

Review Article

Telemedicine and virtual consultation: The Indian perspective

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ABSTRACT

Telemedicine was considered futuristic and experimental some years ago, but it is a reality today. It is now emerging as an important tool for convenient as well as specialized healthcare, particularly for patients in remote locations with limited access to standardized healthcare services. However, there are multiple challenges to realizing its full potential. We focus on some key medicolegal and ethical issues such as doctor–patient relationship, informed consent, rights of the patient, malpractice, and principles of confidentiality relevant to the practice of telemedicine and virtual consultation. We explore the global as well as the Indian legal perspective pertaining to the application of telemedicine. The absence of specific laws for registration and practice of telemedicine and virtual consultation in India acts as a deterrent for medical practitioners to engage in its potential use. Hence, there is a need for specific legislation.

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INTRODUCTION

The field of telemedicine is growing rapidly. With advances in technology, there is better accessibility and affordability of tools of telemedicine. Telemedicine was started to manage patients in remote locations with limited access to healthcare services. However, it is becoming a tool for convenience in healthcare. For patients who do not want to waste their time in the waiting room of the doctor's clinic, telemedicine can provide an alternative solution. In certain situations such as stroke, it cannot replace the time-critical initiation of therapy to the patient at a distant location; though, it is helpful in the recognition of stroke.¹

An important factor responsible for growth in this field is the increasing use of mobile phones.¹ The presence of health applications enables patients to monitor their health status on their own. This proactive approach leads them to use alternative ways to get healthcare services such as telemedicine.

The growth of telemedicine services is likely to lead to medicolegal and ethical challenges;^{2,3} these include issues of confidentiality of patients, maintaining the standard of treatment, consent from patients, professional misconduct, credentials of doctors, licensure, reimbursement, penalties and liabilities according to various prevalent laws.^{4,5} These may adversely affect the acceptance and adoption of telemedicine and virtual consultation.^{1,3,6}

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WHAT IS TELEMEDICINE AND VIRTUAL CONSULTATION?

Telemedicine means 'healing from a distance'. WHO has adopted the following description of telemedicine: 'The delivery of health care services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities'.⁷

A virtual consultation is a process of getting a medical opinion without visiting the specialist in person, which is the only difference from a traditional medical consultation.⁸ Virtual consultations also allow a physician to start a chat session with another physician to consult various electronic medical records.⁹

To provide quality healthcare services all over India is the main purpose of telemedicine and virtual consultation. This includes facilitating access to healthcare to both privileged and underprivileged populations, providing faster, cheaper and better communication for treatment, follow-up by experts and to store records. It helps remove geographical barriers to healthcare, especially by reaching distant areas poorly connected by any means of transport.

Pros

In most situations, telemedicine is beneficial. It gives access to healthcare services in remote areas and to those with mobility issues such as the elderly. Therefore, it has the power to overcome geographical barriers to provide healthcare services. It may provide an opportunity to reduce healthcare spending and save time for the patient and caregiver. With the advent of telemedicine, a medical practitioner or hospital can consult with different specialists, irrespective of their location. Telemedicine helps patients to engage with their healthcare providers more frequently, in a convenient way, which may result in a better doctor–patient relationship. The follow-up of patients is likely to be better, which may improve outcomes. Overall, telemedicine has the potential to provide better healthcare services to the masses.⁸

Cons

Telemedicine has some downsides because of its virtual nature. It requires infrastructure and technical training. It may reduce direct interaction of patients with doctors because online interactions are impersonal and, to make a complete diagnosis, physical examination needs to be done. There is a lack of a standardized format to the interaction and the absence of a consent form for either opting for or refusing the service. Telemedicine is still not included in the medical curriculum. Besides ambiguity regarding

responsibilities in case of negligence, there are concerns about privacy, confidentiality, security of patient information and treatment. There is no clarity with respect to medicolegal issues arising out of telemedicine. Currently, no health insurance policy in India factors in telemedicine.¹

MEDICOLEGAL ISSUES

Doctor–patient relationship

Patients trust healthcare professionals while seeking treatment and confide in them. The lack of face-to-face contact in some modes of telemedicine is seen as a barrier to adequate development of the doctor–patient relationship.² It is essential to maintain the trust of the patient to meet legal requirements. Healthcare providers are obliged to establish good doctor–patient relationships.¹⁰

Informed consent

Informed consent is an important medicolegal requirement while treating a patient; failure to do so is a tort and crime.¹⁰ Consent should be obtained for any medical interaction, whether it is in-person or at a distance such as telemedicine and virtual consultation.¹¹ Consent should be obtained for telemedicine interaction, transmission of data, treatment, monitoring and consultation. Further, it is important to clarify whether the medicolegal value of informed consent in telemedicine is the same or different with respect to traditional face-to-face interactions.³ There is enough evidence that in many specialties, virtual consultation such as video conference is clinically as good as an in-person consultation.^{6,11,12} Hence, informed consent can be taken traditionally and properly documented. This is also highlighted by the World Medical Association's statement of the Guiding Principles for the Use of Telemedicine for the Provision of Health Care (2009). Informed consent in telemedicine is mandatory in Malaysia, France, the UK, South Africa and in California, USA.¹¹

Malpractice and liability

Once the doctor–patient relationship is established, it is the responsibility of the doctor to provide due care and treatment, which is expected from the professional in the given circumstances.³ Can physicians be sued for medical malpractice in telemedicine and virtual consultation and can they be protected by medical indemnity insurance?² The following are some important points in this context.

1. The 'duty of care' must be established in all telemedicine encounters to clarify responsibility(s) for the patient/caregiver as well as other involved healthcare providers.
2. Healthcare professionals should clearly define their roles and responsibilities regarding the various aspects and extent of treatment.

Privacy

The right to privacy has been an integral part of medical ethics since the time of Hippocrates and is supported by various codes including the International Code of Medical Ethics.¹³ It mandates that the health practitioner must maintain confidentiality regarding personal information of the patient even after his/her death. Every individual has a right to privacy even in telemedicine.¹⁰ There is the potential for leakage of electronic records of a patient. The onus for safeguarding this information has to be on the medical practitioner.⁹ Information must be transmitted in a secure way. Password security should be maintained to avoid unauthorized access to the information. However, privacy cannot be guaranteed with the use of telemedicine.^{5,8,12}

Product liability

It is the liability of manufacturers for any harm caused to the patient by a defective product. Thus, it means the duty of care is owned by the manufacturer, which includes the manufacturer of the computer system compatible for telemedicine, manufacturer of compatible software, manufacturer or supplier of various accessories related to telemedicine, network provider, healthcare service provider who is using the technology and the service company responsible for maintenance of the whole telemedicine unit.¹⁰

Rights of patients

In traditional medical practice, certain rights of patients have been recognized, such as the right to get treatment, choose a doctor freely, change doctor at any stage of treatment, right of compensation, right of confidentiality, right of dignity, right of grievance redressal, right of information and right to refuse treatment. The same applies to the practice of telemedicine and virtual consultation. The patient has a right to receive one's medical record in the electronic format, to know standards and safety guidelines. He/she has the right to be informed regarding authorization or registration status of the service provider and to know the various complaint processes which he/she can use in case he/she suffers any harm during the consultation.⁸

Reimbursement

Currently, there is no provision for reimbursement from medical insurance in telemedicine practice.² Whether telemedicine was required or not in the given situation is another condition which should be cleared for reimbursement.

LAWS IN INDIA APPLICABLE TO TELEMEDICINE

Telemedicine is a blend of information and communication technologies (ICTs) with medical science. It has been recognized by the Government of India and included in various schemes and policies. Presently, the laws applicable to telemedicine in India are the laws governing the medical profession and information technology.

Some of the laws relating to the medical profession include the Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945,¹⁴ the Indian Medical Council Act, 1956,¹⁵ the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002,¹⁶ and the Clinical Establishments (Registration and Regulation) Act, 2010 ('Clinical Establishments Act').¹⁷

The laws related to ICT include the Information Technology Act, 2000 (IT Act),¹⁸ the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011,¹⁹ the Information Technology (Intermediaries Guidelines) Rules, 2011,²⁰ Unsolicited Commercial Communications Regulations, 2007,²¹ and Telecom Commercial Communication Customer Preference Regulations, 2010 ('TCCP Regulations').²²

The Information Technology (IT) Act contains provisions safeguarding the security and privacy of information exchanged using means recognized under the IT Act. All companies registered under technology or providing technology services are governed by the IT Act.

Telemedicine involves a constant exchange of information between the patient and the service provider. The patient's personal information, such as medical history and physiological conditions, is considered sensitive personal data or information ('SPDI' under the Data Protection Rules).¹⁹ When a corporate body collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered.¹⁸

Informed consent is one of the major requirements of the Data Protection Rules. Before a doctor or an institution does anything with a patient's data, they are required by law to obtain the recipient's consent in writing. The patient must be informed about the fact that the data are being collected, what will be their use and whether they would be transferred to any third parties, along with contact details of the agency collecting the information. There is also a requirement for the corporate body to have a privacy policy in place and publish it on its website.¹⁹

If the SPDI is planned to be disclosed to a third party, prior permission of the owner of the SPDI has to be obtained. If the SPDI is being transferred, the body transferring the SPDI must ensure that the receiver of the SPDI has adequate security practices in place (Rule 7 of the Data Protection Rules). This requirement is fulfilled if the body conforms to the international standard IS/ISO/IEC 27001 on 'Information Technology—Security Techniques—Information Security Management System—Requirements' or similar standards that are approved and notified by the Central Government.

There is a requirement to appoint a 'Grievance Officer', whose contact details should be published on the website. Apart from these, there are requirements such as allowing users to opt-out or modify their SPDI, if required.¹⁹

In 2013, the Ministry of Communications and Information Technology, Government of India clarified that corporate bodies that collect, store, process or transfer information out of a contractual obligation were not required to obtain consent from the owner of the SPDI for collecting or disclosing the SPDI.²³ Some electronic services merely facilitate interaction between the patient and the service provider and are not directly involved in the provision of the services. In such cases, the service provider would be considered an intermediary (intermediary under the IT Act is defined) under the Intermediary Guidelines and the IT Act.

Liability in civil negligence

Civil suits could arise out of a breach of contractual obligations between the telemedicine service provider and the patient/user. The Supreme Court of India has explained negligence as 'breach of a duty caused by the omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something, which a prudent and reasonable man would not do'.²⁴ The integral components to prove negligence are establishment of duty and dereliction of duty, which are directly related to the damage caused.

Liability in criminal negligence

Criminal prosecution takes place before the criminal courts for grounds such as the commission of offences under any criminal statute, most notably the Indian Penal Code, 1860 (IPC) where the negligence is 'gross' in nature and proven beyond doubt. The common charges faced by doctors and other providers of such services are causing death by negligence (Section 304-A of the Indian Penal Code [IPC]), endangering life or personal safety of others (Section 336 of the IPC), causing hurt by an act endangering life or personal safety of others (Section 337 of the IPC) and causing grievous hurt by an act endangering the life or personal safety of others (Section 338 of the IPC). Punishment includes imprisonment as well as fine under the relevant sections.²⁵

Vicarious liability

In the provision of eHealth services such as telemedicine where there is an employer–employee relationship, the employer could

be proceeded against due to the principle of vicarious liability if deemed liable for acts and omissions of the employee arising in course of his/her employment. The principle of vicarious liability does not apply to criminal prosecutions.²⁶

Liability under the Consumer Protection Act, 1986

The Consumer Protection Act (CPA) allows consumers to claim compensation from service providers in case there is a deficiency in the service provided. Consumers can file claims for defective products and unfair trade practices. Consumer forums have been set up at the district, state and national levels to hear such matters. The Supreme Court in the case of Indian Medical Association versus V.P. Shantha and others held that medical services would fall within the ambit of the CPA, provided the patient is being charged for the service. One of the essential elements of a claim is the payment for the services, as the CPA excludes services that are rendered free of charge.²⁷

Disciplinary control by the Medical Council of India

A patient is entitled to raise a complaint with the relevant state medical council against a doctor for professional misconduct. If a complaint against a doctor has not been decided by the state medical council within 6 months from the date of receipt of the complaint, the Medical Council of India (MCI) may, on its own or on the request of the patient, ask the state medical council to decide on the complaint or refer the same to the Ethical Committee of the MCI.¹⁶ Consumers who are aggrieved by the decision of the state medical council also have the right to appeal to the MCI within a period of 60 days from the date of the order that was passed by the state medical council.¹⁶

TELEMEDICINE LAWS AND REGULATIONS ELSEWHERE *Singapore*

In 2015, National Telemedicine Guidelines were formulated to ensure the safety of patient and provider and to ensure a holistic approach to provide healthcare services. Individual specialties were encouraged to modify these guidelines according to their specific requirements.²⁸

South Africa

The Health Professions Council of South Africa has issued 'General ethical guidelines for good practice in telemedicine', which states that telemedicine consultation should be given only in those situations where face-to-face consultation is not possible because of a geographical barrier.²⁹

European Union (EU)

Telemedicine is included as a healthcare service under the Treaty on the Functioning of the EU. Different data protection directives and data protection regulations have been instituted by the EU to increase the use of telemedicine. The eHealth Action Plan was adopted in 2004, to support the application of ICTs in the health sector, which was followed by the eHealth Action Plan for 2012–20.⁸

United States of America

Laws related to telemedicine are prevalent in many States. In the State of California, the Telemedicine Development Act of 1996 prohibits face-to-face visit if the service can be provided through telemedicine. The Telehealth Advancement Act, 2012, includes a larger number of telemedicine services and reimbursement processes.³⁰ The Louisiana Telehealth Access Act, in the State of

Louisiana, and Minnesota's Medicaid programme enable patients to reimburse their expenses.³⁰

In Washington DC, there is a provision for reimbursement of services rendered through telemedicine under the Telemedicine Reimbursement Act of 2013.³⁰ The States of California and Louisiana have an 'Informed consent policy' for telemedicine.³⁰

CHALLENGES AND THE FUTURE

There is much hope for the future of telemedicine. With rapid advances in technology, telemedicine will become easier and more widely accepted in coming years. For successful integration of telemedicine with the existing health structure, we need to develop policies and guidelines. The future directions and challenges could be:

1. Institution of a regulatory authority
2. Standardized format of information to patients and consent form with option to opt in/out of telemedicine
3. Mandatory telemedicine courses for all medical students and refresher courses for medical practitioners and technical staff
4. Responsibility for privacy, confidentiality and security of patient information and treatment
5. Accreditation/licensing of doctors using telemedicine
6. Building confidence of both the patient and distant doctor
7. Clear guidelines for teleconsulting insurance
8. Clear guidelines on issues of telemedicine across national borders
9. Standardization of equipment and teleservices with periodic checks and submission to a regulatory authority
10. Equipment liability, maintenance and safety
11. Telemedicine laws for information storage and access
12. Dedicated staff to manage telemedicine services
13. Establishing telemedicine unit at every hospital
14. Proper communication and documentation
15. Maintenance and regular upgrading of the hardware and software

There is an urgent need to clarify medicolegal issues pertaining to the use of telemedicine through legislation so that doctors can use these services without reservation. There is also a need for an open platform for connectivity to use telemedicine, which means that telemedicine facility should be available easily in a secure manner to maintain confidentiality and privacy in the doctor-patient relationship. The use of smartphone-based applications should be developed to avail healthcare services so that a patient can contact a doctor without the need to go for a consultation physically.

CONCLUSION

In India, where access to affordable healthcare service is an issue, telemedicine will provide immense benefit to the public. Telemedicine allows for a new form of doctor-patient interaction, which needs mutual trust and acceptance.

Although WHO has given importance to telemedicine, there is no legislation in India concerning telemedicine and virtual consultation. Hence, it is governed by a combination of the practice of medicine and information technology with their associated rules, regulations or laws. Specific laws governing the practice of 'tele-medicine' are needed to have clarity on legal issues and resolution of technical issues. Regular assessment of quality standards in health-related telecommunication is required.

Conflicts of interest. None declared

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