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Telemedicine in India:

A Critical Analysis on the Regulatory, Legal, & Ethical Consideration of Telemedicine

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ABSTRACT

There are many concerns about the legal and ethical aspects of telemedicine. These include the responsibilities and potential responsibilities of medical professionals, the obligation to maintain the confidentiality and confidentiality of patient records, and the legal issues surrounding cross-border consultations. It also describes the refund of telemedicine expenses. Telemedicine enables the transmission of cross-border health information. Crossborder telemedicine services have been introduced, especially in specialized areas such as long-distance radiology, but the jurisdiction and registration issues have not yet been fully resolved. This can be true for many of the legal and ethical aspects of telemedicine in general, but it is also true for healthcare professionals who use telemedicine carefully to minimize the possibility of forensic complications. Telemedicine is the process of transmitting information from one point to another and using electronic signals to provide medical services. Intuition for many people who want medical care today. Telemedicine looks up the internet. Technically, it is possible to access the database from the outside. Information is included so that can verify the protection and confidentiality of your personal data. It's very difficult. Ethical issues arise especially during the data protection phase. Therefore, on the one hand, the planned use of technical means, on the other hand, the risks that may arise. It is ethically valued.

I. Introduction

The Telemedicine can be described as "the use of technology (computers, video, phone, messaging) by a healthcare professional to provide diagnosis and treatment to patients in a remote location." However, due to the Covid 19 pandemic, which calls for the need of quarantine and social distancing, telemedicine had gained momentum in India, especially during the second wave. Even though Telemedicine has become a popular term even in urban areas, it was originally started in 1999 in India, and the government recognized the potential of telemedicine in 2000. In 2001, the ISRO launched the country's first SATCOM-based

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² What is Telemedicine?, Chiron, https://chironhealth.com/telemedicine/what-is-telemedicine/

telemedicine network.³ It connected Chennai's Apollo Hospital with the Apollo Rural Hospital in Aragonda village in Andhra Pradesh's Chittoor district.

The Ministry of Health and Family Welfare (referred to as "MOHFW") in addition to the Department of Information Technology are jointly responsible for telemedicine services within the nation. The Telemedicine Division of the MOHFW, Government of India, has established a National Telemedicine Portal to enforce a greenfield initiative on e-health, including the establishment of a National Medical College Network (NMCN) for interconnecting Medical Colleges across the nation with the aim of e-Education as well as a National Rural Telemedicine Network with the aim of e-Healthcare delivery.⁴

Telemedicine is certainly a useful tool in a country like India with a population of 139 crores. It can provide those who live in rural areas with better healthcare. It is cost effective and saves the time of patients in addition to the doctors. It also helps the doctors widen their reach. With the increase in use of the tool, the medical professionals in addition to the patients need to know what laws and regulations telemedicine is subject to.

II. LEGAL CONSIDERATION OF TELEMEDICINE IN INDIA

Telemedicine is essentially a complex blend of medical practice and information technology which can also be defined as imparting medical consultation via technology. It has been very advantageous to patients in need of urgent access to doctors. Even though it is vital for the advancement of the health and medical arena, telemedicine is regulated in only a few nations throughout the world. Malaysia is among the few countries that has enacted the Telemedicine Act of 1997. The Telemedicine Development Act of 1996, enacted by the state of California, restricts face-to-face visits if the treatment may be offered via telemedicine.⁵

In India, there was no distinct or unique law or regulatory guideline dealing with the practice of telemedicine until the COVID-19 pandemic compelled the government to issue the guidelines to practice telemedicine.

Prior Legislative Framework

Since there was no special law, all existing legislation in India dealing with medicine and information technology would absolutely adhere to Telemedicine. A review of the Guidelines'

³ Dr Sandeep Singh, Telemedicine in India, DocOnline, (Feb. 18, 2020) https://www.doconline.com/forbusiness/blog/telemedicine-india

⁴ Vinoth G. Chellaiyan, et al. Telemedicine in India: Where do we stand?, 8, JFPMC, 1872–1876, (2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6618173/.

⁵Kirit Javali, *Season of Virtuals: Corona provides impetus to Telemedicine Guidelines in India – Legal challenges going forward*, SCC Online (May 20, 2020), https://www.scconline.com/blog/post/2020/05/22/season-of-virtuals-corona-provides-impetus-to-telemedicine-guidelines-in-india-legal-challenges-going-forward/.

many components also reveals that RMPs and Telemedicine must adhere to several laws that pertain to medical practitioners in India.⁶

The laws that are applicable to the medical field in India include: Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945⁷, The Indian Medical Council Act, 1956⁸, The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002⁹, Clinical Establishments (Registration and Regulation) Act, 2010 ('the Clinical Establishments Act'). ¹⁰

The laws that regulate information technology include: Information Technology Act, 2000¹¹, Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011¹² and Information Technology (Intermediaries Guidelines) Rules, 2011.¹³

All these laws collectively regulated the medical practice and the safeguarding of private information of the patients. Only a certified medical practitioner who offers a valid and lawful prescription under the Drugs and Cosmetics Rules, 1945 is permitted to practise medicine in India under such laws. A handwritten prescription with the signature of a qualified medical practitioner is usually provided. A prescription is legal in telemedicine even if it is signed using digital signatures¹⁴ and the electronic documents are acceptable as evidence in a court according to the Evidence Act of 1872 because of the IT (Amendment) Act of 2008.¹⁵

Even though in 2003, the Department of Information Technology of the Ministry of Communications and Information Technology released the Recommended Guidelines and Standards for Telemedicine Practice in India but since these rules were non-binding, as the name implies and all these existing laws were neither comprehensive nor sufficient in addressing RMPs' and patients' concerns during telemedicine consultations, ¹⁶ there felt the need for proper legislation to regulate this advancing field.

The 2018 judgment of Bombay High Court in Deepa Sanjeev Pawaskar v. State of

⁶Aishani Singh, *India: Telemedicine & Law – An Indian Perspective*, mondaq (Jun. 02, 2020), https://www.mondaq.com/india/healthcare/944860/telemedicine-law-an-indian-perspective?login=true.

⁷The Drugs and Cosmetics Act, 1940.

⁸The Indian Medical Council Act,1956.

⁹Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

¹⁰The Clinical Establishments (Registration and Regulation) Act, 2010.

¹¹The Information Technology Act,2000.

¹²Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011.

¹³The Information Technology (Intermediaries guidelines) Rules, 2011.

¹⁴The Information Technology Act, 2000 § 5.

¹⁵Kirit, *supra* note 4.

¹⁶Seema Jhingan, *India: Legal And Regulatory Framework For Digital Health – Telemedicine Practice Guidelines*, mondaq (Apr. 08, 2020), https://www.mondaq.com/india/healthcare/915292/legal-and-regulatory-framework-for-digital-health-telemedicine-practice-guidelines.

*Maharashtra*¹⁷ supported this need for an adequate framework for the legality of telemedicine. In this case, a doctor couple was held liable for criminal negligence since it was ordered that the patient be hospitalized without the presence of doctors, and drugs were given according to telephonic orders. Furthermore, there was no on-site medical practitioner. The patient eventually died as the staff formed a different strategy for a doctor due to which the practitioner was held liable as he took the risk of acting recklessly and without regard for the repercussions.¹⁸

Telemedicine Practice Guidelines

The MOHFW announced the Telemedicine Practice Guidelines¹⁹ ("Guidelines") on March 25, 2020, in a landmark step that would allow Registered Medical Practitioners (RMPs) to deliver treatment via telemedicine. These guidelines were inserted as Appendix 5 of the The Ethics Regulations of 2002²⁰ issued by the Indian Medical Council ("The Ethics Regulations").²¹

The fundamental ideas as well as a practical structure are included in these guidelines. While the fundamental tenets would apply to any future guidelines, the other focuses on the immediate necessity in the light of the COVID-19 pandemic. It was agreed to provide the "Telemedicine Practice Guidelines" a legal foundation. As a result, "The Ethics Regulations" of 2002, have been amended to incorporate Regulation 3.8 headed "Consultation by Telemedicine" in the aforementioned Regulations.

The Medical Council of India's Board of Governors, with the prior approval of the Indian Union Government, also issued new regulations on May 12, 2020, titled Indian Medical Council (Professional Conduct, Etiquette, and Ethics) (Amendment) Regulations, 2020²³ which included both the fundamental principles and the practical structure.²⁴

The key features of these guidelines include that RMPs would be able to provide telemedicine to patients in any area of India while adhering to the same ethical and legal criteria as conventional in-person treatment.²⁵ The RMP and the patient should recognize one another's identities, and the telemedicine practice should not be confidential.²⁶ The principles of Medical

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¹⁷Deepa Sanjeev Pawaskar v. State of Maharashtra, (2018) SCC OnLine Bom 1841.

¹⁸A CRITICAL ANALYSIS OF THE GUIDELINES AND LEGALITIES OF TELEMEDICINE, Indian Review of Advanced Legal Research (Aug. 22, 2021), https://www.iralr.in/post/a-critical-analysis-of-the-guidelines-and-legalities-of-telemedicine.

¹⁹The Medical Council of India, Telemedicine Practice Guidelines, (Issued on March 25, 2020).

²⁰ Supra note 8.

²¹ Seema, *supra* note 15.

²²Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Reg. 3.8.

²³Indian Medical Council (Professional Conduct, Etiquette, and Ethics) (Amendment) Regulations, 2020.

²⁴Kirit, *supra* note 4.

²⁵Supra note 18.

²⁶ *Ibid*.

Ethics, Data Privacy, and Confidentiality are also discussed in the guidelines, which must be followed throughout the procedure.²⁷

However, there are certain legal issues that may emerge during the delivery of telemedicine consultations which are as follows:

• Relationship between RMP and Patients

Patients place their faith in healthcare providers and rely on them when seeking care. The scope of the IT Act, 2000 is rather restricted in the context of the aforementioned telemedicine rules, and it does not directly engage with the practice of medicine using technology. However, some aspects of the aforementioned Act may apply to the use of Telemedicine. The IT Act has made electronic records and digital signatures legal.²⁸ The IT Act has given proper attention to the preservation of electronic records, their ownership, recognition, delivery (time and location), and receipt, and thus its major objective is to offer legal legitimacy to contractual agreements through electronic transactions. A doctor-patient relationship will almost probably develop as a result of the aforementioned factors. Furthermore, the aforesaid electronic record might be utilized to show the relationship in a court of law.

• Misconduct in the Digital Space

When a doctor–patient relationship has been created, it is the doctor's job to offer the level of care and medication that is anticipated of a professional in the given situation.

Any breach of the Telemedicine Act shall be treated as a misconduct case by the RMP in charge. As a result, if the RMP's misbehavior is proven, they may be punished, or their license may be revoked or canceled.

Other liabilities under the law may also arise such as liability in civil negligence, liability in criminal negligence, Liability under the Consumer Protection Act of 1986²⁹ and Vicarious liability.³⁰

III. REGULATORY CONSIDERATIONS IN INDIA

Registration

A Registered Medical Practitioner (RMP) means someone who is listed in the State Medical

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²⁷A CRITICAL STUDY OF THE LEGAL FRAMEWORK OF TELEMEDICINE PRACTICE IN INDIA, TECH & IP LAW POLICY REVIEW (Sep. 14, 2020), https://www.tiplpr.com/post/a-critical-study-of-the-legal-framework-of-telemedicine-practice-in-india.

²⁸The Information Technology Act, 2000 § 4 & 5.

²⁹ The Consumer Protection Act, 1986.

³⁰Aishani, *supra* note 5.

Registry or the Indian Registry of Medicine, as defined by the Scientific Council Rule of 1956. The state medical boards need medical providers to register with them (SMCs). Names are entered into the Indian medical register once the Medical Council of India (MCI) receives state medical documents and verifies them (if necessary). These health professionals are then permitted to practice in India. Nonetheless, several jurisdictions, through their state appropriate medical bodies, permit healthcare professionals to get a license to practice in their respective states. In terms of telemedicine, it's unclear if a medical professional licensed in one state can provide care somewhere else in the country without further authorization. Notwithstanding the premise that the MCI's Ethics Committee had concluded that a medical practitioner doesn't need to register with more than one SMC, no modification to the IMCA had been made to this effect.³¹

Several medical specialties, including radiology, dermatology, anatomy, ophthalmology, and others, are considered to be advanced in their use of ICT tools, while others are still in the initial phases. Guidelines support and encourage collaboration with RMPs/specialists who use information technology to cure, manage, and avoid disease. Teleradiology is the capacity to transport radiographic images from one location to another. Telepathology employs technology to send image-rich pathology findings across remote places for treatment, teaching, and research. Tele-ophthalmology provides people in rural locations with availability of eye doctors, as well as monitoring, diagnosis, and surveillance of ocular conditions.

Phases in telemedicine

The aforementioned steps are followed for telecommunication –

Consultation for the first consult – The patient requests the online consultation, for example, by making a video or audio conversation with an RMP, or by sending a message or email with a medical issue. The RMP agrees to arrange the consultation. The preliminary appointment shows that the patient meets with the RMP for the first session; however, greater than Six months have lapsed since the prior consultation, or the patient previously checked with the RMP for a different health concern.

Identification and consultation of the patient - RMP must authenticate the person's identity to the patient's content by seeking the patient's names, birthdate, address, email, mobile number, or any other suitable identification.³²

³¹ Sunil Nandraj, et al, *Regulation Of Health Care Delivery In India A Landscape Study*, Health Systems Transformation Platform, https://www.hstp.org.in/wp-content/uploads/2021/08/Regulation-of-Health-Care-Delivery-in-India_-A-Landscape-Study_HSTP-2021.pdf.

³² Telemedicine in India The Future of Medical Practice?, Nishith Desai Associates (Oct. 2020)

Evaluation of the patient - The RMP must identify the patient's position quickly based on proper data, as well as if urgent attention is required. The RMP employs its medical skills to assess if urgent treatment is required. If the patient's condition necessitates prompt attention, first aid / immediate treatment advice is provided, as well as referral data if necessary.

Patient evaluation - The RMP may request the patient to submit relevant data regarding complaints, data about any prior treatments related to the same issue if any. The patient is accountable for the accuracy of the information he or she provides to the RMP. If the RMP believes the data provided thus far is inadequate, he or she may request the patient for further information. This data can be sent instantly or afterwards by email/text, depending on the nature of that information. After the extra data has been collected, the consultation can be rescheduled (this may consist of lab radiological testing).

Supervision of the patient - If the ailment could be appropriately controlled by telemedicine, the RMP may use his or her skilled judgment to deliver health education as suitable in the case, guidance on particular medical symptoms, such as recommendation on fresh investigations to be performed prior to the next appointment, or particular medical care by prescribing medications as outlined in List O. Additional drugs (as listed in List A) may be administered if the teleconsultation is being conducted through video.³³

Technique for telecommunication

RMP could use any telemedicine platform suited for conducting virtual patient consultations, including mobile, videoconferencing, Internet, landline phones, messaging platforms including Facebook messenger, Whatsapp, etc., or mobile applications or web digital telemedicine portals, or Data transmitting systems like Skype, e-mail, etc. Telemedicine consultations can be provided using a variety of techniques. Audio, video and message are the three main mediums. All of those approaches have their own set of advantages and shortcomings, as well as situations wherein it may or may not be suitable to make a thorough diagnosis.³⁴

Inside the inherent constraints of telemedicine, RMPs employing it must adhere to the identical ethical and professional rules and expectations that apply to conventional in-person treatment. A web - based program would be established and made accessible by the Governing board inside the MCI's supersession to allow all RMPs who choose to practice telemedicine to

https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Telemedicine-in-India.pdf.

³³ Nathaniel M. Lacktman, Understanding Telehealth https://accessmedicine.mhmedical.com/content.aspx?book id=2217§ionid=187795865.

³⁴ Sakshi Shairwal, *Regulations around telemedicine in India*, Lexology, (Dec 6. 2021) https://www.lexology.com/library/detail.aspx?g=8f247a2f-04e1-4c48-b5cc-5b629350b652.

familiarize themselves with such rules along with the method and restrictions of telemedicine practice. Within 36 months of receiving notice, both licensed health professionals who intend to provide online consultations must finish an obligatory training course. During the interim period, the requirements indicated in such Guidelines should be followed. Then, before telemedicine may be performed, it will be necessary to complete and pass a prescribed curriculum.

Prescribed Norms of telemedicine

Consultation - The RMP should make a decision whether or not to use text, video, or audio as a mode of interaction. The RMP should implement medical discretion when conducting telemedicine consultation and must advocate in-person consultation if it appears that it is required. In most cases, emergency treatment or assessment should be carried out in person, although the RMP could continue through telemedicine diagnostics if it is timely and required in its expert assessment. RMPs have the option to stop prescribing and revert to in-person consultations at any moment, and patients have the same option.

Prescription - The Central Govt may, periodically, provide alerts concerning medical items which may be prescribed by virtual consultation, as well as any limits that may be applicable, in the accompanying classifications: List O: teleconsultation-safe medical medicines, like those used for certain diseases (paracetamol, ORS) List A: Medications which may be provided after the initial video appointment and prescribed to re-fill in the event of a follow-up visit. List B: Drugs that can be recommended for the same health issue to a patient who has a next appointment, supplementary to those administered after the in-person appointment.

Confidentiality - Any data shared by the client is confidential, and the RMP is obligated to exercise reasonable care by using means to maintain the confidence of such knowledge. RMP is obliged to submit all details and keep a complete track of all documentation or materials utilized during the examination and treatment of the patient.

Cost - RMP could charge the appropriate fee, and online consultations will be conducted in the identical manner as traditional consultations. RMP shall provide an invoice for the amount paid against telemedicine consultation.³⁵

IV. ETHICAL CONSIDERATION IN INDIA

The main areas of ethical issues are: Insufficient transfer of clinical information to the other

³⁵ Khyati Basant, *Regulation of telemedicine in India*, iPleaders, (Nov. 6, 2020) https://blog.ipleaders.in/regulation-telemedicine-india/

side, Broken doctor-patient communication, inaccurate and unclear reports, safety electronic personal health information, placement reliability and risks, methods much of the doctor's responsibility during consultation with the patient is how and how it happens if the treating doctor disagrees with the patient's doctor after notifying the patient (Gülhan, Y., 2006, p.138). The use of technology that causes a lack of patient information and grows poses difficulties in autonomy on its own in individual cases, these technological developments may contain inference errors, reducing the notion of trust.

Today, in telemedicine, many people and businesses looking for medical care are looking at internet sites. Provide medical services, share data, Knowledge of internet services. External access is technically possible in a database where information is evaluated while maintaining the confidentiality of the information provided. Protecting information and personal data seems difficult.

It occurs at the stage of privacy protection that is stored for personal data. Catching the patient recordings by unauthorized persons may jeopardize the principles of personal information protection. There is potential for abuse with the patient. For one of the main problem areas of retaining stored personal data that is processed electronically, Health data protection and privacy protection are diverse nationally and internationally. Therefore, Article 12 of the Universal Declaration of Human Rights states this. "No one should arbitrarily interfere with his privacy, family, home or communications. ³⁶It also does not attack his honor and reputation "(Resmi Gazete, 1949) and Article 8 of the statement by Adnan Ataç et al. / Procedia Social and Behavioral Sciences 103 (2013) 116 – 121 119 Published in 1981 and revised in 2005.

Remote Radiology Methods: Patients and doctors are not directly related to the clinic data confusion and feedback while producing this report and becoming more sensitive to doctors. The doctor does not face the patient and cannot know all the details of the patient's story.

You should also avoid relatively accurate diagnoses and, in some cases, carry out additional investigations. This unnecessarily loses work, time, and material (Gürkan, M., 2009). Nevertheless, the time spent and the cost is decreasing through telemedicine, also by leaving the classic methods in the physician patient relationship decreases morale and confidence. By decreasing confidence, the healing process is negatively affected. This leads us to the technological methods that can not be replaced, a well established patient-physician relationship. Another example is the classical system makes it relatively difficult to falsify

³⁶ Physiopedia, Ethical and Professional Considerations with Telehealth, (Nov 2,2012), https://www.physiopedia.com/Ethical_and_Professional_Considerations_with_Telehealth.

radiographs and it can be perceived easily. However, the data generated in a computer still can be changed via the computer, which can be much easier than the conventional method. In addition, the existence of electronic data networks .Internet, data sent over long distances where security gaps may exist, etc. This patient information should be kept confidential as it occurs in the form of unauthorized access.

Foreclosure of data by a third party, or even a proposal to change this data, is not only a legal issue, Ethical issue. In terms of medical ethics, patient secrets may be introduced and we find those violations

The principle of "confidentiality". This fact can be explained with some examples of Real life. According to Glucan; healthcare professionals who may have access to medical information about 4000 HIV (+) patients in two newspapers.

Also, avoid relatively accurate diagnoses and, in some cases, conduct additional investigations. This requires an unnecessary loss of labor, time and material (Gürkan, M., 2009). Leaving the classic methods in the doctor-patient relationship also reduces morale and trust. Lowering trust negatively affects the healing process. This leads us to the fact that technological methods cannot replace a well-established doctor-patient relationship. Another example is in the classic system that makes it relatively difficult to fake on X-rays and can be easily perceived. ³⁷

V. CONCLUSION

Despite its lack of infrastructure facilities, India's quality hospitals employ cutting-edge medical equipment; more crucially, India has a world-class digital infrastructure that enables quick and cost-effective data exchange. As a result, the country is a fertile environment for tele-healthcare providers. Telemedicine is helping to close the healthcare gap in India. With a click of the device, the most respected, well-trained doctors can now treat patients in far-flung, faraway corners of the country. Patients who live far away can receive excellent medical treatment and care because of good digital infrastructure.

There is still a need for specific legislation governing telemedicine or virtual consultations. It is being governed by a combination of medical practice and information technology laws in addition to the practice guidelines issued in the year 2020.

India provides for regulatory considerations for telemedicine as well to ensure proper access which includes registration of medical practitioners and steps that need to be taken and tools for telecommunication. It also consists of the principles of telemedicine which are: the mode of

³⁷ Adnan Ataç et al. / Procedia - Social and Behavioral Sciences 103, 116 – 121 (2013).

consultation would be chosen by the RMP, maintenance of secrecy of the patient by the RMP and charging of appropriate consultation fee.

However, there are certain legal and ethical issues which creates a barrier in the advancement of telemedicine. The requirement of the moment is to meet standards, computer security, and privacy. Informed consent, the doctor–patient relationship, patient rights, misconduct, and confidentiality are all major medicolegal and ethical issues that must be addressed. The digital gap, or unequal access to technology based on numerous geographic and societal variables, is a key impediment to telemedicine development and it needs to be addressed.

Telemedicine's future has a lot of promise. Notwithstanding these obstacles, the expansion of telemedicine since the start of the current COVID-19 pandemic has been spectacular, and it is likely to continue to grow with greater vigor in the future.
