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ABOUT US

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TELEMEDICINE- creating a strong legal structure

Revati Devasthale

ABSTRACT

This article highlights the need for establishing robust regulations to govern the field of Telemedicine, especially during current scenario. Although the Ministry of health and Family welfare has provided with guidelines pertaining to the usage of Telemedicine, there are various other legal challenges that remain to be addressed.

MOTIVATION

What do we mean by Telemedicine/ Cybermedicine? Telemedicine means "**healing from distance"**, caring and aiding patients who are physically not present for examination by means of Telecommunication. There is no precise definition of Telemedicine, however, The World Health Organization (WHO) has adopted a broad description : "The delivery of health care services, where distance is a critical factor, by all health care 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 health care providers, all in the interests of advancing the health of individuals and their communities"[1]. Telemedicine has long been thought as an effective way to provide access to medical services ameliorating the travel restrictions that the patients might face. Essentially, a health care provider can diagnose, treat, prescribe and educate a patient from distance. In response to the coronavirus, either due to patient's inability to travel or hospital's inability to physically treat patients, vast majority of routine and in some cases even more advanced diagnosis and health-care provision has shifted towards Telemedicine.

Easy and comfortable it might sound, the challenges in providing Telemedicine can be humongous --- incorrect diagnosis, excess medication just to name the few. More importantly, there could be legal challenges as well. In this article we will be tackling some of the legal aspects of Telemedicine- Are doctors allowed to treat patients from distance? In case patient is unsatisfied or faces medical consequences, does patient have same legal remedies available to him if he was to be treated physically? The article tries to examine the current legal structure regarding Telemedicine and provides a solution-oriented legal perspective on the same.

HISTORY

Telemedicine was discovered in the early 20th Century. In the early 20th century one of the first published accounts occurring was when electrocardiograph data were transmitted over telephone wires from the physiology laboratory to the clinic about a mile away[2]. In 1950's, a Canadian doctor built upon this technology and developed a Teleradiology System that was used in and around Montreal. Then, in 1959, Doctors at the University of Nebraska used a two-way interactive

[1]As per WHO definition in the report https://www.who.int/goe/publications/goe_telemedicine_2010.pdf
[2] Electrocardiograph data https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2435435/

television to transmit neurological examinations to medical students across its campus. By 1964, they had built a telemedicine link that allowed them to provide health services at Norfolk State Hospital, 112 miles away from campus[3].Telemedicine also was woven into various projects funded and initiated by the U.S. Government for a far wider reach. One such project, called the STARPAHC (Space Technology Applied to Rural Papago Advanced Health Care) which basically enabled the U.S. Government to render medical services to Native Americans on the remote Tohono O'odham Reservation in Arizona, U.S.A by linking the patients in mobile support units in such remote areas with physicians in hospitals in Sells and Phoenix, Arizona, U.S.A. Telemedicine found its role in disaster management as well when NASA first used telemedicine services during the 1985 Mexico City earthquake, and then again in the year 1988, during the Soviet Armenia earthquake, where the estimated casualties were more than 50,000 people with approximately 5,00,000 people who were left homeless[4]. Thus, began the era of international use of Telemedicine. Over many decades, the technology has advanced with the use of smart devices, which are capable of transmitting high quality videos and with everyone using mobile and internet to access information, it is now becoming a convenient tool for delivering prompt medical care. It is now easy to educate people with videos and images transferring information specially images like X-ray, scan, etc to patient and/or specialist doctors.

TELEMEDICINE IN INDIA

India is a large nation with a population of more than 1.38 billion[5] of people and 65.97%[6] of the national population living in the rural areas. The concentration of healthcare services is more focused in the towns and cities which makes it difficult for the people in the rural areas to avail the healthcare services at ease. Nearly 75 per cent of dispensaries, 60 per cent of hospitals and 80 per cent of doctors are located in urban areas, serving only 28 per cent of the Indian populace[7]. India has taken a few steps contributing towards the development of Telemedicine of which Indian Space Research Organization (ISRO) being the first. ISRO made a modest beginning in telemedicine in India with a Telemedicine Pilot Project in 2001, linking Chennai's Apollo Hospital

[3] History of Telemedicine https://evisit.com/resources/what-is-telemedicine/#1
[4] NASA report https://www.nasa.gov/content/a-brief-history-of-nasa-s-contributions-to-telemedicine
[5] Data is from https://en.wikipedia.org/wiki/Demographics_of_India
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[7] Healthcare concentration data https://economictimes.indiatimes.com/industry/healthcare-biotech/80-per-cent-of-indian-doctors-located-in-urban-areas/articleshow/53774521.cms?from=mdr

with the Apollo Rural Hospital at Aragonda village in the Chittoor district of Andhra Pradesh[8]. The initiatives taken by ISRO along with the Department of Information Technology (DIT), Ministry of External Affairs, Ministry of Health and Family Welfare and the state governments have played a vital role in the development of telemedicine services in India. As the ongoing Covid-19 Pandemic demands higher use of the Telemedicine services, India should adopt a concrete model to facilitate in improving the quality, accessibility and consistency of these services.

ACTS GOVERNING TELEMEDICINE IN INDIA

The laws applicable to telemedicine in India are the laws governing the medical profession and information technology. The Indian Medical Council Act, 1956, Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, Drugs and Cosmetic Act, 1940 and other statutes and rules framed thereunder regulate the practice of medicine by doctors. The law provides that any person registered with the State Medical Council or Medical Council of India is eligible to practice as a medical practitioner in India [S.2 clause (h) Indian Medical Council Act,1956][9].

Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 states duties and responsibilities of the Physician towards the patient and in general[10] For covering online services, it is important to jointly interpret and understand the aforementioned statutes and rules and the Information Technology Act, 2002 ("IT Act"). The IT Act contains provisions safeguarding the security and privacy of information exchanged and shared over means recognized under the IT Act. The scope of the Information Technology Act, 2000 is quite limited and it does not specifically deal with the practice of medicine through technology. However, there are certain provisions in the said Act which will certainly have application on Telemedicine. Section 4 & 5 of IT Act has given legal recognition to the electronic record and digital signatures. The IT Act has also amended Indian Evidence Act, 1872 thereby making the electronic record admissible in evidence. Section 2(1)(t) of the IT Act defines "electronic record" as data, record or data generated, image or sound stored, received or sent in an electronic form or microfilm or computer-generated

[8] ISRO initiative http://www.televital.com/downloads/ISRO-Telemedicine-Initiative.pdf
[9] Definition of Registered Medical Practitioner http://legislative.gov.in/sites/default/files/A1956-102_0.pdf
[10] Code of Ethics Regulations, 2002 http://wbconsumers.gov.in/writereaddata/ACT%20&%20RULES/Relevant%20Act%20&%20Rules/Code%20of%20Medical%20Ethics%20Regulations.pdf

micro fiche[11]. These provisions can be used while practicing Telemedicine with regards to the maintenance of medical electronic records and the RMP using digital signature on the prescription.

The Drugs and Cosmetics Rules, 1945, specify the essentials of a valid prescription, which require such prescription to be in writing and be signed by the person giving the prescription, in addition to other details pertaining to the professional information of the person and the drugs being prescribed. These provisions can be used while practicing Telemedicine with regards to the maintenance of medical electronic records, RMP using digital signature on the prescription.

NEED FOR CLARITY IN TELEMEDICINE LAWS AND REGULATIONS

"3.8.1 Consultation through Telemedicine by the Registered Medical Practitioner (RMP) under the Indian Medical Council Act, 1956 shall be permissible in accordance with the Telemedicine Practice Guidelines contained in Appendix 5"[12]. RMP is any person who is enrolled in the State Medical Register or Indian Medical Register under the Indian Medical Council Act, 1956 ("Act")[13] is qualified to practice Telemedicine under the Guidelines.

Although the guidelines were issued by the Board of Governors (BoG) of the Medical Council of India (MCI) in partnership with NITI Aayog dated 25th March 2020[14], they are not enough to suffice the legal complexities arising out of Telemedicine usage such as – determination of jurisdiction across national borders, issues pertaining security and licensure, maintenance of hardware and software containing the medical data, teleconsulting insurance, need to be addressed with more clarity and specially with the ongoing pandemic crisis demanding for the same. It has been held by the Supreme Court in Mr. 'X' v. Hospital 'Z' (1998) 8 SCC 296[15] that in the doctor-patient relationship, the most important aspect is the doctor's duty of maintaining secrecy. A doctor cannot disclose to a person any information regarding his patient which he has gathered in the course of treatment nor can the doctor disclose to anyone else the mode of treatment or the advice given by him to the patient. The doctor-patient relationship, though basically commercial, is professionally, a matter of confidence and, therefore, doctors are morally and ethically bound to

[11] IT Act https://www.indiacode.nic.in/bitstream/123456789/1999/3/A2000-21.pdf
[12] Telemedicine guidelines https://www.indialegallive.com/special-story/analysis-of-telemedicine-guidelines
[13] Indian Medical Council Act,1956 http://legislative.gov.in/sites/default/files/A1956-102_0.pdf
[14] Practice guidelines for Telemedicine India https://www.mohfw.gov.in/pdf/Telemedicine.pdf
[15] Mr. `X' v. Hospital `Z' https://indiankanoon.org/doc/382721/

maintain confidentiality. Hence, privacy and confidentiality regulations with regards to Telemedicine need to be taken into deep consideration.

Prior to 2020, were few concerns regarding the practice of telemedicine which were largely due to lack of guidelines and ambiguity that accordingly existed. In fact, in the matter of Deepa Sanjeev Pawaskar & Anr. Vs the State of Maharashtra[16], the judgement of High Court of Bombay caused panic amongst doctors who offered teleconsultation. In the case, two gynecologists were denied anticipatory bail on the grounds that, prima facie, they were criminally negligent towards their patient who unfortunately died while under their care. The material facts of the case are that the deceased patient had presented herself with a complaint of fever and severe vomiting. She was admitted to the nursing home of the accused doctors by the hospital staff without examination, as the doctors were out of town, one of the doctors started treatment for the patient telephonically, by instructing the on-duty nurse. Unfortunately, the patient died. The Court held that the patient died because, amongst other things, she was prescribed treatment over telephone without appropriate diagnosis, and found such practice to be an act of criminal negligence. The application of the doctors for bail in anticipation of arrest was rejected. However, the doctors were successful in receiving the bail in appeal and were not arrested. The case involved use of telecommunication as a medium of consultation. As there existed no legislation in India which governed the practice of telemedicine consultation, said judgement led to medical bodies repeatedly petitioning Medical Council of India and the government to issue regulations to govern Telemedicine. This judgement was interpreted by some doctors as deeming the practice of telemedicine and teleconsultation itself illegal. However, such an interpretation is without basis and incorrect. The Court was only concerned about the failure of the doctor to diagnose the patient. The fact that the drugs for treatment of patient were communicated by the doctor through telephone is only incidental to the outcome of the judgement. It is not the basis of the judgement. In other words, had the doctor communicated the same drugs to the nurse orally while being physically present but without examining the patient, and then patient would have died, the Court would have come to the same conclusion. Thus, the judgement should not be concluded to state that the practice of telemedicine and teleconsultation itself is illegal. Therefore, the above judgement of Bombay High Court does not interfere with the Telemedicine Guidelines at all. In fact, it supports it. In the process of telemedicine, since the patient is not diagnosed physically, a higher standard of duty of the doctor may be established. On the contrary, it can also be argued that because the doctor has not seen

[16] Deepa Sanjeev Pawaskar & Anr v. State of Maharashtra https://indiankanoon.org/doc/160266477/

the patient, the doctor's duty is not as strong. Moreover, contributory negligence by the patient could be established.

In order to tackle all the above legal complexities arising with the usage of Telemedicine, there is a need to establish a broader legal structure that encompasses all these obstacles.

TELE LAWS AROUND THE WORLD

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[17] The Louisiana Telehealth Access Act, in the State of Louisiana, and Minnesota's Medicaid program enable patients to reimburse their expenses. In Washington DC, there is a provision for reimbursement of services rendered through telemedicine under the Telemedicine Reimbursement Act of 2013. The States of California and Louisiana have an 'Informed consent policy' for telemedicine[18]. Australia's government have vastly expanded its telehealth services to make them available to the whole country[19]. Canada is also allocating resources and changing its billing practices to expand telemedicine as quickly as possible[20]. Telemedicine is set to become a key feature of Singapore's healthcare landscape[21]

[17] Telemedicine regulations in the U.S https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine-laws-and-developments-a-state-by-state-analysis.html

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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 the guidelines provided by the Government of India provide for a basic structure, there is a need to establish more clarity and a robust framework with deals with all the legal issues mentioned above.

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