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CRITICAL ANALYSIS OF LEGAL VACUUM IN TELEMEDICINE REGULATION OF INDIA

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ABSTRACT:

Although telemedicine has increased access to healthcare, particularly in underserved areas, there are serious risks to patient safety and provider accountability due to a lack of legal clarity on issues like shared liability, the validity of digital consent, data privacy breaches, professional negligence, and technological failures. The paper examines the socioeconomic effects of new online platforms, tracks the historical development of telemedicine, and describes the current consultation arrangements under the 2020 Telemedicine Practice Guidelines. Inadequate data protection measures in the face of sensitive health data exposure, unclear liability division between practitioners and platform operators, difficulties verifying remote informed consent, and gaps in professional and technology regulation are some of the main issues. The study identifies the shortcomings of current authorities' enforcement, such as the National Medical Commission, and suggests extensive changes, such as specific telemedicine laws, uniform digital consent procedures, and strict data protection rules. To guarantee fair, secure, and long-lasting telemedicine practice in India, strict data security regulations, specified negligence standards, and market control are needed. In order to close legislative loopholes and fully achieve telemedicine's transformational potential in India's digital healthcare ecosystem, this research offers policymakers and stakeholders a fundamental roadmap.

Objective and the Scope of the study:

The objective of the research is to overview the existing regulatory framework concerned with practice of telemedicine in India and highlight the major legal vacuum regarding it. This paper discusses the nexus of shared liability in the case of telemedicine, concept of consent in telemedicine It also highlight the dilemma of practicener in upholding professional autonomy

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parallely safeguarding the privacy . This study further analyses the vacuum in the legal regime of virtual medical consultation, technical hurdles and lack of single disciplinary body addressing the technical, legal as well as medical aspects of telemedicine at one place.

Introduction:

The integration of healthcare with information and communication technology has reshaped the relationship between patient and healthcare professional. This intersection is broadly defined under the term 'Telemedicine'. For a country like India, which has stark socio-economic disparity, telemedicine can be a gamechanger in assuring access to healthcare. It has potential to bridge the gap of accessibility in terms of healthcare between urban and rural population. In India practice of telemedicine is governed by the telemedicine practice guideline (TPG) 2020. As per the Guideline, telemedicine is way of delivery of health care services where distance play a significant role by health care professionals through the means of employing information and communication technology for the purpose of diagnosis, treatment, prevention of diseases and also research, evaluation and education.[3]

Till 2019, there was not any guideline in India regarding telemedicine. It was the covid-19 pandemics that pushed the government to think about it, in order ensure the primary healthcare accessibility across both rural and urban population. Due to its, cost effective nature and easy accessibility because of the technology integration, it have potency to positively influence the public health outcome. It overcome the geographical barrier, to provide healthcare facilities till the remote corner of the country. One the main ingredient in rapid growth of telemedicine is the surge in the number of digital devices users and easy availability of internet as services.

Brief history of Telemedicine:

The historical overview highlights the technical evolution that acted as rider for the growth of telemedicine, ranging from early telephonic experiment to satellite based system, shaping the modern day face of telemedicine that is internet based. The roots of primitive form telemedicine extend back over a century. With rapid growth of telecommunication technology, telemedicine also parallelly evolved. There is information showing that the telegraph was used

[3] *Mohfw*. Available at: https://esanjeevani.mohfw.gov.in/assets/guidelines/Guidelines_for_Telemedicine_Services.pdf (Accessed: 02 November 2025).

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in Australia in 1874 to help with the medical treatment of an injured person[4]. In early 20th century there exist some of the documented incidents of remote clinical communication. William Einthoven, in 1905 transmitted heart sounds from hospital to his lab over telephone and in 1910 Electrocardiogram were transmitted over cable in New York[5]. Modern face of telemedicine emerged in 1950s and 1960s due to development in video communication technology. NASA's focus on astronaut health and telecommunication significantly advanced the development of telemedicine in the 1970s.

In India, initial initiative regarding telemedicine started in 1999 and early 2000 with contribution of ISRO facilitating communication between rural health centre and city hospitals[6]. Later the covid-19 pandemic catalysed the rapid growth of telemedicine and its adoption in our country.

Legal structure overseeing Telemedicine:

The telemedicine practice Guideline (TPG) issued in March of 2020, is a guide to the healthcare professional for providing digital services. Before this guideline telemedicine was regulated in limited and ad-hoc manner under several act. It's main goal was to help registered medical practitioner provide safe, effective and informed consultation. TPG only apply to RMP not dentists, under NMC act and remain in force till the time new regulation are introduced. The conduct, professionalism and ethics of registered medical practitioner are governed by National medical Commission Act, 2019 and Indian medical commission act 2002[7]. The prescription[8] made is needed to complied as per the Drug and Cosmetics act, 1940 and Drug Rules 1945.

The information, communication and technological aspect of telemedicine is governed by IT Act 2000, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or information) Rules, 2011 (together the "Data Protection Rules") and the Information Technology (Intermediaries Guidelines) Rules, 2011. The latest addition to this is Digital Personal Data Protection Act, 2023

[4] Robert H Eikelboom, *Global Telehealth 2012*, 67-72 (182nd vol. 2012).
[5] Carylee Gali, *History of Telemedicine*, https://curogram.com/ (Feb. 8, 2022), https://curogram.com/blog/history-of-telemedicine.
[6] *Evolution of Telemedicine: Quick access to Healthcare*, www.apollotelehealth.com https://www.apollotelehealth.com/evolution-of-telemedicine-quick-access-to-healthcare.
[7] Section 61(2) of NMC act
[8] Rule 65(10)(a,b,c) of the Drug rules

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Concerns Regarding Telemedicine regulation

1. **Nexus of shared liability**

The current system of shared liability led to slow and reactive justice. This intersection of shared liability in telemedicine practice of India pertains to intricate legal framework deployed to address the blame, when patient experience injury. It is the result of the fragmented framework that is enforced by separate bodies (NMC for RMP, MeitY for IT, CPA for consumers).TPG 2020 anchored majorly for professional responsibility, but the legal challenge lie in establishing liability of digital ecosystem provider. One major legal challenge is how much liability telemedicine platforms carry for the actions of the physicians using their service. Indian laws, like the Information Technology Act of 2000, provide certain protections for intermediaries, generally shielding platforms only if they act merely as conduits and not as decision-makers. However, this protection applies only if the intermediary does not exercise control over the content or actively manage the consultation. If platforms recommend specific physicians, use AI for diagnoses, or manage data, they risk losing this protection and facing legal liability.

Due to the lack of specific telemedicine legislation that defines shared liability it led to the confusion. The Telemedicine Practice Guidelines (TPG) issued in 2020 offer some guidance but are non-binding in nature. Much of the interpretation falls back on older medical malpractice laws and consumer protection rules, which may not fully address telemedicine's unique features as per modern requirement.

Shared liability also connects with consumer protection laws, especially since the Consumer Protection Act of 2019 expanded the definition of medical services. Patients increasingly submit complaints against multiple parties to improve their chances of compensation. This often leads to lengthy legal battles and unclear accountability.

Internationally, shared liability models differ. Some countries enforce strict liability on telemedicine platforms to protect patients, while others maintain a balance that encourages innovation. India’s disorganized regulatory approach creates legal uncertainty and may hinder telemedicine adoption due to fear of legal issues.

To clarify liability, legislative action is needed to outline the following: the responsibilities of platforms compared to RMPs, conditions for intermediary liability exemptions, clear due diligence requirements for platform operators, and effective consumer redress mechanisms that assign accountability. Without this clarity, the issue of shared liability in Indian telemedicine creates a significant legal gap that threatens trust, patient safety, and the growth of digital healthcare.

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2. **Price of remote digital consent**

Digital consent in telemedicine basically means getting patient agreement online for the purpose of diagnosis, treatment, or sharing data. While it increases access to healthcare and adds convenience, but digital and remote consent also brings significant legal and ethical issues. The main concern is in assuring whether patients really understand the nature, risks, and limitations of telemedicine consultations before they consent online. On the other hand, in-person visits allow for comparatively detailed advice, which digital formats do not provide.

The lack of consistent standards for verifying patient identity and the authenticity of consent raises worries.It raise concerns about coercion, misrepresentation, and mistakes in recording consent. In addition, India's digital divide and inconsistent literacy rates make these challenges more worse. Marginalized groups may agree to terms without fully understanding digital consent forms, which raises questions about whether their consent is truly voluntary. If consent is invalid or uninformed, the legal consequences can be serious, potentially voiding the entire teleconsultation and exposing providers to claims of negligence.

Current guidelines, such as the Telemedicine Practice Guidelines and new data protection laws like the Digital Personal Data Protection Act (DPDP) 2023, stress the importance of informed consent.But do not fully outline how to validate digital consent. Methods like biometric checks, multi-factor verification, or oversight by third parties are not widely used or regulated. The “cost” of remote digital consent includes:

- The risk of invalid consent affecting the legal standing of telemedicine.
- Patients potentially facing unapproved use of their data given for treatments.
- Legal risks for practitioners and platforms due to disputes over consent.
- Ethical concerns about superficial consent processes.

Finding a balance between making technology user-friendly, respecting patient privacy, and ensuring legal reliability requires creating strong protocols for digital informed consent. These protocols should consider usability for different groups, use secure authentication methods, and require clear disclosure about the limitations of telemedicine. Ongoing legal reforms and court decisions will be key in addressing and harmonizing these challenges, ensuring that digital consent serves as a dependable tool rather than a legal risk in the future of telemedicine.

3. **Data breach as type of harm to patient**

Telemedicine include exchange of sensitive personal details between practitioner and

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patient over a tech platform. In the context of telemedicine, data privacy breaches have become a unique and significant form of patient damage. Since telemedicine fundamentally relies on electronic exchange and storage of sensitive personal health information (PHI), unauthorized access or use of this data can have severe consequences. Indian telemedicine currently works without a specific, comprehensive health data law. The upcoming Digital Personal Data Protection Act (DPDP) 2023 and the IT Act, 2000 and its related regulations offer some protection, but they don't contain any protections unique to telemedicine. The breadth of protections, breach reporting requirements, and the penalties for non-compliance are all unclear under a fragmented regime.

Data breaches can hurt patients in a number of ways:

1. Fraudulent use of personal data and identity theft,
2. Social stigma and discrimination based on medical conditions,
3. Psychological distress and loss of trust
4. harm to healthcare providers' finances and reputations.

Significantly, telemedicine platforms frequently compile enormous amounts of data, raising the potential of vulnerability. Software flaws and insider threats continue to exist, and their cybersecurity infrastructure varies greatly. Furthermore, patients are still not well-informed about their rights regarding data privacy. Globally, strict laws like GDPR (EU) and HIPAA (USA) set strict guidelines for the safety of electronic health data and impose severe fines for violations. There are currently no patient-centric protections or corresponding enforcement teeth in India's regulatory system. Reforms should focus on: Enacting clear health data protection regulations including telemedicine provisions, Enforcing security audits and certification standards for telemedicine platforms, requiring clear procedures for reporting breaches and granting patients the right to corrective action, encouraging consent management tools and patient data literacy.

Although it makes access easier, digital consent raises questions about its voluntariness, authenticity, and informed nature. The absence of consistent validation requirements in the current provisions could result in disagreements regarding the legitimacy of permission, particularly among disadvantaged groups with low levels of digital literacy[9]. Hence, ongoing legal reforms and judicial precedent will play important

[9] Mondal, H., Haldar, R., & Mondal, S. (2020). Informed consent for telemedicine. Journal of family medicine and primary care, 9(10), 5402–5403. https://doi.org/10.4103/jfmpc.jfmpc_1752_20

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resolving these issues to bring reliability in the digital consent

4. **Professional culpability for negligence**

Violations of the recognized standard of care during remote consultations give rise to professional negligence in telemedicine. Comparing liability to conventional in-person medical care, however, presents new difficulties. The clinician's capacity to physically evaluate patients is limited by the digital medium, which may reduce the accuracy of the diagnosis. Risks can be increased by inadequate patient history or poor internet quality.

It is necessary to modify current law or create standards unique to telemedicine in order to ascertain if telemedicine consultations satisfy the legal standard of care.

Although telemedicine and other medical services are protected under India's Consumer Protection Act of 2019, the way negligence claims are interpreted frequently differs. Courts have yet to develop consistent precedents explicitly defining telemedicine negligence boundaries.[10]

Factors that complicate this issue

1. The scope and limitations of the telemedicine technology employed,
2. The sufficiency of the documentation and the integrity of the digital records
3. Appropriate patient counselling of telemedicine limitations
4. Need for referral of patients to in-person care.
5. Many practitioners are still unsure of their telemedicine malpractice risk, which can lead to defensive medical practice or resistance to the use of telemedicine.

The Medical Council of India and the National Medical Commission ought to create clear norms for professional negligence and telemedicine medical ethics. Legal risk mitigation must be emphasized in telemedicine RMP training and certification programs. Practitioners should be covered by insurance packages designed to address the risks associated with telemedicine. In order to safeguard patients and healthcare practitioners and promote the responsible expansion of telemedicine, a strict yet equitable professional responsibility framework must be developed.

5. **Digital failure as cause of adverse patient outcome**

In telemedicine, technological malfunctions are one of the most underregulated issues, despite being a major cause of patient harm. Data loss, inaccurate diagnosis, or postponed treatment might result from disruptions brought on by software crashes,

[10] Shivani Mohan Gaikwad, *Medical Negligence in Telemedicine : Legal Challenges in India*, 4 Journal of Legal Research and Juridical Science (2025).

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communication problems, improper use of AI technologies, or cybersecurity breaches. Because software developers, network providers, healthcare professionals, and platform operators all play layered roles, assigning blame for digital mistakes is more difficult than for physical medical blunders. As of right now, India has no explicit requirements for telemedicine software and hardware quality assurance, testing, certification, and risk reduction. The lack of legally binding quality standards makes patients more susceptible to technical errors that compromise patient safety. Data loss from insufficient backup or hacking incidents, software bugs that misrepresent clinical data, AI faults that provide erroneous clinical decision assistance, and dropped video consultations that hinder full diagnosis are a few examples of digital failure harm[11]. Legally speaking, present malpractice regulations offer few recourse for damages that result directly from digital failure as opposed to practitioner error. Introducing required security and quality certifications in line with healthcare digital standards is necessary to address this issue. Defining the boundaries of legal liability for healthcare providers and technology vendors, creating suitable regulatory processes for telemedicine technology approval, and promoting open communication and prompt technical problem solving.

6. Regulation & supervision of Competent authority

In India, jurisdictional ambiguity, enforcement gaps, and a changing legislative environment continue to be obstacles to effective telemedicine regulation and oversight. In addition to supervising Registered Medical Practitioners in telemedicine, the National Medical Commission (NMC) is primarily in charge of regulating medical education, practice, and professional conduct. Nevertheless, the NMC's telemedicine-specific regulatory framework is restricted to guidelines (TPG 2020) and lacks formal legislative support or enforcement procedures specifically designed to address the particularities of telemedicine. State Medical Councils are involved in licensing as well, but they deal with complicated cross-state telemedicine consultations that create multi-jurisdictional problems that have not yet been addressed by legislation. Other government agencies, such the Digital Health Authority (part of the Ayushman Bharat Digital Mission) and the Ministry of Electronics and Information Technology (MeitY), have developing but yet tentative roles in establishing standards and supervising data

[11] Rowland, S. P., Fitzgerald, J. E., Lungren, M., Lee, E. H., Harned, Z., & McGregor, A. H. (2022). Digital health technology-specific risks for medical malpractice liability. NPJ digital medicine, 5(1), 157. https://doi.org/10.1038/s41746-022-00698-3

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protection and technology interoperability. The absence of a single telemedicine law results in disparate regulation between states and domains, uneven oversight, and inconsistent disciplinary action. Enacting specific telemedicine law with explicit delegation of regulating, licensing, and disciplinary responsibilities is one suggestion for bolstering competent authority regulation. Other suggestions are enabling coordination for integrated oversight between the NMC, State Councils, MeitY, and Digital Health Authority, creating grievance redress and penalty systems unique to telemedicine, mandating the registration of telemedicine platforms and digital practitioners.

Critical examination of online telemedicine platforms

India's booming digital health business has seen tremendous expansion in telemedicine platforms such as Practo, 1mg, DocsApp, and government programs like eSanjeevani. These platforms have democratized access, enabling millions to avoid geographic and infrastructural healthcare restrictions. However, this market growth presents crucial socio-economic and regulatory challenges:

1. Verification and Credentialing: Some platforms allow unverified or minimally credentialed practitioners to give consultations, jeopardizing patient safety. The absence of obligatory platform accreditation and physician authentication standards is worrisome.
2. Market Transparency and Pricing: Platforms often adopt opaque pricing methods and subscription systems.
3. Concerns regarding over-prescription, up-selling, and costs burdening vulnerable people persist without market control.
4. Digital Divide and Equity: Rural and economically disadvantaged communities encounter challenges owing to low internet connectivity, device affordability, and digital literacy. This exacerbates existing healthcare disparities despite telemedicine's promise as an egalitarian.
5. Commercialization and Quality: Gaming of telemedicine markets for profit without strong quality assurance and ethical monitoring risks deterioration of medical standards and consumer trust.

   Addressing these socio-economic factors requires Establishing strong regulatory frameworks mandating platform accreditation, transparent pricing disclosures, and strict practitioner vetting, Government interventions to enhance rural digital

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infrastructure and literacy programs. Ther is need for Consumer protection policies adapted for digital health service markets, and monitoring mechanisms assuring adherence to ethical and quality standards.

Conclusion:

TPG filled some of the existing gap in this field but Despite significant geographical and infrastructure obstacles, telemedicine is poised to transform healthcare delivery in India by providing previously unheard-of access to high-quality care. The COVID-19 pandemic dramatically increased the use of telemedicine, highlighting its vital importance. But this quick growth has also exposed significant regulatory flaws and legal gaps. There is insufficient clarity on shared liability, digital consent, data breach repercussions, negligence standards, technology failures, authority supervision, and platform regulation in the current frameworks, which are mainly the Telemedicine Practice Guidelines 2020 and fragmented digital data regulations. Patient safety, provider accountability, and digital equity are still at risk in the absence of comprehensive, cogent law that is adapted to the technological and socioeconomic complexity of telemedicine.

A coordinated legal strategy that connects established medical jurisprudence, new data protection laws, and technological governance is necessary due to the convergence of healthcare and digital platforms. Legislators and regulators must pass specific laws, bolster enforcement organizations, create uniform procedures, and encourage fair access to technology if telemedicine is to fulfil its potential in India. Telemedicine is a crucial tool for democratizing healthcare, but it can only be protected and used sustainably with an integrated legal framework. This paper emphasizes how urgent reform is and offers fundamental analysis for developing such revolutionary telemedicine legislation in India.