Guideline-11

NATIONAL MEDICAL COMMISSION

# Guidelines for Practice of Telemedicine in India

Enabling Registered Medical Practitioners to Provide Healthcare Using Telemedicine

2022

## TABLE OF CONTENTS

S. No.	Description	Page No.
	Background	7
1	Definitions	11
•	Definitions of Telemedicine	
	Definition of Telehealth	
	<ul> <li>Definition of a Registered Medical Practitioner</li> </ul>	
	Scope of Telemedicine	
	RMP's are entitled to Practice	
	TelemedicineApplications of Telemedicine	
	Mode of Communication	
	Timing of Information Transmitted	
	Purpose of the consultation	
	Individuals involved	
2	Technology Used/ Modes of Communications	15
•	Video, Audio, Text	
3	Guidelines for Telemedicine in India	16
•	Elements specific to Telemedicine	
	Appropriateness of	
	Telemedicine as per context	
	<ul> <li>Identification of RMP and the</li> </ul>	
	patient	
	Mode of Telemedicine	
	communication/Appropriatene	
	ss of technology	
	Informed Consent	
	Type of consultation	
	Patient Evaluation	
	Patient Management: Health	
	education, counseling and	
	medication	
	Duties and responsibilities of RMP in general	
	Ethical issues in Telemedicine	
	<ul> <li>Medical Ethics, Data Privacy &amp; Confidentiality</li> </ul>	
	Documentation and Digital	
	Records of Consultation	
	Fee for Telemedicine	

4	Framework for Telemedicine	27
	Patient and RMP	
	Care Giver and RMP	
	<ul> <li>Patient and RMP through Health Worker at a Sub Center or peripheral center</li> </ul>	
	RMP and another RMP / Specialist	
	Telemedicine Triage and COVID Care for Patients	
5.	Guidelines for Technology Platforms enabling Telemedicine	36
6	Special Responsibilities of NMC	37
7	Figures (Teleconsultation flow charts 1-3)	38
8	Annexures	43
	1. Drug Lists	
	2. Sample Prescription Format	
	3. Sample Patient Information Sheet	
	4. Sample Informed Consent format	

## (1) Telemedicine: Definitions and Applications

#### 1.1 **DEFINITIONS**

#### i. Definition of Telemedicine

#### World Health Organization defines telemedicine 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 health-care workers, with the aim of advancing the health of individuals and communities."

#### ii. Definition of Telehealth

NEJM Catalyst defines telehealth as "The delivery and facilitation of health and health-related services including medical care, provider and patient education, health information services, and self- care via telecommunications and digital communication technologies."

In general, telemedicine is used to denote clinical service delivered by a Registered medical practitioner, while telehealth is a broader term of use of technology for health and health-related services, including telemedicine.

#### 1.2 SCOPE

- These guidelines are designed to serve as an aid and tool to enable RMPs to offer access to medical and health services to patients in remote locations and vulnerable populations. The guidelines cover norms and standards of the RMP to consult patients via telemedicine
- Telemedicine includes all communication channels with the patient that leverage Information Technology platforms, including Voice, Audio, Text & Digital Data exchange.

These guidelines should be used in conjunction with the other national laws, rules, regulations, clinical standards, protocols, policies and procedures.

#### **EXCLUSIONS:**

The guidelines **exclude** the following:

- Specifications for hardware or software, infrastructure building & maintenance.
- Data management systems involved; standards and interoperability.
- Use of digital technology to conduct surgical or invasive procedures remotely.
- Other aspects of telehealth such as research and evaluation and continuing education of health- care workers.
- RMPS outside the jurisdiction of India. REGISTERED MEDICAL PRACTITIONERS ARE

#### ENTITLED TO PRACTICE TELEMEDICINE

- i. A Registered Medical Practitioner (RMP) is eligible to provide telemedicine consultation to patients from any part of India. In case of any complaints of misconduct, the complaint will be lodged in the State Medical Council of the State, where the RMP is located at the time of providing teleconsultation.
- ii. RMPs using telemedicine shall uphold the *same professional and ethical norms and standards* as are applicable in routine in-person consultations within the intrinsic limitations of telemedicine.
- iii. All RMPs who wish to practice telemedicine should be made familiar with these Guidelines as well as with the processes and limitations of telemedicine practice. They need to undergo CPD training in telemedicine practice as per the ethics guidelines of NMC 2022:

#### 1.4 TELEMEDICINE APPLICATIONS

#### i. Tools for Telemedicine

RMPs may use any telemedicine tool suitable for carrying out technology-based consultations with patients / caregivers or colleagues.

For example: Telephone, Video, devices connected over LAN, WAN, Internet, Mobile or Landline phones, Chat Platforms like WhatsApp, Facebook Messenger etc., or Mobile Apps or Internet based digital platforms for telemedicine or data transmission systems like Skype/ email/ fax etc.

Irrespective of the tool of communication used, the core principles of telemedicine practice remain the same.

Telemedicine applications can be classified into *four basic types*, according to 1) *mode of communication*, 2) *timing of the information transmitted*, 3) *the purpose of the consultation* and 4) *the interaction between the individuals involved* – be it RMP to patient/caregiver, or RMP to RMP.

#### 2.1. According to the Mode of Communication

- 1) Video (Telemedicine facility, Apps, Video on chat platforms, Skype/Face time etc.)
- 2) Audio (Phone, VOIP, Apps etc.)
- 3) Text Based:
  - Telemedicine chat-based applications (specialized telemedicine smartphone Apps, Websites, other internet-based systems etc.)
  - General messaging/text/chat platforms (WhatsApp, Google Hangouts, Facebook Messenger etc.)
  - Asynchronous (email/ Fax etc.)

#### 2.2. According to timing of information transmitted

Real time Video/audio/text interaction	Asynchronous exchange of relevant information
Video/audio/text for exchange of relevant information for diagnosis, medication and health education and counseling	Transmission of summary of patient complaints and supplementary data including images, lab reports and/or radiological investigations between stakeholders. Such data can be forwarded to different parties at any point of time and thereafter accessed per convenience/need

## 2.3. According to the purpose of the consultation

	First consult with any RMP *	Follow-up consult with the same RMP
di fo * f	atients may consult with an RMP for agnosis and treatment of their condition or or health education and counseling for diagnosis/treatment/health education/ ounseling	Patients may use this service for follow up consultation on their ongoing treatment with the same RMP who prescribed the treatment in an earlier in-person consult or an earlier tele-consult.

#### *Emergency consult* for immediate assistance or first aid etc.

- In case alternative in-person care is not available, tele-consultation might be the only option for timely care. In such situations, RMPs should provide consultation to the best of their judgement. Telemedicine services should, however, be avoided for emergency care when alternative inperson care is available, and telemedicine consultation should be limited to first-aid, life-saving measures, counselling and advice on referral.
- 2) In all cases of emergency, the patient should be advised to seek an appointment for in-person care with an RMP at the earliest possible.

#### 2.4. According to the individuals involved

#### Patient to RMP

Telemedicine services may connect patients to an RMP

#### Caregiver to RMP

Telemedicine services may connect Care givers to an RMP, under certain conditions as detailed in Framework (Section 4)

#### RMP to RMP

An RMP may use telemedicine services to discuss issues of care of one or more patients with other RMPs (specialist), or even for the purpose of dissemination of information or to share knowledge.

#### Health worker to RMP

A Health Worker<sup>1</sup> can facilitate a consultation for a patient with an RMP. In doing so, the former can help in taking history, examining the patient and convey the findings. They can also explain/reinforce the advice given by the RMP to the patient.

<sup>&</sup>lt;sup>1</sup> Nurse, Allied Health Professional, Mid-level health provider, ANM or any other health worker designated by anappropriate authority

## (2) Technology Used & Mode of Communications

Multiple technologies may be employed for telemedicine consultation. There are 3 primary modes of doing so: 1) **Video**, 2) **Audio**, and 3) **Text** (chat, messaging, email, fax etc.) Each one of these have their respective strengths, weaknesses and contexts, in which they may either be appropriate or inadequate to deliver a proper diagnosis.

It is therefore important to understand the strengths, benefits as well as limitations of different technologies. Broadly, though telemedicine consultations offer safety to the RMP from contagious conditions, however, they cannot replace physical examination that may require palpation, percussion or auscultation. Newer technologies may provide solutions to overcome this drawback.

Mode	Strengths	Limitations
VIDEO: Telemedicine facility, Apps, Video on chat platforms, Facetime etc.	<ol> <li>Closest to an in person-consult, real time interaction</li> <li>Patient identification is easier</li> <li>RMP can see the patient and discuss with the caregiver</li> <li>Visual cues can be perceived</li> <li>Inspection of patient can</li> </ol>	<ol> <li>Is dependent on high quality internet connection at both ends, else will lead to a sub optimal exchange of information</li> <li>Since there is a possibility of abuse/ misuse, ensuring privacy of patients in video consults is extremely important</li> </ol>
<b>AUDIO:</b> Phone, VOIP, Apps etc.	<ol> <li>Convenient and fast</li> <li>Unlimited reach</li> <li>Suitable for urgent cases</li> <li>No separate infrastructure required</li> <li>Privacy ensured</li> <li>Real-time interaction.</li> </ol>	<ol> <li>Non-verbal cues may be missed</li> <li>Not suitable for conditions that require visual inspection (skin, eye or tongue examination), or for physical touch</li> <li>Patient identification needs to be clearer, higher chances of impersonation</li> </ol>
TEXT BASED: Specialized Chat based telemedicine Smartphone Apps, SMS,Websites, Messaging systems e.g. WhatsApp, Google hangout, FB Messenger	<ol> <li>Convenient and quick</li> <li>Documentation and Identification may be an integral feature of the platform</li> <li>Suitable for urgent cases, or follow-ups, second opinionsprovided RMP has enough context from other sources,</li> <li>No separate infrastructure required</li> <li>Can be real time</li> </ol>	<ol> <li>Besides visual examination and physical touch, text-based interactions also tend to miss the verbal cues</li> <li>Difficult to establish rapport with the patient.</li> <li>Both, the RMP and the patient cannot establish each other's identities with surety.</li> </ol>

#### STRENGTHS AND LIMITATIONS OF VARIOUS MODES OF COMMUNICATION

<b>ASYNCHRONOUS:</b> Email, Fax, recordings etc.	<ol> <li>Convenient and easy to document</li> <li>No specific app or download requirement</li> <li>Images, data, reports readilyshared</li> <li>No separate infrastructure required</li> <li>More useful when accompanied with test reports and follow upand second opinions</li> </ol>	1. 2. 3. 4.	Not a real time interaction, so just one- way context is available, relying solely on the articulation by the patient Patient identification is document based only and difficult to confirm Non-verbal cues are missed There may be delays because the Doctor may not see the mail immediately
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## (3) Guidelines for Telemedicine in India

A. ELEMENTS SPECIFIC TO TELEMEDICINE

The professional judgment of a Registered Medical Practitioner (RMP) should be the guiding principle for all telemedicine consultations:

An RMP is well-positioned to decide whether a technology-based consultation is sufficient or an in-person review is needed. The practitioner shall exercise proper discretion and not compromise on the quality of care.

Seven essential elements listed in the panel below need to be considered by the RMPs before beginning any telemedicine consultation.

7 ł	Key Elements of Telemedicine Consultations
1	Context
2	Identification of RMP and Patient
3	Mode of Communication
4	Consent
5	Type of Consultation
6	Patient Evaluation
7	Patient Management

#### 3.1 CONTEXT - TELEMEDICINE SHOULD BE APPROPRIATE AND SUFFICIENT

- 1. The RMPs should exercise professional judgment to ascertain whether a telemedicine consultation would be appropriate in a given situation or would an in-person consultation be a better option keeping the patient's best interest in mind.
- 2. RMPs should consider the mode of communication and technologies available based on their strength and limitations to ascertain adequacy for a proper working diagnosis before proceeding with any sort of intervention health education, and/or counseling and/or medication.

#### 3. The Complexity of Patient's health condition

No two patients/cases/medical conditions are the same. Two patients with similar symptoms may have very different presentations and findings on the one hand, while on the other a new patient might present with a complaint of a headache and a known diabetic during a follow-up may present

with an emergency such as Diabetic Ketoacidosis. The RMP should uphold the standard of care as s/he does for in-person consultations within the inherent limitations of telemedicine.

#### 4. The Complexity of Patient's location and connectivity

The RMP should also be aware that the choice of mode of communication may at times be dependent on the quality of the patient's connection (phone, internet etc.) in case the patient resides is in a remote location with below-par connectivity.

#### IDENTIFICATION OF THE RMP AND THE PATIENT IS MANDATORY

- **1.1.** Telemedicine consultation should not be anonymous: the patient and the RMP should know and establish each other's identities.
- **1.2.** The teleconsultation should be carried out by the RMP in a language that the patient is comfortable in comprehending for an effective consultation.
- **1.3.** RMPs should begin the consultation by introducing themselves to the patient with details of their name, qualifications (modern medicine or other systems of medicine duly enrolled in the State Medical Register/Indian Medical Register under the IMC Act 1956), area of specialty if any, and their location along with affiliation to a hospital or institution if applicable.
- **1.4.** For specialty consultations, the RMPs/specialists may choose to disclose their specialty qualifications (MD/MS and/or DM/MCh/other equivalent recognized qualifications.
- **1.5.** The RMP should verify and confirm the patient's identity by name, age, address, email ID, phone number, registered ID (Aadhar/Voter ID) or any other identification as may be deemed to be appropriate and document the same for the purpose of records. The RMP should then ensure that there is a mechanism for the patient to verify the credentials and contact details of the RMP.
- **1.6.** For issuing a prescription, the RMP should explicitly ask the age of the patient, and if there is any doubt, seek proof of age. In cases where the patient is a minor, after confirming the patient's age, tele consultation should proceed only if the minor is accompanied by an adult (preferably a parent or adult sibling or legally appointed guardian) during the entire duration of the consultation. The identity of the adult should be ascertained and documented for records.
- **1.7.** Every RMP shall display the registration number accorded to her/him by the State Medical Council or NMC, on all prescriptions, their website, electronic communications (WhatsApp/ email etc.) and receipts etc. given to her/his patients.

#### 3.3 MODE OF COMMUNICATION

- 1. Multiple technologies can be used for telemedicine consultations. They all have strengths, weaknesses and contexts in which they may be appropriate or inadequate to deliver proper care.
- 2. Primarily there are three modes: 1) Video, 2) Audio, and 3) Text. The RMP should consider their strengths, limitations, and appropriateness as detailed in Section 2 before utilizing them for a consultation. Invariably, the combination of the above mode occurs to complete a telemedicine consultation.

3. There might be situations in which, in order to arrive at a diagnosis and to better understand the context, a real-time consultation is preferable over an asynchronous exchange of information. Similarly, there might be instances when the RMP wishes to hear the patient speak, and hence a voice interaction may be preferred over an email or text for a diagnosis. Also, in some circumstances, the RMP might want to visually examine the patient to clinch a diagnosis. In such a case, the RMP could recommend a video consultation. Considering the situation, by using their best judgment, RMPs should decide on the best technology to be employed to arrive at a diagnosis and treat the patient.

#### 3.4 PATIENT CONSENT – MANDATORY REQUIREMENT

- 1. Obtaining and duly recording the Patient's consent is mandatory for any telemedicine consultation. The RMP must ascertain whether the patient is competent to give consent for it to be considered valid. Also, the RMPs should ensure that consent is obtained in a language that the patients can comprehend with ease.
- 2. Consent may be **implied** or **explicit**, depending on who has initiated the telemedicine consultation:
  - If, the patient has initiated or solicited the telemedicine consultation, then the consent is **implied** as is the case with in-person consultations, wherein it is assumed that the patients has consented for a consultation by the very act of reaching the hospital or RMPs clinic, willingly soliciting a consultation.
  - If the RMP, healthcare worker or a caregiver initiates the consultation, then the consent is **explicit** and hence, mandatory. These instances are likely to be very few, but in these circumstances, the RMP should obtain consent from the patient (verbal or written) and document it for records.
- 3. Explicit consent must be recorded in any form. Electronic media can be used to provide information as in the written in-person informed consent process. Consent can be administered and documented using electronic formats such as text, graphics, audio, video, podcasts or interactive websites to explain information related to a study and to document informed assent/consent from a participant or Legally Appointed Representative. The RMP must retain this in his patient records.
  - The RMP should obtain the Patient's Signature or Thumb impression and Date of Signing on the Informed Consent document either as a scanned document through email or as an image over the smartphone in cases where written consent is required, or record the same by having the patient read it aloud in a language they understand and give consent for the consultation. In case the patient is illiterate or is not competent to give consent, the RMP may request the patient to have an independent adult explain the same and affix a Thumb impression and emailed as mentioned above or read it out aloud to the patient and the same may be recorded as an audio-visual file wherein the patient says that the same has been fully understood.
  - In case of minors (less than 18years), consent has to be obtained from a parent or from an adult sibling or legally appointed guardian.

#### 3.5 TYPES OF CONSULTATION: FIRST CONSULTATION/ FOLLOW-UP CONSULTATION

#### There are two types of patient consultations, namely, **first consultation** and the **follow-up consultation**.

An RMP may not have a very comprehensive idea about the patient seeking audio or text consultation for the first time, if there have been no prior in-person consultations. If the first consultation happens to be via videoconferencing, the RMP can make a much better judgment and hence may be in a position to provide much better advice including additional medication, health education or counseling if indicated.

On the other hand, if a patient has been seen in-person earlier by the same RMP, then it is possible to have a more comprehensive picture of the patient's condition, which helps managing the patient more effectively.

#### 1. First Consultation

- This is when the patient is consulting with the RMP for the very first time; (or)
- The patient has consulted with the same RMP earlier, but more than 6 months have lapsed since the previous consultation; (or)
- The patient has consulted with the RMP earlier, but for a different health condition.

#### 2. Follow-Up Consultation

- This happens when the patient is consulting the same RMP within 6 months of their previous in-person consultation for continuation of care for the same health condition for which the previous consultation was sought (or) for a pre-specified longer duration up to no longer than 1 year in cases where the RMP has advised the patient to fix up an appointment for review after a period between 6 to 12 months. For e.g. the RMP advises a patient with hypothyroidism for a review after 1 year, to revise the dose of medication based on TSH levels.
- If a patient is not able to obtain an appointment with the same RMP for a follow-up consultation owing to operational reasons of the digital platform being used, consultation with another RMP will be considered as a follow-up consultation ONLY if the second RMP is comfortable in comprehending the patient's medical condition after having been provided with adequate information (details of the condition and reports of all relevant investigations) by the patient.

This will, however, not be considered as a follow-up consultation if:

- There are new symptoms that are not in the spectrum of the same health condition; and /or
- The RMP does not remember the details and context of the previous in-person consultation as well as the advice and treatment provided.

#### 3.6 PATIENT EVALUATION - EXCHANGE OF INFORMATION

RMPs must make all efforts to gather sufficient medical information about the patient's condition before making any professional judgment.

#### 1. Patient's Information

- RMPs should use their professional discretion to gather the **type and extent of patient information** (history/examination findings/Investigation reports/past records etc.) required to be able to exercise proper clinical judgement.
- This information may be **supplemented** through conversation with a healthcare worker/ provider' or by any information supported by **technology-based tools**.
- If the RMPs feel that the information received is inadequate, they can request for additional information from the patient. This may be shared in real-time or later via email/text, depending on the nature of the information. For e.g., the RMP may require laboratory and/or radiological investigations. In such cases, the session may be considered as suspended to be resumed at a later predetermined time. RMPs should provide health education as deemed appropriate at any time.
- Telemedicine has its own set of limitations as far as adequacy of examination is

considered. If the information desired from a physical examination is critical for the management of the patient, the RMP should not proceed with the consultation till such time that a physical examination can be arranged through an in-person consultation. Whenever deemed necessary, depending on professional judgement of the RMP, they shall recommend:

- Video consultation
- Examination by another RMP/ Health Worker;
- In-person consultation
- The nature and/or amount of information required from the patient may vary from one RMP to another based on their professional competence, experience and discretion, and may also vary for different medical conditions based on defined clinical standards and standard treatment guidelines.
- RMPs shall maintain all patient records including case history, investigation reports, images, etc. meticulously and ensure their safety at least for a period of three years from the day of last consultation.

#### 3.7 PATIENT MANAGEMENT: HEALTH EDUCATION, COUNSELING & MEDICATION

- 1. If the patient's condition can effectively and appropriately be managed via telemedicine, following a successful consultation, the RMP may proceed with a professional judgement in order to:
  - Provide Health Education as appropriate in the case; and/or
  - Provide **Counseling** related to the specific clinical condition; and/or
  - Prescribe **Medicines** as per standard of care or standard practice
- 2. Health Education: RMPs may impart education related to health promotion and prevention if diseases. These could be in relation to lifestyle diet, physical activity, cessation of smoking, cutting down on or stopping consumption of alcohol or about precautions to follow and other measures to avoid contagious infections and so on. Likewise, they may also provide advice on immunization, exercise, personal and household hygiene practices, mosquito control and so on. It would also be very relevant if the RMP can educate and counsel the patients regarding measures to protect the environment in the context of health and disease.
- **3. Counseling:** This is specific advice given to patients and it may, for instance, include food restrictions, dos and don'ts for patients on anticancer drugs, advise on proper use of a hearing-aid, instruction for home-based physiotherapy and so on to mitigate the underlying condition. This may also include advice for investigations that may be required before the next consultation.
- 4. **Prescribing Drugs:** Prescribing medication via telemedicine consultation is solely at the professional discretion of the RMP. It entails the same professional accountability as for in-person consultations. If a particular medical condition requires a specific protocol to be followed for the diagnose and prescription as for in-person consultations, then the same prevailing principles will be applicable to a telemedicine consultation.
- 5. RMPs may prescribe Drugs via telemedicine ONLY when they are satisfied that they possess adequate and relevant information about the patient's medical condition and that the prescribed Drugs are appropriate for and in patient's best interest.
- 6. Prescribing Drugs without following due process of arriving at an appropriate provisional

#### diagnosis/diagnosis might amount to professional misconduct.

- 7. Specific Restrictions: There are certain limitations on prescribing drugs during consultation via telemedicine depending upon the type and mode of consultation. After a telemedicine appointment, doctors often have enough information to advise patients on which over the counter medications to take or to write a prescription. Majority of decisions and recommendations can be made based on the patient interview and reviewing lab and diagnostic studies. The RMPs are expected to prescribe drugs for all conditions that they are able to diagnose with certainty, with the EXCEPTION of Schedule X drugs mentioned in the Drugs and Cosmetics Rules 1945, substance regulated under the under Narcotics Drugs and Psychotropic Substance Act, 1985 and all pharmaceutical drugs that can cause addiction or dependency.
- 8. The categories of drugs that can be prescribed during a teleconsultation will be notified in consultation with the Central Government from time to time. The categories of drugs that can be prescribed are listed below. This list is only **INDICATIVE** and does not restrict the RMPs from prescribing other drugs. RMPs may prescribe any drug (except Schedule X drugs) provided they are satisfied that the drugs being prescribed are optimal for the patient's medical condition in any type of consultation be it for the First-consultation or a Follow-up consultation which might require an add-on drug or a refill/repeat prescription:
- 1. List O: It will comprise those drugs that are safe to be prescribed through any mode of tele-consultation.
  - Drugs for common ailments that are available 'over the counter' called OTC drugs, defined as drugs that are safe and effective for use by the general public without seeking treatment by a health professional. OTC Drugs are legally allowed to be sold 'Over the Counter', without the prescription of RMPs. All the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs). For example:
    - 1. <u>Anti-Hemorrhoid Drugs</u>
    - 2. <u>Topical Antibiotics</u>: Some topical antibiotics are available without a prescription
    - 3. <u>Cough-Suppressants</u>
    - 4. Anti-acne Drugs
    - 5. <u>Non-steroidal Anti-inflammatory Drugs</u>: Some can be bought OTC; others are available only with a prescription from a physician or dentist.
    - 6. Antiseptics
    - 7. <u>Analgesics</u>
    - 8. <u>Decongestants</u>: Some require a physician's prescription but many are OTC products.
    - 9. <u>Aspirin</u>
    - 10. <u>Vasodilators</u>: Some Vasodilators such as Minoxidil are sold without prescription.
    - 11. Antacids
    - 12. Expectorants: Many expectorants are available OTC.
    - 13. Anti-fungal Drugs
    - 14. <u>Anti-Histamines</u>: Some can be bought without a prescription.
    - 15. Anti-flatulence Agents
    - 16. <u>Smoking Cessation Drugs</u>: Many drugs can be bought OTC without prescription.
  - Drugs that may be deemed necessary during public health emergencies and pandemics.

- 2. List A: These are drugs which can be prescribed during the first consultation **ONLY** in cases of video consultations, and if they are being repeated, prescribed for a re-fill, in case of follow-up consultations.
  - This list would include relatively safe drugs with low potential of misuse/ abuse. RMPs may prescribe these drugs to patients during a follow-up consultation if they are repeated for a re-fill. For e.g., drugs that were earlier prescribe in an in-person consultation being prescribed again (repeated) in a follow-up teleconsultation. In these situations, the patient has been seen, investigated and the diagnosis has been established by the RMP.
- 3. List B: Is a list of drugs that RMPs may prescribe for patients during follow-up consultations as add-on drugs, in addition to those drugs that were prescribed during an earlier in-person consultation for the same medical condition NOT a new drug for a different medical condition or disease. For e. g. to better control the Hypertension, the RMP may prescribe an add-on diuretic to a patient on an anti-hypertensive drug prescribed earlier. Prescriptions for injectable medicines can only be given if the consultation is between an RMP with another RMP or a Health Worker for administration to a given patient. In such a scenario, the RMP must be confident of the facility's setting and the technical expertise of the RMP or the Health Worker. The exceptions to these would be prescribing some follow-up medications which are marketed as self-administered drug injections, such as insulin.
- 4. List of Prohibited drugs: These are drugs that RMPs providing consultation via telemedicine CANNOT prescribe.
  - These drugs have a high potential for abuse and harm to the patient and/or the society at large if used improperly. Drugs regulated in Schedule X of the Drug and Cosmetic Act and Rules or any Narcotic and/or Psychotropic substance listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985. Except Clobazam, Clonazepam and Phenobarbitone as per MCI-211(2/2019)(ethics)/201874, dated 11.04.2020. See Annexure 1.

#### 9. Issue a Prescription and Transmit

- The RMP who has prescribed drugs shall issue a prescription as per the NMC Act and shall not contravene the provisions of the Drugs and Cosmetics Act and Rules. A sample format suggested in Annexure 2 may be followed. The following **essential elements**, however, **MUST** be included in all prescriptions:
  - 1. Name, qualifications, registration number, address and contact details of the RMP.
  - 2. Name, age, sex, identification and contact details of the patient.
  - 3. Name of the drug/s being prescribed in CAPITAL letters along with a clear mention of the formulation, dose, frequency and duration for which the drug/s is/are to be taken.
  - 4. Date, time and place of writing the prescription with signature and stamp.
- RMPs shall provide a clear photograph, scanned or digital copy of a duly signed prescription (e-Prescription) to the patient via email or over any other messaging platform with their full name, qualifications and registration number with the State medical council or the Indian Medical register clearly visible on the prescription.
- Prescriptions can be conveyed to patients who do not have a smartphone by using an online web application that can be accessed from a mobile browser. Link for the prescription can be sent as SMS to the recipient.
- There is no need to take print out of the e-prescription. E-priscription should comply with the guidelines. The e-prescription is valid for two weeks from the date of issue or once a pharmacist dispenses the prescribed medications, whichever is earlier. In cases where RMPs have to

transmit the e-prescription directly to a pharmacy, they must **ensure** that the patient explicit consent is taken or the patient's right of choice of the pharmacy where the prescription has to be transmitted is respected so that they procure the drugs dispensed from a pharmacy of their choice and convenience.

Table	e: Matrix of permissible drug	lists based on the type and mode o	f Teleconsultation
Lis t	Mode of Consultation [Video/Audio/Text]	Nature of Consultation [First / Follow-up]	List of Drugs (Refer section 3.7.7)
ο	Any	Any	List O <sup>1</sup>
A	Video	First consultation Follow-up or for continuation of medication; refill	List A <sup>2</sup>
В	Any	Follow-up	List B <sup>3</sup>
Prohibit ed	Not to be prescribed	Not to be prescribed	Prohibited List <sup>4</sup>

1. Drugs that are safe to be prescribed through any mode of tele-consultation, that are used for common conditions and are often available 'over the counter' without a prescription from RMPs. These drugs are NOT included in the list of 'Prescription drugs'. For e.g. Antacids, anti-histaminics, antipyretics, analgesics, expectorants, oral rehydration packets and so on,

Drugs that may be deemed necessary during public health emergencies and shall be notified from time to time.

- 2. These are drugs which can be prescribed during the first consultation ONLY in cases where the diagnosis is established over video consultations or if they are being repeated, prescribed for a re-fill, in case of follow-up consultations. For e.g. antifungal agents for skin ailments, antibiotic eye drops for conjunctivitis, antibiotics for abscesses, laryngitis and other conditions that can be diagnosed over video consultations and in follow-up consultations, drugs for chronic ailments like Asthma, diabetes, hypertension, tuberculosis etc.
- 3. This list is of 'add-on' drugs which can used to optimize or better manage an existing condition not a new drug for a different medical condition or disease. For e.g. an ACE inhibitor like Enalapril prescribed as an add-on drug to a patient with hypertension whose blood pressure is not controlled on Atenolol that was prescribed earlier.
- 4. For instance, Anti-Cancer drugs; Psychotropic drugs and Narcotics such as Morphine, Codeine etc. (Drugs listed in the 'Schedule X' of the <u>Drug and Cosmetic Act and Rules</u>, and substances regulated in the <u>Narcotic Drugs and PsychotropicSubstances</u>, Act, 1985.

[List of Approved New Drugs (cdsco.gov.in).]

#### DUTIES AND RESPONSIBILITIES OF RMPs IN TELEMEDICINE

#### 1. Ethical issues in telemedicine

These imply a consideration of patient's best interest and professional conduct in providing telemedicine services and the patient's right to consent to the therapy and complaint about unsatisfactory services. Telemedicine is used for patients who cannot visit an appropriate RMP in time because of inaccessibility due to distance, physical disability, employment, family commitments (including caring for others), patients 'cost and physician schedules. It has capacity to reach patients with limited access to medical assistance and potential to improve health care.

Face-to-face or in-person consultation between physician and patient remains the gold standard of clinical care. The delivery of telemedicine services must be consistent with in-person services and discretionary. The principles of medical ethics that are mandatory for the profession must also be respected in the practice of telemedicine.

#### 1.1. Physicians must respect the following ethical guidelines when practicing telemedicine:

- The RMP-patient relationship should be established. Telemedicine should be employed primarily in situations in which an RMP cannot be physically present within a safe and acceptable time period. It could also be used in management of chronic conditions or follow-up after initial treatment where it has been proven to be safe and effective.
- 2. The RMP-patient relationship must be based on mutual trust and respect. It is therefore essential that the RMP and patient be able to identify each other reliably when telemedicine is employed. In case of consultation between two or more professionals within or between different jurisdictions, the primary RMP remains responsible for the care and coordination of the patient with the distant medical team/other professionals.
- 3. The RMP must aim to ensure that patient confidentiality, privacy and data integrity are not compromised. Data obtained during a telemedicine consultation must be secured to prevent unauthorized access and breaches of identifiable patient information using appropriate and up to date security measures in accordance with prevailing legislation. Electronic transmission of information must also be safeguarded against unauthorized access.
- 4. Proper informed consent requires that all necessary information regarding the distinctive features of telemedicine visit be explained fully to patients including, but not limited to: explaining how telemedicine works, how to schedule appointments, privacy concerns, the possibility of technological failure including confidentiality breaches, protocols for contact during virtual visits, prescribing policies and coordinating care with other health professionals in a clear and understandable manner, without influencing the patient's choices.

#### 1.2. Autonomy and privacy of the RMP

- 5. The RMP should not participate in telemedicine, if it violates the legal or ethical framework of professional behaviour or any rules/regulations under the NMC Act 2019.
- 6. Telemedicine can potentially infringe on the free time of RMPs if there is round the clock virtual availability. The RMP needs to inform patients about their availability and recommend alternative or emergency services if they are inaccessible.
- 7. The RMP should exercise their professional discretion in deciding whether a telemedicine or an in-person consultation would be appropriate.

8. RMPs should exercise professional judgement & discretion in selecting the appropriate telemedicine platform to be used. The RMP has the right to pause his/her teleconsultation and recommend an in-patient consultation.

#### 1.3. Responsibilities of the RMP

- 9. RMPs should keep a detailed record of the advice they deliver as well as the information they receive on the basis of which advice was given to ensure accountability, responsibility and traceability.
- 10. If a decision to use telemedicine is made, it is necessary to ensure that the users (patients and healthcare professionals) have optimal access to the necessary telecommunication system optimally.
- 11. The RMP must seek to ensure that the patient has understood the advice and treatment suggestions given and take steps in so far as possible to promote continuity of care.
- 12. The RMP asking for another RMP's advice or a second opinion remains responsible for treatment and other decisions and recommendations given to the patient.
- 13. RMPs should be aware and respect special difficulties and uncertainties that may arise when they are in contact with the patient through telecommunication. They must be prepared to recommend direct RMP-patient contact when they believe it is in the patient's best interests.
- 14. Only Qualified and licensed RMPs only should practice telemedicine-
- 15. RMPs should ensure that their medical indemnity cover includes cover for telemedicine.

#### 1.4. Quality of Care

16. The possibilities and weaknesses of telemedicine in emergencies must be duly identified. If it is necessary to use telemedicine in an emergency situation, the advice and treatment suggestions will be influenced by the severity of the patient's medical condition and the competency of the persons who are with the patient. Entities that deliver telemedicine services must establish protocols for referrals to emergency services.

#### 2. MEDICAL ETHICS, DATA PRIVACY & CONFIDENTIAILITY

- **2.1.** Principles of medical ethics, including professional norms for consent, standard of care, protecting patient privacy and confidentiality as per NMC Act, 2019 shall be binding and must be upheld and practiced.
- 2.2. RMPs would be required to fully abide by NMC Act, 2019 rules & regulations and with the relevant provisions of the IT Act, Data protection and privacy laws or any applicable rules notified from time to time for protecting patient privacy and confidentiality and regarding the handling and transfer of such personal information regarding the patient. This shall be binding and must be upheld and practiced.
- **2.3.** RMPs will not be held responsible for breach of confidentiality if there is reasonable evidence to believe that patient's privacy and confidentiality has been compromised by a technology breach or by a person other than the RMP. The RMPs should ensure that reasonable degree of care is undertaken while hiring such services.
- 2.4. It is the responsibility of the RMP and / or the telemedicine service provider to be cognizant of the current Data Protection and Privacy laws. RMPs shall protect the patient's confidentiality as in normal circumstances
- 3. **Misconduct**: It is specifically noted that in addition to all general requirements under the MCI Act for professional conduct, ethics etc., while using telemedicine all actions that willfully compromise patient care or privacy and confidentiality, or violate any prevailing law are

explicitly not permissible. Some examples of actions that are not permissible:

- **3.1.** RMPs insisting on Telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation.
- **3.2.** RMPs using patient images and data without the consent of the patient
- **3.3.** RMPs who use telemedicine to prescribe drugs from the prohibited list and all those drugs are known to cause dependence or addiction.
- 3.4. RMP prescribes medicine without diagnosis or provisional diagnosis
- **3.5.** RMPs are not permitted to solicit patients for telemedicine through advertisements or inducement.
- 1. **Penalties**: As per, NMC Act 2019, and other prevailing laws.

#### 2. MAINTAIN DIGITAL TRAIL/ DOCUMENTATION OF CONSULTATION

It is incumbent on RMPs to meticulously maintain the following records/documents for three years from the date of the last consult with the patient.

- 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) utilized in the telemedicine consultation should be retained by the RMP for the duration prescribed by various acts and also to avoid problems in case of litigation.
- the RMP is required to maintain the prescription records as required for in-person consultations.
- If audio and/or video recording of the consultation is required, the RMP must take explicit informed consent from the patient. Similarly, if the patient and/or the family members want to record the audio and/or video of the consultation, they should take consent from the RMP. Those recording without consent will not be accepted as evidence

#### 6. FEE FOR TELEMEDICINE CONSULTATION

- Telemedicine consultations should be treated the same way as in-person consultations with regard to consultation charges or fees. RMP may charge an appropriate fee for the Telemedicine consultation provided.
- RMPs should issue a duly signed receipt/invoice to the patient for the fees charged for the telemedicine based consultation provided.

## (4) Framework for Telemedicine

This section lays out the framework for practicing telemedicine in 5 scenarios:

- a. Patient with RMPs
- b. Caregiver with RMPs
- c. Health Worker with RMPs
- d. RMP with RMP
- e. Emergency Situations

#### **Essential Principles:**

- The **professional judgement** of the RMP should be the guiding principle: the RMP is well positioned to decide whether a technology-based consultation is sufficient, or an in-person review is needed. Practitioner shall exercise proper discretion and not compromise on the quality of care
- Same principles apply irrespective of the mode (video, audio, text) used for a telemedicine consultation. However, the patient management and treatment can be different depending on the mode of communication used.
- The RMP should exercise **their professional discretion** for choice of mode of communication depending on the type of medical condition being addressed. For e.g., if a case requires a video consultation for examination, RMP should explicitly ask for it.
- The RMP can choose not to proceed with the consultation at any time, after informing the patient of the decision.
- At any stage, the **patient has the right to choose to discontinue** the teleconsultation and may inform the RMP accordingly

#### 4.1 CONSULTATION BETWEEN PATIENT AND RMPs

Specifically, this section details with the key elements of the process of teleconsultation to be used in the First consultation and Follow-up consultations between a patient and an RMP.

In these 2 situations, the patient initiates telemedicine consultation and thereby consent is implied

#### 1. First Consultation: Patient with RMP

#### 1.1. First Consultation means

- 1. This patient is consulting with the RMP for the very first time; (or)
- 2. The patient has consulted with the same RMP earlier, but more than 6 months have lapsed since the previous consultation; (or)
- 3. The patient has consulted with the RMP earlier, but for a different health condition.

#### **1.2.** Tele-Consultation Process

The flow of the process is summarized in the Figure 1 and the steps are detailed below.

#### **1.** Start of a Telemedicine Consultation for the First Consultation

• The telemedicine consultation is initiated by the patient (For e.g., a patient may initiate an audio or video call with the RMP or send an e-mail or text with a health query)

• RMP accepts to undertake the consultation

#### 2. Patient identification and consent

- RMPs should establish the patient's identity to their satisfaction by asking their name, age, address, email ID, phone number or other identification that is reasonable
- If Telemedicine consultation is initiated by the patient, consent is implied.

#### 3. Quick assessment:

- Based on the input received, the patient's condition is quickly assessed by the RMP who decides whether emergency care is required or not, using professional discretion.
- If the condition of the patient merits emergency intervention, then advice for first aid/ immediate relief is provided and guidance is provided for referral, as appropriate.

#### If the condition does not merit an emergency intervention, the following steps are undertaken:

#### 4. Exchange of Information for Patient Evaluation

- The RMP may ask the patient to provide relevant information (complaints, information about other consults for the same problem, available investigations and medication details, if any). The patient shall be responsible for the accuracy of information shared with the RMP.
- If the RMPs feel that the information received is inadequate, they can request for additional information from the patient. This may be shared in real-time or later via email/text, depending on the nature of the information. For e.g., the RMP may require laboratory and/or radiological investigations. In such cases, the session may be considered as suspended to be resumed at a later predetermined time. RMPs should provide health education as deemed appropriate at any time.
- If the RMP is satisfied that adequate patient information for offering a professional opinion, has been received, then they shall exercise their professional judgment for appropriateness and suitability for management via telemedicine.
- If the situation is NOT appropriate for further telemedicine consultation, then the RMP should provide Health advice/ Education as appropriate; and/or refer for in-person consultation.

#### 5. Patient Management

# If the condition can be appropriately managed via telemedicine, then the RMP may take a professional judgement to either:

- Provide Health Education as appropriate in the case; and/or
- Provide **Counseling** related to a specific clinical condition, including advice related to new investigations that may be required before next consult; and/or
- Provide **specific treatment by prescribing drugs** as in List O (which are over the counter drugs or others as notified). Additional drugs (as per List A) can also be prescribed if the ongoing tele-consultation is on video.

#### 2. Follow-up Consult: Patient with RMP

In a follow-up consultation, as the RMP-patient interaction has already taken place for the specific medical condition being followed-up and the RMP comprehends the context well with previous records available, it allows for a more definitive and secure interaction between the RMP and the patient.

#### 2.1. Follow-Up Consultation means

- The patient is consulting the same RMP within 6 months of their previous in-person consultation and this consultation is for the continuation of care of the same health condition.
- Follow-up can be in situations when an in-person consultation is not necessary, for e.g., for management of a chronic disease for renewal or change in medications. Examples of such chronic diseases are: asthma, diabetes, hypertension and epilepsy etc.

#### 2.2. Tele-Consultation Process

The flow of the process is summarized in Figure 2 and the steps are detailed below:

#### 1. Start of a Telemedicine Consultation for Follow Up

- Patients may initiate a follow-up consultation with the RMP for the continuation of their ongoing treatment or for a new complaint or complication arising in the course of their ongoing treatment using any mode of communication. For e.g., the patient may initiate an audio or video call with the RMP or send them an email or text message with a specific health query.
- RMP accepts to undertake the consultation.

#### 2. Patient identification and consent

- RMPs should be reasonably sure that they are communicating with the same patient. For e.g., if the patient is communicating with RMP through a previously saved or registered phone number or previously used or registered email id.
- In case of any doubt the RMP should request the patient to reinitiate the conversation from a registered phone number or email id or should establish the patient's identity to their satisfaction by asking their name, age, address, email ID, phone number or other identification that is reasonable [Details in the section 3.2].
- $\circ$  , The patient, initiates the Telemedicine consultation and thereby, consent is implied

#### 3. Quick Assessment for Emergency Condition

• Suppose the patient presents with a complaint that the RMP identifies as an emergency condition necessitating urgent care. In that case, the RMP should provide advice first-aid to provide immediate relief and guide for referral of the patient, as deemed necessary.

## 4. In case of routine follow-up consultation, the following would be undertaken:

- If the RMP has access to previous records of the patient, then they may proceed with the continuation of care.
- RMPs shall use their professional discretion regarding type of consultation based on adequacy of patient information (history, examination findings, Investigation reports, past records) available.
- If additional information is warranted, the RMP should seek the required information before proceeding and resume the teleconsultation at a later point in time.

#### 5. Patient Management

o If RMPs are satisfied that they have access to adequate patient information and if the

condition can appropriately and satisfactorily be managed by teleconsultation, they should go ahead with the management of the patient.

- If the follow-up is for continuation of care, then the RMP should make a professional judgement to either:
  - Provide Health Education as appropriate in the case; and/or
  - Provide Counseling related to specific clinical condition, including advice related to new investigations that may be required before next consult; and/or;
  - Prescribe Medication. The medications could be either of the below:
    - If the follow up is for **continuation of care for the same medical condition**, the RMP should repeat the original prescription for a refill (List A of drugs that have already been prescribed for the patient earlier).
    - If the RMP considers addition of a new drug as **'add-on' medication** to optimize the treatment of the underlying medical condition, then the RMP can prescribe additional drugs listed under List B.
    - If the follow-up consultation is for a new minor ailment necessitating only 'over the counter' medications or those notified for this purpose, medications under List O may be prescribed.
    - If the follow-up consultation **reveals a new symptom pertaining to a different disease**, then the consultation is not considered as a Follow-up consultation and the RMP should inform the patient about the same and proceed with the condition as described for a first-time consultation (4.1.1).

#### 4.2 CONSULTATION BETWEEN PATIENT AND RMP THROUGH A CAREGIVER

- 1. For the purpose of these guidelines a **Caregiver** could be a family member, or any person authorized by the patient or law to represent them.
- 2. There are two possible settings:
  - 1. Patient is present with the Caregiver during the consultation.
  - 2. Patient is not present with the Caregiver. This may be the case in the following:

**2a.** The Patient is a minor (under the age of 18 years) or the patient is incapacitated, for example, in medical conditions like dementia or physical disability etc. In these circumstances the caregiver is authorized to represent the patient.

**2b.** The **Caregiver** has a formal authorization or a verified document establishing his relationship with the patient and/or has been verified by the patient in a previous in-person consultation (explicit consult).

In all of the above situations, the consultations shall proceed as stipulated in the case of a Patient with the RMP (First consultation or Follow-up consultation, vide 4.1)

- 3. CONSULTATION BETWEEN HEALTH WORKER AND RMP
  - 3.1.For the purpose of these guidelines, a **Health worker** could be a Nurse, Allied Health Professional, Mid- Level Health Practitioner, ANM or any other health worker designated by an appropriate authority.

#### 3.2. Proposed Set up

- This sub section will cover interaction between a Health Worker seeking consultation for a patient in a public or private health facility.
- In a public health facility, the mid-level health practitioner at a Sub-center or Health and wellness center can initiate and coordinate the telemedicine consultation for the patient with a RMP at a higher center at district, State or National level. Health and Wellness centers are an integral part of comprehensive primary health care.
- This setting will also include health camps, home visits, mobile medical units or any community-based interaction.

#### **3.3.Tele-Consultation Process**

The flow of the process is summarized in Figure 3 and the steps are detailed below:

#### 1. Start of a Telemedicine Consultation through a Health Worker with an RMP

- The premise of this consultation is that the patient has been seen by the Health Worker
- o In the judgment of the Health Worker, a teleconsultation with an RMP is required
- The Health Worker should obtain informed consent from the patient.
- The Health Worker should explain potential use and limitations of the telemedicine consultation.
- The Health Worker should also confirm the patient's identity patient's name, age, address, email ID, phone number or other identification that may be reasonable.
- The Health Worker initiates and facilitates the telemedicine consultation.

#### 2. Patient Identification (by RMP)

- RMPs should confirm patient's identity to their satisfaction by asking patient's name, age, address, email ID, phone number or other identification that may be reasonable.
- o RMP should also make their identity known to the patient.

#### 3. Patient Consent (by RMP):

• RMP should reaffirm that patient's consent has been obtained to continue the consultation

#### 4. In case of Emergency,

- The Health Worker urgently communicates the patient's underlying condition to the RMP.
- If, based on information provided, the RMP identifies it as an emergency necessitating urgent care, they should advise for first aid to be provided by the Health Worker for immediate relief and guide for referral of the patient, as deemed necessary.

#### In case, the condition is not an emergency, the following steps would be taken:

#### 5. Exchange of Information for Patient Evaluation (by RMP)

- The Health Worker must give a detailed explanation of the patient's problem to the RMP which can be supplemented by additional information by the patient, if required.
- o The RMP shall apply professional discretion for type and extent of patient

information (history/examination findings/Investigation reports/past records) required to be able to exercise proper clinical judgement.

 If the RMPs feel that the information received is inadequate, they can request for additional information from the patient. This may be shared in real time or later via email/text, depending on the nature of the information. For e.g., the RMP may require laboratory and/or radiological investigations. In such cases, the session may be considered as suspended to be resumed at a later predetermined time. RMPs should provide health education as deemed appropriate at any time.

#### 6. Patient Management

- Once the RMP is satisfied that the available patient information is adequate and that the case is appropriate for management via telemedicine, then they should proceed with the management. Health worker should document the same in their records.
- The RMP may take a professional judgement to either:
  - Provide Health Education as appropriate in the case; and/or
  - Provide **Counseling** related to specific clinical condition, including advice related to new investigations that may be required before next consult; and/or;
  - Prescribe **Medication**:
    - as prescribed for use in guidelines from time to time for a particular cadre of Health Workers.

#### **Role of Health Workers:**

In all cases of emergency, Health Workers must seek measures for immediate relief and first-aid from the RMP who is being tele-consulted. Health Workers must provide immediate relief/first aid as advised by the RMP and facilitate the referral of the patient for appropriate care. They must ensure that the patient is advised an in-person interaction with an RMP, at the earliest.

For patients who can be suitably be managed via telemedicine, the Health Worker plays a vital role of:

- Reinforcing health education and counseling advise provided by the RMP
- Providing drugs prescribed by the RMP and counseling on their treatment.

#### 4.4 CONSULTATIONS – RMPs WITH OTHER RMPs

- 1. RMPs might use telemedicine services to consult with another RMP or a specialist for a patient under their care. Such consultations can be initiated by the RMP on their professional judgement.
- 2. The RMP asking for another RMP's advice remains the treating RMP, and shall be totally responsible for the treatment, and other recommendations, provided to the patient.
- 3. It is acknowledged that many medical specialties like Radio-diagnosis, Pathology, Ophthalmology, Cardiology, Dermatology to name just a few may be at advanced stages of adoption of technology for exchange of information and some others may be in early stages. Guidelines support and encourage interaction between RMPs and specialists using information communication technology for diagnosis, management and prevention of disease.
  - **Tele-radiology** is concerned with the **transmission of** radiographic images (X-rays, CT, MRI, Ultrasound etc.) from one location to another for diagnostic purposes.

- **Tele-pathology** is use of technology to transfer image-rich pathology data between distant locations for the purposes of diagnosis, education, and research.
- Tele-ophthalmology delivers care by providing access to eye specialists for patients in remote areas for ophthalmic diseases screening, diagnosis and monitoring.
- The management of critical/severe cases in 'e-ICUs' may be considered in consultation with specialists in situations of limited availability of ICU beds during emergencies like Covid-19 pandemic.

#### 4.5 EMERGENCY SITUATIONS

- 1. In all telemedicine consultations, as per the judgment of the RMP, if it is an emergency situation, the overarching goal and objective should be to provide in-person care at the earliest . However, in the interim, critical steps could be life-saving; timely guidance and counseling could be critical. For example, in cases involving trauma, the correct advice and guidance around maintaining the neck position might prove life-saving by protecting the spine in some cases. The guidelines are designed to provide a balanced approach in such conditions. The RMP, based on their professional discretion, may:
  - Advise first aid
  - Counseling
  - Facilitate referral

Patients may call any RMP during a medical emergency and insist on teleconsultation. However, the RMP may not reply or give any specific advice. In all emergency cases, the patient MUST be advised for in-person interaction with a Registered Medical Practitioner or specialist at the earliest possible.

#### 4.6 TELEMEDICINE TRIAGE AND COVID-19 CARE FOR PATIENTS

## 5. Guidelines for RMPS and Technology Platforms enabling Telemedicine

This specifically covers those technology platforms which work across a network of RMPs and enables patients to consult with RMPs through the platform.

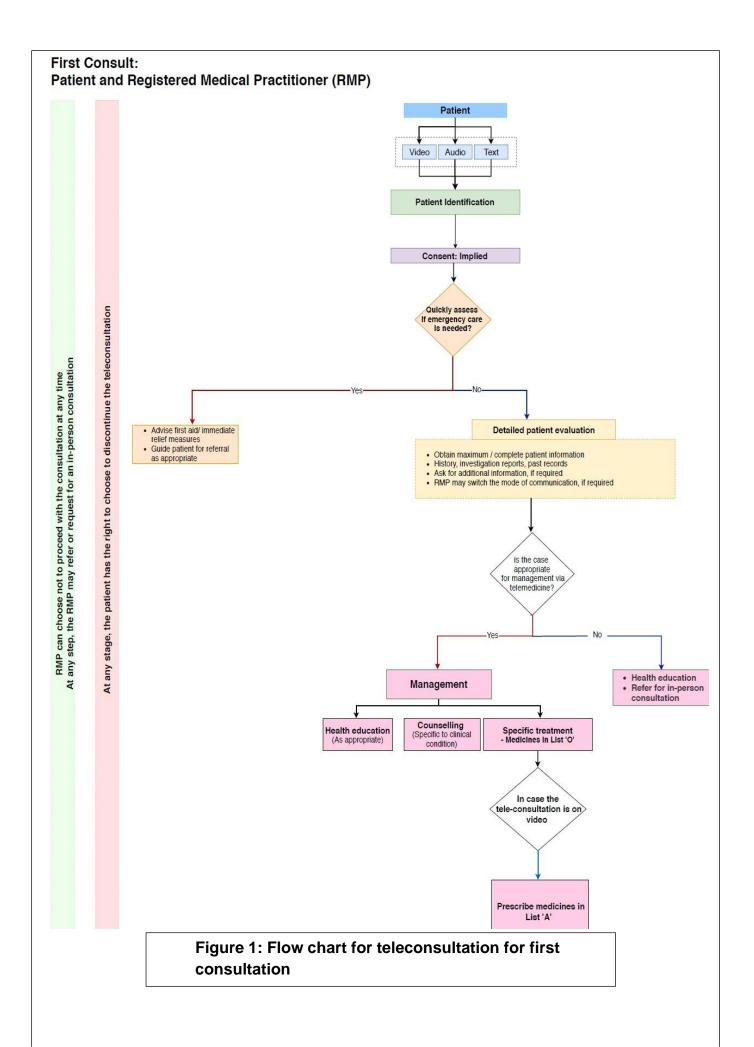
- 5.1. RMPs must ensure that any platform they associate with must comply the following guidelines
- **5.2.** RMPs shall not participate in telemedicine platforms that provide ratings by patient or others including reviews, advertisements, and promotions of RMPs any means. (manipulation of algorithms/search engines etc). Advertising of RMPs is not allowed by anybody under any pretext.
- 5.3. Technology platforms (Mobile Apps, Websites etc.) providing telemedicine services to consumers shall be obligated to ensure that the consumers are provided services and are consulting with RMPs who are duly registered with the National Medical Register or their respective State Medical Councils and comply with their relevant provisions and laws amended from time to time.
- 5.4. The Platform must provide the Name, Qualifications (Graduate and Post-graduate with Super-specialty qualifications if any), Registration Number, Contact details (current Mobile numbers and e-mail addresses) of every RMP listed on their platform. The contact details of the RMPs, however, should not be displayed to the public or shared, except with the patient being consulted.
- **5.5.** The onus of ensuring that all the information regarding the RMP and all their qualifications that have been mentioned on their portal have been authenticated and are registered with the National Medical Register or their respective State Medical Councils rests wholly on the Owners and Administrators of the Technology Platform.
- **5.6.** In the event of non-compliance with these guidelines or infringement of the existing laws applicable to the provision of services provided by the Technology Platform, or if complaints against the Technology Platform are received by the NMC, appropriate action including legal action may be initiated against the Technology Platform by the NMC.
- 5.7. Technology platforms based on Artificial Intelligence/Machine Learning are not allowed to counsel the patients or prescribe any drugs to a patient. Only RMPs are entitled to counsel or prescribe and have to communicate directly with the patients in this regard. While new technologies such as Artificial Intelligence, Internet of Things, advanced data science-based decision support systems etc. could assist and support the RMP on patient

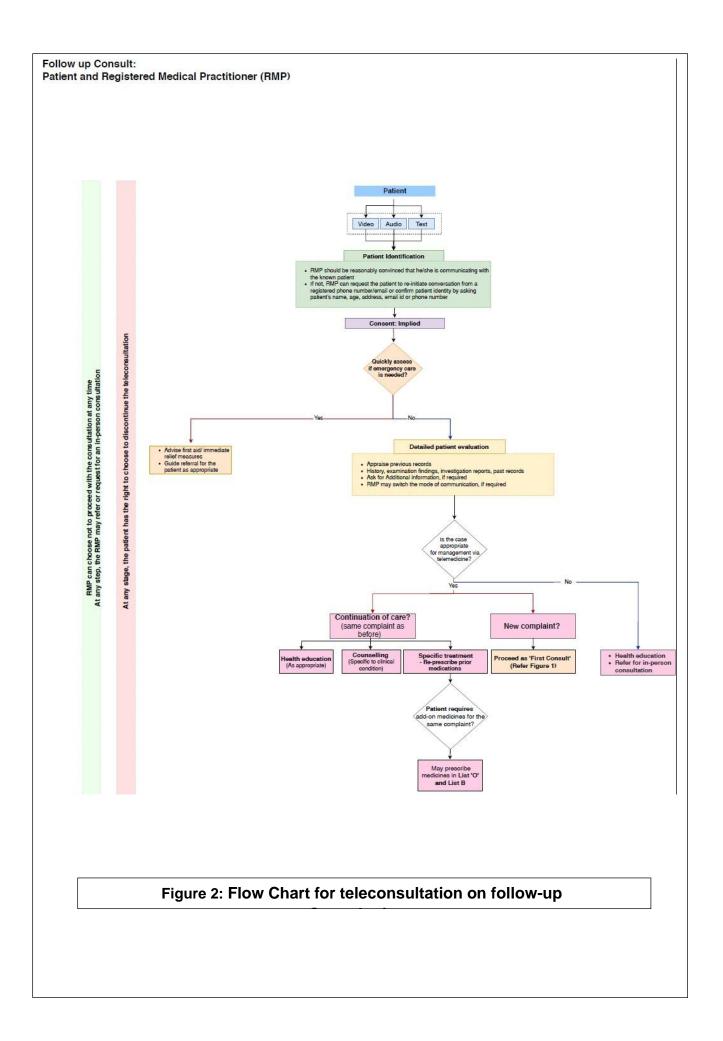
evaluation, diagnosis or management, the final prescription or counseling has to be directly delivered by the RMP.

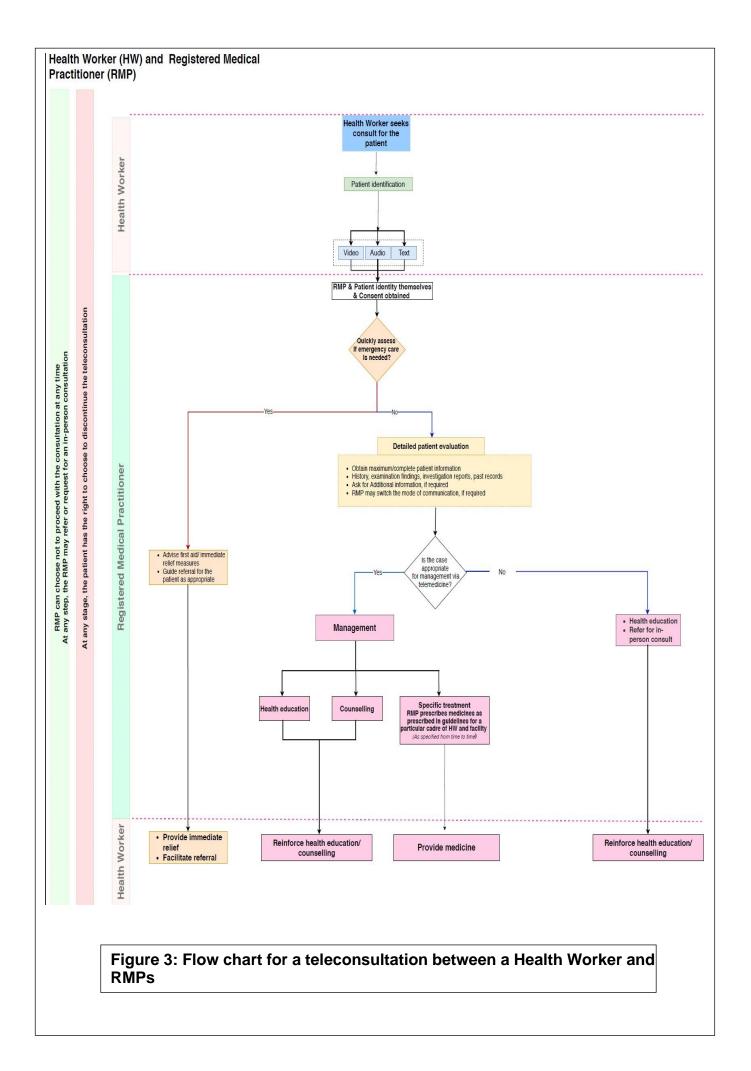
- **5.8.** Technology Platform must ensure a proper grievance redressal mechanism for end users of their services.
- **5.9.** In case any specific Technology Platform is found to violate these guidelines or any applicable existing laws applicable to them, the EMRB/NMC may designate the Technology Platform as blacklisted, and no RMP may then use that platform to provide telemedicine.

## 6. Special responsibilities of EMRB/NMC

- **6.1.** The **drug-lists** contained in Guidelines for Practice of Telemedicine in India may be modified by the EMRB/NMC from time to time, as required. A formal mechanism for the same may be created.
- **6.2.** The EMRB/NMC may issue necessary directions and/or advisories and/or clarifications with regards to these Guidelines, as and when required or deemed necessary.
- **6.3.** The Guidelines for Practice of Telemedicine in India may be amended from time to time in the larger public interest







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# Annexures

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## Annexure 1

#### **DRUG LISTS**

The list given below are INDICATIVE and do not restrict the RMPs from prescribing other drugs from the list of prescription drugs. RMPs may prescribe any drug (except Schedule X drugs) provided they are satisfied that the drugs being prescribed are optimal for the patient's medical condition be it a First-consultation or a Follow-up consultation.

#### LIST O:

- Drugs for common ailments that are available 'over the counter' (OTC drugs) without the prescription of RMPs. All the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs). For example:
  - o <u>Anti-Hemorrhoid Drugs</u>
  - <u>Topical Antibiotics</u>: Some topical antibiotics are available without a prescription
  - o <u>Cough-Suppressants</u>
  - o Anti-acne Drugs
  - o <u>Non-steroidal Anti-inflammatory Drugs</u>: Available OTC or few with prescription from RMP/dentist.
  - o <u>Antiseptics</u>
  - o <u>Analgesics</u>
  - <u>Decongestants</u>: Some require a physician's prescription but many are OTC products.
  - Vasodilators: Some Vasodilators such as Minoxidil are sold without prescription.
  - Antacids and Anti-flatulence Agents
  - <u>Expectorants</u>: Many expectorants are available OTC.
  - o Anti-fungal Drugs
  - <u>Anti-Histamines</u>: Some can be bought without prescription.
  - <u>Smoking Cessation Drugs</u>: Many drugs can be bought OTC without prescription.
- Medications notified by Government of India in case from time to time on an Emergency basis, such as Chloroquine for Malaria control for a specific endemic region, when notified by Government

#### LIST A:

- First consultation drugs prescribed (Diagnosis made ONLY by video mode of consultation)
  - Ointments/Lotion for skin ailments: Clotrimazole, Mupirocin, Calamine Lotion, Benzyl Benzoate Lotion etc; Local Eye drops such as: Ciprofloxacin for Conjunctivitis, etc; Local Ear Drops such as: Clotrimazole ear drops, drops for ear wax etc.
  - Follow-up consultations for above medications
  - Follow-up drugs being repeated, prescribed for a re-fill, in case of chronic illnesses.
    - Hypertension: Enalapril, Atenolol etc
    - o Diabetes: Metformin, Glibenclamide, etc
    - Asthma: Salmeterol inhaler etc

#### LIST B:

- Drugs prescribed on follow-up consultations as add-on drugs to better manage existing disease
  - Thiazide diuretic as add-on drug to Atenolol prescribed earlier for Hypertension
  - o Sitagliptin as add-on drug to Metformin prescribed earlier for Diabetes mellitus

#### LIST OF PROHIBITED DRUGS:

 Anti-Cancer, Psychotropic drugs and Narcotics (Morphine, Codeine etc.). Drugs listed in 'Schedule X' of the Drug and Cosmetic Act and Rules [2016DrugsandCosmeticsAct1940Rules1945.pdf (cdsco.gov.in)]; and substance listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985 [Narcotic-Drugs-and-Psychotropic-Substances-Act-1985.pdf (dor.gov.in)]. All those drugs, which are known to cause dependence or addiction • Except Clobazam, Clonazepam and Phenobarbitone as per MCI-211(2/2019)(ethics)/201874, dated 11.04.2020.

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## Annexure 2

6.1 SAMPLE PRESCRIPTION FORMAT

QUALIFICATION REGISTRATION NUMBER	
ADDRESS CONTACT DETAILS (EMAIL AND	PHONE NUMBER)
	in the numberry
Data of Grandhating	
Date Of Consultation	
Name of Patient	Age Gender
Address	Height
	Weight (whenever application)
	LMP (wherever applicable)
CHIEF COMPLAINTS	DIAGNOSIS OR PROVISIONAL DIAGNOSIS
EXAMINATION / LAB FINDINGS	<ul> <li>R</li> <li>NAME OF MEDICINE (in capital letters only withgeneric name) drug form, strength, frequency of administration &amp; duration.</li> <li>NAME OF MEDICINE (in capital letters only withgeneric name) drug form, strength, frequency of administration &amp; duration.</li> </ul>
	<ol> <li>NAME OF MEDICINE (in capital letters only withgeneric name) drug form, strength, frequency of administration &amp; duration.</li> </ol>
SPECIAL INSTRUCTIONS	

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#### 6.2 SAMPLE PATIENT INFORMATION SHEET

#### Introduction:

You are dealing with a communication platform owned and operated by \_

(Name of the RMP/Hospital/Service provider) for the purpose of providing a virtual space for a doctor-patient consultation otherwise known as Teleconsultation, Online Consultation or Telemedicine. Teleconsultation under this platform complies and follows the protocols and guidelines set forth by the NMC, Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 and with the relevant provisions of the IT Act, Data protection and privacy laws or any applicable rules notified from time to time for protecting patient privacy and confidentiality and regarding the handling and transfer of such personal information regarding the patient, as well as the ethical standards of medical practice in India.

Teleconsultation involves using Information and Communication Technology (ICT) allows Medical Professionals to communicate and interact with their patients remotely and provide consultation, collection and sharing of information to improve patient care. The information exchanged may be used for diagnosis, therapy, follow-up and/or education and/or counselling, and may include any or all of the following:

- 1. Patient medical records
- 2. Medical images
- 3. Live two-way audio and video
- 4. Output data from medical devices and sound and video files

The ICT used will incorporate due diligence and best practice network and software security protocols to ensure confidentiality, protect your identity, imaging data and will include measures to safeguard the data and ensure its integrity against intentional or unintentional corruption, in compliance with Patient Confidentiality and Safety, Data Privacy laws, and Ethical Standards of Medical Practice in India.

Electronic systems used will incorporate certain protocols to protect the confidentiality of the doctor, and most importantly, of you, the patient. Please know that in line with the Privacy Policy, **'Any form of recording is prohibited'** except with the prior express written consent of you as the patient, your RMP as well as the associated Hospital/Service Provider. Reasonable and appropriate efforts would be made to eliminate any confidentiality risks associated with the telemedicine consultation and all existing laws regarding access to medical information and copies of medical records apply to this teleconsultation. Additionally, dissemination of any patient-identifiable images or information from this telemedicine interaction to researchers or other entities shall not occur without your consent, unless authorized under existing privacy and confidentiality laws of India.

#### **Expected Benefits**

Improved access to medical care by enabling you to remain at home or in a remote area for the consultation while allowing your RMP to collect information and make a diagnosis. You might also remotely access and obtain the expertise of a specialist through this platform which you would otherwise not have been able to routinely.

#### **Possible Risks**

As with any medical process, there are several potential risks involved in this procedure. However, we would like to draw your attention to the risks associated with use of telemedicine or online consultation. These include, but are not limited to:

- 1. Information exchanged may not be sufficient to allow appropriate medical decision making by the RMP in some instances, as there is no in-person contact to carry out a thorough physical examination of the patient.
- 2. Delays in medical evaluation and treatment may occur due to the limitations of teleconsultation related to access to healthcare facilities, diagnostic centers and other essential equipment.
- 3. In some instances, security protocols could fail, causing a breach of privacy of the patient's medical information.
- 4. Lack of access to all your medical records might result in adverse drug interactions or allergic reactions or other errors in judgement in some cases.
- 5. The counsel, advise, assessment, recommendation, and opinions rendered by the RMP should be considered for general guidance for your health condition only and should not be considered as replacement of actual diagnosis and physical examination by your personal physician.
- 6. Teleconsultation and is not a substitute for clinics, hospitals, and other medical centers.
- 7. Teleconsultation does not provide emergency services to its users nor is it meant to replace, or supplement emergency services.
- 8. Delays in communication, assessment and advice could occur due to failure of the electronic systems or connectivity.
- 9. In some instances, your failure to provide accurate and/or complete medical records to the RMP may result in adverse drug reactions or allergic reactions or other judgment errors.
- 10. You may expect the anticipated benefits from the use of the medical information or healthcare services provided by the RMPs, but no results can be guaranteed or assured.
- 11. The RMPs, in their sole discretion and professional judgment may determine that their medical information or healthcare services are not appropriate for some or all of your treatment needs and, accordingly, may elect not to provide medical information or healthcare services to you.
- 12. Temporary interruptions in service that are not within the control of the RMP may occur in connection with teleconsultation and telemedicine in general.

## Annexure 4

#### 6.3 SAMPLE INFORMED CONSENT FORMAT PATIENT EXPLICIT CONSENT FOR TELECONSULTATION

Patient Name: Gender: Location at the time of signing consent: Home Address: Date of Signing:

By signing this consent form, I state and understand that:

- 1. I am of legal age and within the territorial jurisdiction of India at the time of teleconsultation.
- 2. The RMP performing teleconsultation is licensed to practice medicine within the territorial jurisdiction of India.
- 3. The laws that protect privacy and confidentiality of medical information also apply to telemedicine, and that no information obtained in the use of telemedicine which identifies me will be disclosed to anyone, including people in the medical field, without my consent.
- 4. I have the right to withhold or withdraw my consent to the use of telemedicine during the course of my care at any point in time, without affecting my right to future care or treatment.
- 5. I have the right to examine all the information obtained and recorded in the course of the telemedicine interaction and may request and receive copies of this information for a reasonable fee.
- 6. My RMP has explained all the alternatives options of care to my satisfaction.
- 7. There are risks associated with the use of telemedicine services which I fully understand as risks that I have to take in order to receive teleconsultation service.
- 8. Telemedicine involves the use of electronic communication of my personal medical information, and is at times, prone to failure of security protocol.
- 9. Any form of recording including, but not limited to, taking screenshots and pictures, and recording audio or video is strictly prohibited, except with prior written consent of myself, the RMP, and the Hospital or Service Provider.
- 10. It is my duty to inform my RMP about any other electronic or in-person interactions regarding my care that I may have with other medical practitioners.
- 11. Any prescription given in the teleconsultation will be used only for this particular consultation and is only applicable in the territorial jurisdiction of India.
- 12. I may expect the aforementioned benefits from the use of telemedicine in my care, but as this is not the optimal means to having a consultation, no results can be guaranteed or assured.
- 13. A consultation fee of Rs. \_\_\_\_\_\_ (amount in figures and words) may be imposed by the RMP and a transaction fee of Rs. \_\_\_\_\_\_ (amount in figures and words) may be imposed by the Hospital/Service provider if any, for the use of the facility.
- 14. I agree to the Terms and Conditions and Privacy Policy and any other published policies shared with me by the RMP/mentioned in the website of the RMP, Hospital or Service Provider.

I have read and understood the information regarding the use of telemedicine provided above (or) the information regarding the use of telemedicine provided above has been read out and explained to me in a language that I fully understand, and I am willing to undergo this innovative means for my health condition to improve my care. I hereby give my informed consent for the use of telemedicine and teleconsultation with full agreement to its Terms and Conditions and Privacy Policy, for my medical care.

Patient's signature/Left Thumb impression

Age: