

REVIEW ARTICLE

Ethical concerns in Telemedicine- An Indian perspective

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Abstract:

Telemedicine is the welcome evolution of health care delivery initiated by phenomenal advances in digital communication technology. Improved access, delivery and reduced health care cost can be considered the gold standard of telemedicine which has come a long way both in terms of quality health care and acceptance at all levels in countries like India. Telemedicine has immense potential and promise and offers innumerable opportunities and is set to revolutionize the traditional health care delivery. However, there are certain issues, concerns and challenges which are usually encountered in the beginning of any innovative approach and are likely to be faced during practice of telemedicine. The important ethical concerns include protection of autonomy of the patient, his right to privacy, confidentiality and non-disclosure of sensitive data, issues of ownership and right to its access, sound doctor patient relationship, establishment of duty of care and its standard and issues revolving around liability of doctors. These issues are of immense importance and need immediate attention and hence, this effort to discuss them within the scope of Telemedicine Practice Guidelines along with existing legal provisions controlling medical profession and practice in India and other relevant guidelines and other binding provisions including laws related to information technology.

Keywords: Telemedicine; Telehealth; Ethics; Telemedicine practice guidelines 2020.

Introduction:

Telemedicine literally means 'Healing from the distance' which implies the use of ICT resources in increasing the accessibility and affordability of health care delivery to the disadvantaged or underserved population living in remote areas. With passage of time, advances in technology have broadened the scope of Telemedicine and has come to be seen as an effective tool in improving the patient outcomes in diverse situations as highlighted in recent pandemic of Covid-19. Although there is no universal definition of telemedicine, WHO group of consultation on Health Telematics, it is the delivery of health care services by all health care professionals using information and communication technologies for the diagnosis, treatment, and prevention of disease and injuries, as well as research and development.¹

Indian Medical Council Regulations of 2020 contains 'Telemedicine Practice Guidelines,' which are designed to facilitate, motivate, and assist doctors and provide a guiding framework for them.² The guidelines adopt the same definition of Telemedicine as that of WHO. As per these guidelines, there is a subtle difference between telemedicine and telehealth as "Telemedicine refers to a clinical service offered by RMP, whereas Telehealth refers to its use of technology for health and

health-related activities, which encompasses Telemedicine."²

Indian perspective: Telemedicine has become more relevant in countries like India where population is around 130 crores with a large population having issues of affordability, rising costs of treatment, deficient and inequitable distribution of health care services, low doctor- patient ratio, rising concentration of specialists and super specialists mostly in urban and to some extent in semi-urban regions and underprivileged population living in remote areas with limited access and availability of convenient and affordable transport etc.

In India, the Indian Space Research Organization (ISRO) took the lead and launched the Telemedicine Pilot Project in 2001, connecting Apollo Hospital in Chennai with its rural hospital in Andhra Pradesh using satellite technology. Today, the activity has picked up speed, and ISRO now has a network of roughly 100 hospitals spread across the country, with 78 rural sites linked to 22 speciality hospitals in major cities.³

The Ministry of Health and Family Welfare and the Department of Information Technology are jointly responsible for telemedicine services in the country, and they have made a number of initiatives. The National Telemedicine Portal was created by the Ministry of Health and Family Welfare's Telemedicine Division with the goal of developing a National Medical College Network (NMCN) to connect medical colleges and implement a National Rural Telemedicine Network for e-Healthcare delivery.⁴ Other significant projects include the government's establishment of the National Digital Health Authority of India, the government's National Rural AYUSH Telemedicine Network, ISRO's Village Resource Centre (VRC), and ICMR's Arogyasree.⁵

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Critical Issues in Practice of Telemedicine: Increased access to quality health care, ease and convenience in getting medical opinions, seeking consultations from specialists and super specialists across geophysical barriers and mitigating their shortage to some extent, cost effective and timely care, desired follow up, and better quality of health care are some of the benefits of using technology in providing health care services.⁶ However, the use of technology also brings with it issues such as a scarcity of funds, equipment failure, electronic and technical glitches, including disruption of connectivity, the need for proper training of manpower, including health care providers, and certain inherent legal and ethical issues that require immediate action. In view of current guidelines restricting the use of Telemedicine in India, the purpose of this study is to focus on ethical difficulties that arise in Telemedicine and approaches to alleviate them.

In response to concerns about a lack of clarity and subsequent ambiguity, the Ministry of Health and Family Welfare of the Government of India issued 'Telemedicine Practice Guidelines-2020,' which were developed in collaboration with the 'National Institution for Transforming India' (NITI Aayog), a premier 'research institute' of the Government of India that provides policy inputs to the Government of India.⁶ These recommendations offer helpful advice on topics such as the doctor-patient relationship, consent, liability, and negligence as well as confidentiality and privacy. They also address evaluation, management, and treatment, as well as prescribing, health education, and counselling services.²

Informed Consent: Consent is a legal and ethical aspect of health care that highlights an individual's essential right to make choices and conscience, which is established in Article 21 of the Constitution.

Consent is considered a contract under Section 13 of the Indian Contract Act, which describes it as when two or more persons agree on the same thing in the same sense (manner). Subsequent parts of the legislation go through to say that agreement should be free and not the consequence of undue pressure, fraud, distortion of facts, or error.

Consent is as crucial in teleconsultation, and the rules specify that informed consent in teleconsultation has the same medico-legal value as consent in face-to-face discussions.⁷ The patient's consent for teleconsultation is a must and can be in the form of either text, email or audio-video message. It may be oral or written depending upon the circumstances, but should always be informed, voluntary and explicit and should be obtained after explaining fully (doctrine of full disclosure) to the patient in simple and understandable language, the nature and scope of communication, costs involved, need for transmission of patient's health data, its privacy and security and related issues concerning confidentiality. The patient is expected to take 'informed decision' and is at liberty to refuse consent or withdraw it at a later stage if he/she desires so.

The consent should be obtained prior to providing consultation in all communications initiated by the practitioner or the caregiver. Implied consent can be considered valid when patient himself/herself initiates telemedicine services.² In case, the

primary teleconsultant desires to obtain and seek senior's or specialist's opinion or advice during consultation or refers the patient to him, a fresh consent shall be required. This view has been earlier endorsed by World Medical Association's Statement on Guiding Principles on the Use of Telemedicine for Health Care, 2009.⁸

Confidentiality, Privacy and Ownership of Data: Article 12 of the Universal Declaration of Human Rights, 1948 and article 17 of the International Covenant on Civil and Political Rights (ICCPR), 1966, both of which India ratified in 1979, recognise the right to privacy as a fundamental human right.⁹ "No person should be deprived of his life or personal liberty," declares Article 21 of the Indian Constitution. But according to procedure established by law" The Supreme Court of India has, in *Puttuswamy v. Union of India* case (2017) held that right to privacy is a fundamental right and is an integral part of right to life and liberty.¹⁰ Information privacy is defined by the International Association of Privacy Professionals as "the right to have some control over how your personal data is produced and utilised."⁹

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) in the United States and the Data Protection Act of 2018 in the United Kingdom are two examples of different legal frameworks for collecting and disclosing health-related data.⁷ In India, third parties are expected to secure and maintain the safety and security of patients' medical histories and other health records under the requirements of the IT Act and Rules. This includes the patient's "sensitive data," such as information on the patient's physical and psychological health, albeit the term "sensitive data" has yet to be defined.⁷ Following the Supreme Court's ruling that the right to privacy is a basic right protected by the Constitution, the Indian government introduced the Personal Data Protection Bill, which was introduced in Parliament in late 2019 and is still under review.

In India, the recent guidelines, although, do not provide specific inputs regarding the issue, the doctors and third parties are expected to make 'reasonable' efforts towards providing protection to and maintenance of privacy of patient's health data, ensuring avoidance of spillage of information or illegal transmission of sensitive data. In other words, according to the laws governing practice of medicine in India, a doctor or a corporate body is legally required to obtain a patient's data only after receiving his informed consent on the one hand, and to maintain its confidentiality and disclosure only with informed consent or in compelling situations on the other, as described by the laws governing medical practice in India.

A related problem is the patient's right to access personal information received with his agreement but produced or maintained by the doctor, as medical records compiled by the doctor are regarded RMP's property in several countries. Although there is no legislation in India, the government gives a "Charter of Patient's Rights," which is inscribed in the Indian Constitution.⁷ The National Human Rights Commission (NHRC) of India has adopted a Convention of Human Rights that includes the right to confidentiality and access to medical data. The Guidelines 3.7.1-3 emphatically state that the principles of medical ethics, confidentiality and privacy including

maintenance and transfer of data, as laid down in IMC Act, relevant sections of I.T. Act, Data protection and privacy laws etc shall be binding and must be upheld and protected. It further clarifies that the doctor may not be held liable in situations where the breach of confidentiality and privacy, provided that the said breach has occurred due to technical error.⁴

Doctor-Patient relationship: A good doctor patient relationship is essential for satisfaction of the patient, proper understanding of his ailment, compliance with doctor's advice and treatment and its outcome.¹¹ Generally speaking, doctor patient relationship is established when the doctor accepts the patient for consultation. The Guidelines provide that RMP can and should use his professional judgement and is free to decide whether to go for tele-consultation or for in person consultation. He is also at liberty to choose which telemedicine platform is best suited in the given situation. Proper communication helps to establish rapport and trust between the two leading to the patient confiding his secrets in the health care professional, in absence of which, in person consultation gets an edge over tele-consultation. The American Medical Association emphatically endorses the importance of trust in doctor patient relationship. It suggests, "The patient-doctor relationship is built on trust, which gives rise to the doctor's ethical responsibility to take on priority the patient's welfare over his or her own self-interest or obligations to others, to use sound medical judgement on the patient's behalf, and to advocate for the patient's rights."¹² Despite the fact that telemedicine changes the setting of face-to-face consultations, the formation of a good doctor-patient connection is just as crucial. The better the communication, the greater the mutual trust, which assures more acceptability and compliance with the doctor's advice and treatment, minimising the likelihood of future claims and counter-accusations.

Standard of Care: The doctor is required to use the same level of care and expertise that any other doctor of his standing would use in identical circumstances. The Guidelines advocate a telemedicine level of care that is comparable to face-to-face consultation. However, tele-consultations have obvious limitations and the guidelines allow doctors to only provide consultation, prescribe a restricted number of drugs, suggest first aid, and advise the RMP to use his or her judgment in determining whether emergency measures or face-to-face consultation are required in appropriate situations. When a tele-consultant believes a face-to-face consultation is required, the Guidelines propose that the patient attend a doctor in person.⁷

The World Medical Association (WMA) statement on telemedicine ethics, as amended by the 69th WMA General Assembly in Iceland in October 2018, suggests that healthcare quality provides focus be put in place and used on a periodic basis to maintain patient safety and security, as well as the best diagnostic and treatment during telemedicine procedures.¹³ It also emphasises that, to the extent possible, telemedicine services must adhere to evidence-based procedures in order to promote patient safety, high-quality care, and beneficial health outcomes.

Summary: Technological advances and innovations bring progress and also new challenges but are here to stay and so is telemedicine. It is not expected to totally replace traditional

practice but it is here to offer cost effective and timely health care services to the underprivileged population across geophysical barriers where patients can be examined, monitored and treated.

In spite of success stories in and outside India, telemedicine brings with it certain concerns and challenges including important ethical issues. The critical ethical issues include maintaining confidentiality and security of patient's health data, liability in cases of noncompliance and misinterpretation of the data and consequences arising out of unauthorized access to confidential information and data ownership. The protection of the right of the patient to autonomy and self determination and importance of his free will and informed consent in accepting telemedicine is another important issue. Mutual faith and trust in the wake of changed contours of doctor-patient relationship is also paramount. All these important issues can be looked into and taken care of in the light of The Guidelines along with existing legal framework governing medical practice, Codes of Ethics and relevant provisions pertaining information technology.

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