TELEMEDICINE GUIDELINES
- A REVIEW
Telemedicine i.e. the practice of medicine using remote access technology such as telephone, email, video conferencing, etc., has many advantages and disadvantages. It has the potential to save cost and effort for patients, especially for rural patients. In cases where there is no need for the patient to physically see a medical practitioner e.g. for regular, routine check-ups or continuous monitoring, telemedicine can reduce the burden on the secondary hospitals. Telemedicine makes it easier to maintain records and documentation. Therefore, the likelihood of missing out advice from the doctor is reduced. Conversely, the doctor has an exact document of the advice provided via tele-consultation. Written documentation increases the legal protection of both parties. Telemedicine also ensures the patient’s safety, as well as doctor’s safety in situations where there is risk of contagious infections, such as the current Covid–19 pandemic.

The main disadvantage is that in many situations, it is necessary for the doctor to be physically proximate to the patient before reaching a diagnosis and prescribing any medicine.

The Board of Governors of the Medical Council of India (“MCI”) has issued the Telemedicine Guidelines dated March 25, 2020 (“T Guidelines”) under the Indian Medical Council Act, 1956 in order to enable registered medical practitioners to provide healthcare using telemedicine. The T Guidelines seek to give practical advice to doctors so that doctors and health workers are encouraged to use telemedicine as a part of their normal practice. The T Guideline provide norms and protocols relating to the physician-patient relationship, issues of liability and negligence, evaluation, management and treatment, informed consent, continuity of care, referrals for emergency services, maintenance of medical records, privacy and security of the patient records, fees, etc.

The T Guidelines constitute Appendix 5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulation, 2002.

**Who can practice Telemedicine?**

A Registered Medical Practitioner (“RMP”) is a person enrolled in the State Medical Register or the Indian Medical Register under the Indian Medical Council Act, 1956. The T Guidelines provide that only an RMP is entitled to provide telemedicine consultation to patients from any part of India. RMPs using telemedicine are required to uphold the same professional and ethical norms and standards as applicable to traditional in-person care, within the intrinsic limitations of telemedicine.

**Was Telemedicine Illegal in the First Place?**

The T Guidelines note that in the past, there has been concern regarding the practice of telemedicine. Lack of clear guidelines created significant ambiguity for registered medical professionals whether the practice of telemedicine is permitted. The T Guidelines refer to the case of Deepa Sanjeev Pawaskar vs. The State of Maharashtra Criminal Anticipatory Bail Application No. 513 of 2018 dated July 25, 2018, in which the judgment passed by the Bombay High Court created uncertainty about the place and legitimacy of telemedicine. In this case, two doctors, a husband and wife (“Applicants”) were held liable for criminal negligence resulting in the death of a woman, one Dnyanada. Dnyanada was pregnant and the Applicants had delivered her baby in their hospital. One day after she was discharged, Dnyanada started vomiting and the Applicants prescribed some medicines to the chemist by telephone to be given to Dnyanada. Later that day, Dnyanada was taken to the Applicants’ hospital, however there was no available doctor present. She was told that she did not need to be taken to any other hospital. However, when Dnyanada’s condition worsened, the hospital staff called a doctor to come to the hospital and check the condition of Dnyanada. On seeing the poor condition of Dnyanada, the doctor took Dnyanada to another hospital, but she died shortly thereafter. The cause of death was revealed to be embolism.
The Bombay High Court ("Court") ruled that prescription without diagnosis by the Applicants, which resulted in the death of Dnyanada, amounted to criminal negligence under section 304 of the Indian Penal Code, 1860 and held the Applicants to be guilty of culpable negligence, stating that "the element of criminality is introduced not only by a guilty mind but by the practitioner having run a risk of doing something with recklessness and indifference to the consequences. It should be added that this negligence or rashness is gross in nature." According to the Court, the fact that Dnyanada was directed to be admitted in the absence of doctors, that medicines were administered without enquiring about the nature of symptoms or pain felt by her, the fact that there was no resident medical officer nor any alternative arrangements made, and that the staff had to call a doctor to examine Dnyanada while the Applicants did not bother to ask about the treatment or the condition of Dnyanada, all contributed to gross negligence on part of the Applicants.

**Modes for Practice of Telemedicine**

An RMP may practice telemedicine through telephone, video conferencing, devices connected over LAN, WAN, Internet, mobile or landline phones, chat platforms like WhatsApp, Facebook Messenger, Skype, email, fax, etc. If the RMP requires to hear the patient speak, voice interaction should be preferred over an email or text for the diagnosis. If the RMP needs to visually examine the patient and make a diagnosis, the RMP should recommend a video consultation.

In all cases of emergency, the patient must be advised for an in-person interaction with an RMP at the earliest, other than for first aid, life-saving measures, counselling and referrals. However, in case alternative care is not possible during an emergency, tele-consultation is permitted to provide timely care.

Irrespective of the tool of communication used, the core principles of telemedicine practice shall remain the same as that of traditional medical practice.

**Suitability Assessment**

RMPs should exercise their professional judgment to decide whether a telemedicine consultation is appropriate in a given situation or if an in-person consultation is needed in the interest of the patient. The RMP should be reasonably comfortable that telemedicine is in the patient's interest after taking a holistic view of the given situation. There may be situations where in order to reach a diagnosis and to understand the context better, a real-time consultation may be preferable over an exchange of information using technology. In such situations, in-care consultation should be insisted upon.

**Identity Verification and Consent**

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

The patient's consent is necessary for any telemedicine consultation. Such consent can be implied or explicit. If the patient initiates the telemedicine consultation, then the consent is implied. An explicit patient consent is needed if a health worker, caregiver or another RMP initiates the telemedicine consultation.
**Diagnosis and Prescription**

RMPs must make all efforts to gather sufficient medical information about the patient’s condition before making any professional judgment. An RMP may prescribe medicines *via* telemedicine only when the RMP is satisfied that he/she has gathered adequate and relevant information about the patient’s medical condition and the prescribed medicines are in the best interest of the patient.

The T Guidelines make it clear that prescribing medicines without an appropriate diagnosis/provisional diagnosis will amount to a professional misconduct.

The T Guidelines imposes limitations on the medicines that can be prescribed *via* telemedicine, based on the type and mode of consultation. Medicines in ‘List O’ may be prescribed through any mode of tele-consultation. These are medicines which are used for common conditions and are often available ‘over the counter’, such as paracetamol, ORS solutions, cough lozenges, etc. or medicines that may be deemed necessary during public health emergencies, such as Chloroquine for the control of malaria. Medications in ‘List A’ are those which can be prescribed during the first consult which is conducted through video conferencing or are being re-prescribed for re-fill, in case of follow-up. This would be an inclusive list, containing relatively safe medicines with low potential for abuse. The medicines in ‘List B’ are those which an RMP can prescribe for a patient who is undergoing follow-up consultation in addition to those which have been prescribed during in-person consult for the same medical condition. Medicines listed in ‘Schedule X’ of Drug and Cosmetic Act, 1940 and the corresponding rules or any Narcotic and Psychotropic substance listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985 fall under the ‘Prohibited List’ and cannot be prescribed *via* telemedicine.

The RMP is required to provide a photo or scan, or digital copy of a signed prescription or e-prescription to the patient *via* email or any other method. In case the RMP is transmitting the prescription directly to a pharmacy, he/she must have the patient’s agreement to purchase the medicines dispensed from such pharmacy.

**Ethics and Compliance**

An RMP practising telemedicine is required to fully abide by Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 and with the relevant provisions of the Information Technology Act, 2000 and applicable data privacy laws. However, an RMP will not be held responsible for breach of confidentiality if there is reasonable evidence to show that a patient’s privacy and confidentiality has been compromised by a technology breach or by a person other than the RMP. The RMPs should take a reasonable degree of care when hiring third party services for the practice of telemedicine.

RMPs should not insist on telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation. RMPs should not misuse patient images and data, especially which are private and sensitive in nature (e.g. RMP uploads an explicit picture of a patient on social media etc.). RMPs are also not permitted to solicit patients for telemedicine through any advertisements or inducements.

**Maintenance of Records**

RMPs are required to maintain the following records/documents for the periods prescribed from time to time:-
- Log or record of telemedicine interaction (e.g. phone logs, email records, chat/ text record, video interaction logs etc.);
- Patient records, reports, documents, images, diagnostics, data etc. (digital or non-digital) utilised in the telemedicine consultation.
If a prescription is given to the patient, the RMP is required to maintain a copy of the prescription, as is required for an in-person consultation.

**Fees for Telemedicine Consultation**

Telemedicine consultations should be treated at par with in-person consultations for the purpose of charging fees. An RMP should also give a receipt/invoice for the fee charged by it.

**Guidelines for Technology Platforms enabling Telemedicine**

Technology platforms (mobile apps, websites etc.) providing telemedicine services to consumers are required to ensure that the consumers are consulting with qualified RMPs. Technology Platforms are required to conduct their due diligence before listing any RMP on its online portal. The platform must provide the name, qualification, registration number and contact details of every RMP listed on the platform. In the event any non-compliance is noted, the technology platform is required to report the same to the Board of Governors of the MCI who may take appropriate action.

Technology platforms based on artificial intelligence or machine learning are not allowed to counsel patients or prescribe any medicines to a patient. Only an RMP is entitled to counsel a patient or prescribe medicines to a patient. Artificial Intelligence may be used to assist and support an RMP in patient evaluation, diagnosis or management. However, the final prescription or counselling has to be directly delivered by the RMP.

Technology Platforms must ensure that there is a proper mechanism in place to address any queries or grievances that the end-customer may have.

In case any specific technology platform is found to be in violation of the T Guidelines, the Board of Governors of the MCI may blacklist such technology platform, and no RMP may then use such platform to practice telemedicine.

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