and explained. Sufficient warnings should be provided on the limitations of the product. Deployers (hospitals/clinics/app companies) should ensure that a safe product is chosen, properly managed and patients are made aware that AI is being used. Finally, doctors should make the final medical decisions. This is in line with current opinion within the General Medical Council within the UK.[55] This is also in line with the Bolitho principle.[56] If expert opinion has no logical justification, it may be disregarded by the court. As many other medical professionals may be blindly following

[48] Ministry of Elecs. & Info. Tech., India AI Governance Guidelines (2025) (India).

[49] Medical Devices Regulations 2002, SI 2002/618 (UK).

[50] Medicines & Healthcare Prods. Regul. Agency, Software and AI as a Medical Device Change Programme (2022) (UK).

[51] Medical Devices Rules, 2017, G.S.R. 78(E) (India).

[52] Drugs and Cosmetics Act, 1940, No. 23, Acts of Parliament, 1940 (India).

[53] Medicines & Healthcare Prods. Regul. Agency, AI Airlock: The MHRA's Regulatory Sandbox for AI as a Medical Device (2024) (UK).

[54] Ministry of Health & Family Welfare & NITI Aayog, Telemedicine Practice Guidelines (2020) (India).

[55] Gen. Med. Council, Good Medical Practice (2024) (UK).

[56] Bolitho v. City & Hackney Health Auth., [1998] A.C. 232 (H.L.) (appeal taken from Eng.).

AI advice, blind following of AI cannot be justified. In order for this to be effective, changes need to be made to the Consumer Protection Act, 2019. AI and software should specifically be included within the definition of products.[57] Even if the service is free,[58] health AI should be included within product liability.[59] As free services are excluded within current law, most users of chatbots are not protected. To overcome the black box issue, it should be a legal requirement for developers to keep a record of how the system works. If a dispute arises, this record should be provided. If developers do not comply with this, a defect may be presumed in court. Developers may attempt to disprove this. This has already been implemented in the EU. Software is included within product liability rules and evidence may be requested to be disclosed.[60] This means less pressure on the claimant as without this, they may be unable to prove what occurred within the system.

Finally, further protections should be given to patients. If AI is being used for medical advice, this should be made clear to the user. Limitations of the AI should be clearly displayed. In serious situations, users should be advised to see a doctor/emergency. Important medical decisions should require human oversight. This is currently required to an extent in the UK under GDPR. People have a right not to be subject to decisions made solely by automated processes.[61] If AI has played a role in the treatment of a patient, this should be made clear to the patient by the doctor. This is in line with the Montgomery principle, that material risk information must be given to patients.[62] Patients should also have clear methods to make complaints and be fairly compensated. To do this, insurance may be required to be carried out by developers of high risk tools. Patient health data should be processed under the Digital Personal Data Protection Act, 2023,[63] so that data protection laws can work in conjunction with safety. However, regulation should not be so strict that innovation is discouraged. Regulation should only become stricter as risk increases. The UK have recognised that changes may be required in current law as fault and causation may be difficult to prove in AI.[64] By regulating early, India can learn from the issues in the UK. These changes mean that this research question has been answered. Clearly allocating liability with good regulation and protection for patients is the best solution.

Conclusion

It was hypothesised that the current legal frameworks in place to protect people from harm caused by AI in medical advice are inadequate. In particular, this is true in India as there are no specific

[57] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019, § 2(33) (India).

[58] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019, § 2(42) (India).

[59] Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019, §§ 82–87 (India).

[60] Directive 2024/2853 of the European Parliament and of the Council of 23 October 2024 on Liability for Defective Products, 2024 O.J. (L 2024/2853) (EU).

[61] Regulation 2016/679, art. 22, 2016 O.J. (L 119) 1 (as retained in UK law as the UK GDPR).

[62] Montgomery v. Lanarkshire Health Bd., [2015] UKSC 11, [2015] A.C. 1430 (appeal taken from Scot.).

[63] Digital Personal Data Protection Act, 2023, No. 22, Acts of Parliament, 2023 (India).

[64] Law Comm'n, Artificial Intelligence and the Law: A Discussion Paper (2025) (UK).

laws or regulators. In order to make AI safe in medical contexts in India, a risk-based approach to liability should be implemented. Following research into both countries, this hypothesis has been proven. In medical negligence, liability is placed on a human doctor. As chatbots are not human doctors and do not have legal personhood, they cannot be taken to court. It cannot be said that chatbots meet the standard of a 'reasonably skilled professional'. Under consumer law, it is unclear how patients can be protected. As most medical chatbots are free, they do not qualify as services. It is unclear if software can be considered a product under product liability. If a claim can be made, it would be very difficult to prove negligence and causation. As the reasoning behind AI recommendations is not transparent to users, it would be very difficult to prove. Under medical devices rules (2017), only software with medical purposes will be covered. General health chatbots would not be included. Additionally, Telemedicine Practice Guidelines and ICMR guidelines are not mandatory.

Comparatively, better protections exist in the UK. Before medical software is provided to patients, the MHRA ensures an appropriate standard. AI products are tested in a sandbox in order to improve safety. Finally, doctors will ultimately be held responsible for final medical decisions by the courts and General Medical Council. However, there are still issues. General health chatbots may not be covered under medical device rules. It is unclear whether software can be included under the Consumer Protection Act 1987. Additionally, due to AI products constantly changing, issues may arise with the defences during development. Therefore, issues exist in both countries. However, in India, the issues are more significant as there is no specific regulator. It is also unclear who is liable for issues in India. Therefore, the hypothesis is correct. Although there are issues in the UK, India can take inspiration from the positives in the UK. As AI technology is rapidly developing and patients are beginning to rely on it, India must act quickly to create a suitable legal framework to protect patients, without hindering positive innovation.

Recommendations and Suggestions

- Risk-Based Legislation
  There should be different levels of risk for health AI. Low, medium and high risk AI tools should be identified. Higher risk AI tools should be more heavily regulated, such as by testing and ongoing monitoring.
- Consider Function
  If a chatbot regularly provides health advice, it should be considered medical AI, regardless of the company stating otherwise.
- Specific Regulator
  A specific AI section within the CDSCO could be created (such as the AI Airlock in the UK) rather than creating a new regulator.
- Clarify Responsibility
  Developers: Responsible for creating, testing and providing warnings. Hospitals/applications: Responsible for safe use of AI. Doctors: Responsible for final medical decision.
- Update Consumer Protection Act, 2019
  Clearly include software and AI as products. Include free services.

- Easier Claims
  Developers should provide information on how well the AI performed. If they do not, it will be presumed that there is a problem.
- Protection for Patients
  Patients should be made aware if their recommendation came from AI. Clear warnings should be provided. Important decisions should be made by humans. High risk tools should be insured by the developers.
- Enforce Telemedicine Guidelines
  To hold applications and chatbots accountable, Telemedicine Guidelines should be made legally binding.