

# The Present Scenario, Ethical, Legal Aspects of Telemedicine and Telehealth Services in India

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**Abstract:** Telemedicine is a new health consultation practice where there is the use of information technologies in the diagnosis and treatment of patients when the doctor and patients are separated by long distances. It enables delivering various health services even to the patient in the most remote areas. It is becoming a more convenient and acceptable healthcare practice in India as India has a vast topography with poor transport communication. Just like face-to-face traditional consultation, telemedicine practice is also not devoid of ethical and legal problems. In India, telemedicine practice comes under the combined jurisdiction of the Ministry of Health and Family Welfare and the Department of Information Technology. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 have been amended recently and the guidelines for telemedicine practices are also included.

**Key Words:** —Telemedicine, Telehealth, Information & Technology, e-healthcare, National e-health authority.

## I. INTRODUCTION

The word “Telemedicine” has its origin in two words, the first Greek word “Tele” meaning “Long distance”, and the second Latin word “Medicus or Mederi” meaning “To cure or to heal”. So, in the simplest way, telemedicine may be defined as the practice of delivering health care services to a remote patient by using electronic facilities [1]. According to World Health Organization, telemedicine may be defined as “The delivery of health-care services, where distance is a critical factor, by all health-care professionals using information and communications technologies for the exchange of valid information for the diagnosis, treatment, and prevention of disease and injuries, research and evaluation, and the continuing education of healthcare workers, with the aim of advancing the health of individuals and communities.” Telehealth is the use of electronic information and telecommunications technologies to support long-distance clinical healthcare, patient and professional health-related education and training, public health, and health administration [2].

Telehealth is a broader term where there is the use of technology for health and health-related services including telemedicine. However, both the term may be used interchangeably [3].

India is the largest democratic country in the world with an estimated population of about 1.37 billion according to United Nations data 2020. The major population of doctors is unequally divided, more than 80% of the doctor population is concentrated in the urban areas serving 28% of the total population [4]. Vast geographical area, poor road connectivity, and transport system are major hindrances in the delivery of health care services. The poor economy and low literacy rate amongst the people in these remote villages also magnify the burden. These make India more ideal country for setting telemedicine. In 2001, in an attempt to minimize this burden, the Indian Space Research Organization (ISRO) made a beginning in telemedicine, linking Chennai's Apollo Hospital with the Apollo Rural Hospital at Aragonda village in the Chittoor district of Andhra Pradesh [5]. Now it is developing very fast and it has a very huge prospect in the coming days.

## II. PRESENT SCENARIO AND PROSPECT OF TELEMEDICINE IN INDIA

In India, the venture of telemedicine practice comes under the combined jurisdiction of the Ministry of Health and Family Welfare and the Department of Information Technology. A

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National Telemedicine Portal, based on SATCOM technology, has been set up by the Ministry of Health & Family Welfare, Government of India [6]. The Ministry of Health & Family Welfare (Government of India) has also started various national projects for e-health establishing a National Medical College Network for interlinking medical colleges all over India with the purpose of e-Education and a National Rural Telemedicine Network for e-Healthcare delivery. The National e-health Authority (NeHA), Government of India was proposed to set up as a promotional, regulatory, and standards-setting organization in Health Sector [7]. For safety handling and transmission of medical record data Government of India has established the Electronic Health Records Standard Helpdesk portal<sup>8</sup>. The detailed guideline regarding these e-medical records is governed by Electronic Health Record (EHR) Standards – 2016 issued by the Director (e-health), Ministry of Health & Family Welfare, Government of India [8]. Now many Telemedicine and Telehealth consultation services are available at the state government and private-sector levels. Premier national medical institutions and private sector medical colleges all over India also have taken initiatives with the aim to provide quality health care & services across the country percolating to the remotest villages.

The role of telemedicine has increased remarkably manifold with the outbreak of the Covid 19 pandemic. The Board of Governors which has superseded the Medical Council of India amended the Medical Council Act, 1956, and published the Telemedicine Practice Guidelines as part of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations. This was enacted with effect from 12<sup>th</sup> May 2020 all over India.

The Ministry of Health & Family Welfare, Government of India, has taken up projects like Integrated Disease Surveillance Project, National Cancer Network, National Rural Telemedicine Network, National Medical College Network, and the Digital Medical Library Network [9]. Some successfully established telemedicine services are mammography services at Sri Ganga Ram Hospital, Delhi, oncology services at regional cancer center, Trivandrum, surgical services at Sanjay Gandhi Postgraduate Institute of Medical Sciences, School of Telemedicine, and Biomedical Informatics [10]. Private sectors like Apollo Telemedicine Enterprises, Escorts Heart Institute, Amrita Institute of Medical Sciences, Narayana Hrudayalaya, Asia Heart Foundation, Aravind Eye Care, etc. are also running telemedicine successfully [11].

The Indian Space Research Organization has developed the Village Resource Centre to provide services such as tele-education, telemedicine, online-decision support, interactive farmers' advisory services, tele-fishery, e-governance services, weather services, and water management. About 500 Village Resource Centre have been established across the country. Very recently, during the Covid 19 pandemic, the internet-based mobile app Aarogya Setu was developed by the National Informatics Centre under the Ministry of Electronics and Information Technology [12].

### III. IMPORTANT NATIONAL MEDICAL COUNCIL GUIDELINES [14]

#### 3.1 Who Can Practice

Any registered medical practitioner whose name is enrolled in the State Medical Register or the Indian Medical Register under the IMC Act 1956 can practice telemedicine. All of them will undergo an online course on the practice of telemedicine. All registered medical practitioners intending to provide online consultation need to complete a mandatory online course within 3 years of its notification (To be notified on the NMC website). In the interim period, the principles mentioned in these guidelines need to be followed. Thereafter, undergoing and qualifying for such a course, as prescribed, will be essential prior to the practice of telemedicine. A Registered Medical Practitioner is entitled to provide telemedicine consultation to patients from any part of India.

#### 3.2 Suitability of The Context

It is the duty of the registered medical practitioner to decide whether the case is suitable for telemedicine consultation or not. The doctor must decide the mode and technologies available and their adequacy for making a proper diagnosis before starting any treatment. The RMP shall uphold the same standard of care as in an in-person consultation but within the intrinsic limits of telemedicine. It must be always in the best interest of the patient.

#### 3.3 Proper Identification

An RMP should verify and confirm the patient's identity by name, age, address, email ID, phone number, registered ID, or any other identification as may be deemed to be appropriate. The RMP should ensure that there is a mechanism for a patient to verify the credentials and contact details of the RMP. Telemedicine consultation should not be anonymous: both patient and the RMP need to know each other's identity.

### 3.4 Consent

Patient consent is mandatory for telemedicine consultation. It may be of two types (1) implied consent; and (2) explicit consent. Just like in-person consultation, when a patient initiates online consultation, we may presume that there is implied consent. When a doctor or health care provider initiates the online consultation then explicit patient consent is required. This explicit consent may be recorded in any form of text message, video, audio recording, or even in the form of an e-mail. Thus, obtained consent must be preserved in the patient file for record purposes.

### 3.5 Ethics and Confidentiality

The registered medical practitioner must strictly follow the norms of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. In addition to these regulations, doctors also must observe the relevant provisions of the Information & Technology Act, data protection and privacy laws, or any other applicable laws notified from time to time.

## IV. ETHICS AND LEGAL ASPECTS

Like other traditional health practices, the practice of telemedicine will also lead to many ethical and legal issues. Many problems like the consent of the patient, confidential breach, credentialing of doctors, dereliction of duties, standards of treatment, medical negligence, etc. may arise. The issue may become even more complicated as there are no comprehensive guidelines.

Recently telemedicine has been given legal status in India (10). The National Medical Commission of India has included Telemedicine Practice Guidelines as “Appendix 5” to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002’. This regulation describes various ethical regulations in relation to the practice of telemedicine in India. Further, it also clearly mentions that these guidelines are not applicable to the conduct of invasive procedures or surgeries. It describes various duties and responsibilities of the registered medical practitioners including a tentative list of professional misconduct and penalties for such misconduct.

Some important laws in relation to telemedicine practice are the Drug And Cosmetics Act, 1940 [11], Drugs and Cosmetics Rules, 1945 [11], The Narcotic Drugs and Psychotropic Substances, Act, 1985 [12], The Indian Medical Council Act, 1956 [13], Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002 [Code of Ethics

Regulations, 2002] [14], The Clinical Establishment (Registration and Regulation) Act, 2010<sup>18</sup>, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 [12], the Information Technology (Intermediaries Guidelines) Rules, 2011, Unsolicited Commercial Communications Regulations, 2007 [20], Telecom Commercial Communication Customer Preference Regulations, 2010 (‘TCCP Regulations’)[21].

Just like the traditional face-to-face consultation, telemedicine practices are also liable for civil and criminal negligence suits. The patient party may also claim compensation under the Consumer Protection Act 2019<sup>22</sup>.

If there is professional misconduct, a patient may raise a complaint against the doctor with the concerned State Medical Council. As per the New Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 [14] there are five levels of disciplinary actions.

Level 1: It may be given singly or in conjunction with other levels in the form of advisory, instruction, or warning.

Level 2: This penalty may be awarded even when the role of the doctor in causing direct harm was not conclusively proved but the doctor was found to have breached any of the codes given by NMC. The maximum action is a suspension of the license to practice for up to one month (30 days). Level 3: This penalty may be awarded when the role of the doctor in causing direct harm was conclusively proved and the doctor was found to have breached relevant regulation. This maximum action is a suspension of the license to practice for a maximum period of three months. Holding suspension can be given at this level as per regulations. Level 4: This penalty may be awarded when the role of the doctor in causing direct harm was conclusively proved and the doctor was found to have breached relevant regulations. The maximum action is a suspension of the license to practice for a period ranging from 3 months to 3 years. Level 5: There is a permanent suspension of the license to practice medicine. It is carried out only after a thorough inquiry by an expert committee. This will be taken as a ‘unique case’ and no precedent will need to be cited.

## V. CONCLUSION

As India is advancing very fast in Satellite Technology, there is a bright future prospect for telemedicine in India. This technology is very convenient for handling epidemics and

mass religious gatherings like Kumbh Mela. Though there are some hiccoughs, many healthcare problems can be solved by doctors from remote places.

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