Telemedicine Practice Guidelines

The Telemedicine Practice Guidelines (**Guidelines**) as notified by the Ministry of Health and Family Welfare (**MoHFW**) acknowledges the necessity and the effectiveness of delivery of healthcare by the means of information and communications technology.

The Guidelines have provisioned appropriate preface and purpose of the practice of Telemedicine. Globally accepted definitions for '*telemedicine*', '*telehealth*' have been highlighted therein. The focus continues to be provisioning of healthcare to patients *residing* in India, and specifically excludes extraterritorial application. The requirement for recordkeeping and compliance with law continues to be the focus. In view of the ongoing crisis, these Guidelines have recognized the need to protect and preserve the functioning and efficiency of the healthcare practitioners. While assuming the emerging and necessary role of telemedicine, the purpose outlined also accounts for privacy and security of the patient records as well as the contours of reimbursement schemes.

Scope

1. At the outset the scope has been restricted to the *Registered Medical Practitioners (**RMPs**)* under the Indian Medical Council Act, 1956 only, and lays down the *norms and standards* that must be adhered to by the RMPs for effective consultation with patients via telemedicine.

2. There are no express or implied limitations on the mode / medium of technology. Any and all technology capable of communication by way of *audio, voice, text and digital data exchange, visual* have been scoped in the present Guidelines.

3. **Exclusions.**

a. Specifications for hardware or software, infrastructure building and maintenance;

b. Data management systems involved; standards and interoperability;

c. Use of digital technology to conduct surgical or invasive procedures remotely

d. Other aspects of telehealth such as research and evaluation and continuing education of health-care workers

e. Practice outside India.

4. **Registered Medical Practitioners.** The Guidelines specifically pertain to the persons *who are enrolled on any State Medical Register or the National Register and who possess any of the recognized medical qualifications.*

a. May provide *telemedicine* consultation to patients across state lines;

b. Must uphold *same professional and ethical norms and standards* as applicable to conventional in-person care set-ups;

c. Eligibility

i. Comply with Guidelines;

ii. Complete and qualify online mandatory course within 3 years from the date of March 25, 2020.

Interaction

5. Classification.

a. Mode of Communication.

i. Audio – telephone, VoIP, calling apps, etc.;

ii. Video – telemedicine facilities, Skype, FaceTime, WhatsApp, etc.;

iii. Text based – telemedicine portals, instant messaging platforms; asynchronous (e-mail, fax), etc.

b. Transmission of Information.

i. Synchronous;

ii. Asynchronous – summary of patient complaint, supplementary data, lab reports, radiological investigations between stakeholders. Allows further circulation, ease of access.

c. Purpose of Consultation.

i. Non – emergency consult.

- First time consult - RMP may be contacted for diagnosis/ treatment/ health education/ counseling. If there is a lapse of 6 months since the first in-person consult, or where the in-person consult was for a different health condition, the tele-consult will qualify to be a first-time consult;

- Follow-up consult with *same* RMP who prescribed treatment in an earlier in-person consult, and accounts for a patient who is revisiting via tele-consult within 6 months of the in-person consult. However, if there are new symptoms (beyond the spectrum of the same health condition), or where RMP does not recall the earlier context of treatment, the tele-consult will not be considered to be a follow-up consult.

ii. Emergency consult.

- *Lack of alternate care;*

- RMP may provide consultation to their best professional judgment;

- Limited to first-aid, life-saving measure, counseling and advice on referral;

- Must be advised to refer to an RMP for an in-person interaction.

d. Relationships.

i. Patient – RMP;

ii. Caregiver – RMP;

iii. RMP – RMP;

iv. Health Worker - RMP.

6. **Technology.** The Guidelines have analyzed the strengths and weaknesses of each form / mode of communication and have offered the RMP to evaluate the best mode of communication for a particular fact situation, to be able to deliver proper diagnosis. Video consults have been rightly identified as the closest to an in-person consult, for it allows the parties to establish a rapport, allows the patient to gesticulate, and to establish identities. Separately, while asynchronous interactions come with the default capabilities of creating a documentary trail, and consume less bandwidth as opposed to the other new means of voice and audio/visual interactions, there is a possibility of lag, disruption in continuity of care.

Practice Guidelines.

7. Patient continues to be the focus of these guidelines, and so, the RMP has been burdened with the necessary task of exercising their professional judgment in ascertaining whether a consult via means of telemedicine is sufficient or not. The basic elements for initiating a telemedicine consult are: (i) context; (ii) identification of RMP and patient; (iii) mode of communication; (iv) consent; (v) type of consultation; (vi) patient evaluation; and, (vii) patient management.

8. **Context.** RMP must consider the situation and the circumstances under which the patient has initiated the consult with the RMP, prior to proceeding with the tele-consult. This becomes more relevant in matters of emergency. Issues like the physical condition, state of the patient as may be perceived from the tele-consult must also be accounted for. For instance, a patient who is inebriated may not be in a position to communicate, or follow the advice, *this must be factored in by the RMP.* Depending on the context, the appropriate mode of communication may be adopted.

9. **Identification.** To ensure that a relationship is established between the treating RMP and the patient, both the patient and the RMP must introduce each other, and necessary demographic information must be exchanged for an effective tele-consult. The RMP may seek additional proof of age, as may be required in certain circumstances, including instances where minors are patients.[1] As required in the brick and mortal model, the registration details of the RMP must be highlighted in all forms and modes of correspondence with the patient/caregiver, including prescriptions, instant messages, e-mail signatures, invoices, likewise.

10. **Patient Consent.** Consent has been allowed in the forms of *implied* as well as *explicit*.[2] Any interaction initiated at the option of the patient, is said to have implied consent baked into it. However, explicit consent is sought when the consult is initiated by the RMP, Health Worker, or a Caregiver. The Guidelines mandates the RMP to record such consent in the records. It is advised to ensure consent is captured in a format, which enables a valid audit trail to be created and maintained.

[1] A minor must always be accompanied by a guardian, an adult whose identity, relationship must be ascertained.
[2] This does not account for informed consent; this will have to be revisited in terms of the Personal Data Protection Bill, 2019, when the legislation is in place.

11. **Patient Evaluation.** Deferring to the professional judgment of the RMP, the Guidelines expect the RMP to seek *sufficient* medical information about the patient's condition during a tele-consult. At the discretion of the RMP, further information may be sought from the patient, or the patient may be recommended to switch to video consultation, be physically examined by another RMP/ health worker, or, may be advised to proceed for in-personal consultation as necessary. All records must be available and maintained by the RMP appropriately.

12. **Patient Management.** Upon *satisfaction* of the foregoing, the RMP may proceed with provisioning of health education, counseling or prescribing medicines. It is imperative that the RMP exhausts all avenues of diagnosis, provisional diagnosis prior to prescription of medication over a tele-consult. The Guidelines emphatically state that any prescription generated *without an appropriate diagnosis/ provisional diagnosis will amount to a professional misconduct.*

13. **Restrictions.** While the Guidelines focus and warrant the practice of telemedicine, they have also been released during a period socio-economic crisis, a pandemic, and amidst general chaos. Keeping in view of the same, restrictions have been imposed on the prescription, dispensation of medicines that may be secured from *mere* tele-consults.

    a. **List O.** Medicines which are used for *common conditions*, and are often available '*over the counter*'. *Interestingly, the list also allows for medicines that maybe deemed necessary during public health emergencies.*

    b. **List A.** The scope is restricted to a video tele-consult (first time consult) **and** are being re-prescribed, or is a re-fill, in case of follow up. An indicative list, with low potential of abuse is included.

    c. **List B.** RMP may prescribe medicines from this list via tele-consult, in follow-up consults only.

    d. **Prohibited List.** An RMP cannot prescribe medicines which have a high potential for abuse and could cause harm to the society or public at large when dispensed improperly.

    e. Annexure I of the Guidelines provide for these.

14. **Prescription.** There is a template format provided, and the model is based on the explicit consent of the patient. The standard expected is in lines with the brick and mortar model and does not really go away from what may be expected under the e-pharmacy model. RMP must provide the patient with a copy (physical equivalent) of the prescription in the desirable manner.

Duties and Responsibilities of RMP.

15. **Ethics and privacy.** In addition to the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, the extant data privacy and protection laws will prevail in the context of practice of telemedicine.

16. It is imperative that the RMP ensure that the patient's records, including conversations and correspondence are preserved in a confidential, secure and technologically convenient manner. An RMP is expected to practice caution when onboarding software/ hardware services which enable the tele-consults at their end.

17. Violation of privacy laws, unauthorized usage of personal / sensitive personal information of the patients will amount to misconduct and attract penal provisions as prescribed under the Information Technology Act, 2000, and allied rules thereunder. Violation of the practice guidelines outlined herein will amount to misconduct.

18. In view of the awareness around privacy, and the right to privacy becoming an integral part of the fundamental rights of an individual, to comply with the principles of informational privacy, the Guidelines have made it incumbent on the RMP to ensure records of entire transactions of telemedicine practice are preserved and are retained for as long as necessary.

Platform Owners.

19. With the Guidelines facilitating the practice of telemedicine, the platform owners have become assimilated into the ecosystem and the legal framework. Sweeping them under the scope of this Guidelines, the expectation is for these Platforms to ensure that the consumers of the Platform are consulting with *RMPs* only.

20. It is incumbent on the Platform to make the registration details of the RMP to be made available to the consumers of the Platform, and flowing from the present discussion, it is also incumbent on them to process and secure consent of the consumers appropriately.

21. The Platforms have been afforded the option to report anomalies, irregularities, which may be presumed to be pertaining to the conduct of the RMP, to the Board of Governors.

22. Automated decision making should not be employed by the Platforms for the purpose of generating prescriptions, there is specific requirement for counseling and intervention to flow from the RMP on the Platform, and an RMP must directly be allowed to communicate with the patient.

23. Escalation on the Platform is in-line with the extant data privacy laws, and requirement for a grievance officer has been retained.

24. Keeping in mind the levels of social awareness, and the large population of the country, the Guidelines have retained the power to blacklist a Platform, who operate in violation of these present Guidelines. RMPs will accordingly be desisted from utilizing, exploiting such blacklisted Platforms.

This is only a general overview of the guidelines and may not be treated as legal advice. Please reach out to us separately for specific queries.

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