Telemedicine Practice Guidelines for Doctors



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असाधारण

EXTRAORDINARY

भाग III-खण्ड 4

PART III—Section 4

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THE GAZETTE OF INDIA : EXTRAORDINARY

[PART III—SEC. 4]

The Telemedicine Guidelines were Notified and Gazetted on 14th May 2020

New Delhi, the 12th May, 2020

No. MCI-211(2)/2019(Ethics)/100659.— In exercise of the powers conferred by Section 33 of the Indian Medical Council Act, 1956 (102 of 1956), the Board of Governors in Supersession of the Medical Council of India with the previous sanction of the Central Government, hereby makes the following Regulations to amend the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002:-

- 1. (i) These Regulations may be called the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2020."
- (ii) These regulations shall deemed to have been effective from 25th March 2020 which is the date on which the Central Government has accorded approval to these Regulations.
- 2. In the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002", the following addition shall be made:-

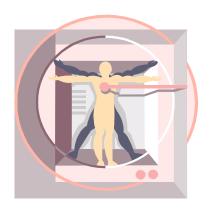
Guidelines for Practice of Telemedicine in India

Dawn of New Era in Healthcare in India

Telemedicine Practice Guidelines Released by Ministry of Health

On 25th March 2020

WHAT IS TELEMEDICINE?



Telemedicine is the delivery of health care anywhere in the world by combining communication technology with medical expertise





Ref- 1. 1. https://www.mohfw.gov.in/pdf/Telemedicine.pdf

- 2. Stud Health Technol Inform. 1999;68:245-6.The telemedicine and second medical opinion.Gersak B, Gorjup V, Jazbec
- 3. https://www.ncbi.nlm.nih.gov/pubmed/10724879 3. https://www.isro.gov.in/applications/tele-medicine

Case for Telemedicine & TeleHealth

Telemedicine: 'An Enabler of Healthcare Access and Affordability'

Patient Friendly

- Saves Travel Time to Clinic
- Saves cost of Travel
- No Waiting in clinics & taking time off from work





Better clinical workflows

- Improves practice efficiency
- Reduces practice over-heads
- Required Social Distancing & Quarantine - COVID19 Pandemic

Purpose of Guidelines

Practical Advice on how to **PRACTICE SAFE TELEMEDICINE**

- To Use Telemedicine as a part of Normal Practice it provides practical advice to doctors
- Provide Guidelines & Regulations to make it Safe for Patient
 & Provider

What are Requirements to Practice Telemedicine for RMP

Get Familiar with National Guidelines & Take a Course to Practice Safe Telemedicine

- Familiarity with Guidelines, its Process and Limitations of telemedicine practice a Must
- Mandatory online course for RMPs
- ONLINE COURSE WITHIN 3 YEARS
- Get Qualification Before License All qualifying RMPs will need to undergo and qualify such a course before they are given license to practice

What the Guidelines Does not provide?

- Consultations Inside India But Not outside India
- Does not allow use of digital technology to conduct surgical or invasive procedures remotely
- Does not allow for research applications
- Does not cover hardware or software, infrastructure building &
 maintenance, data management systems; standards and inter-operability

Standards will be defined but for the moment follow similar standards as in the IT Act

How to Do a Telemedicine Consult?

FOLLOW THE SEVEN ELEMENTS IN THE GUIDELINES

- 1. Context
- 2. Identification of RMP and Patient
- 3. Mode of Communication
- 4. Consent
- 5. Type of Consultation
- 6. Patient Evaluation
- 7. Patient Management

1. What is the Context & Suitable for the Situation

The RMP shall uphold the same standard of care as in a Face to Face or inperson consultation but within the intrinsic limits of telemedicine

Depending on the complexity of diagnosis - RMP can decide on the mode and suitability of such consults —

- Do they require just health education
- Or Counselling
- Or Medication

1. What is the Context – Which Type Consult Most Suitable

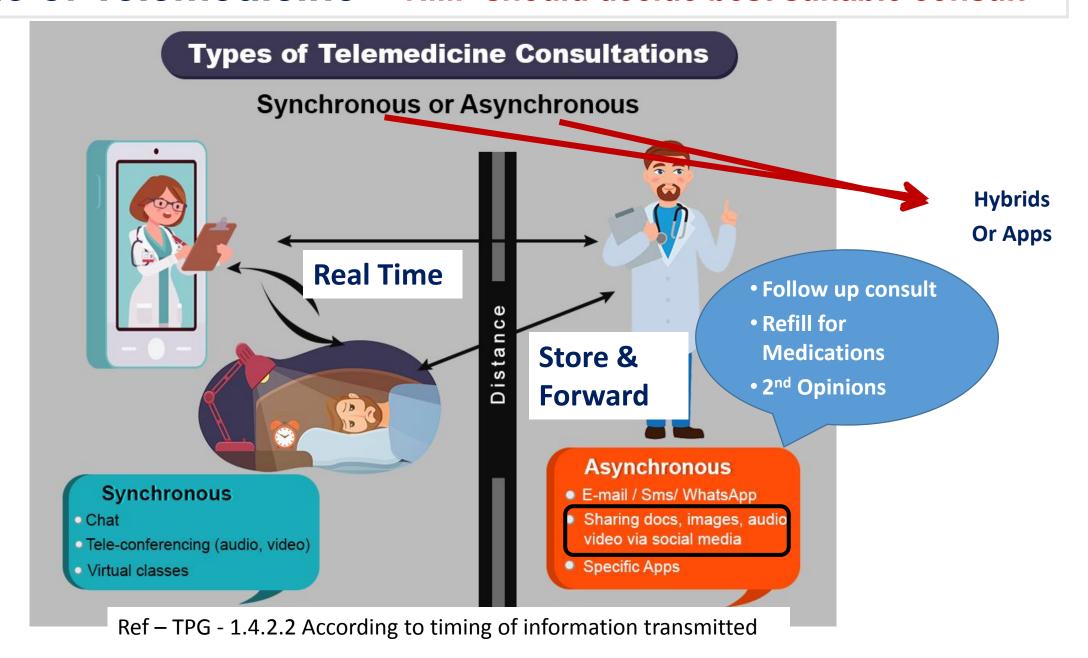
Simple Situations – Tele-consults possible	Complex Situations – In Person consults
35 yrs old male with Dysuria of short duration	35 yrs old with dysuria and hematuria
7 yrs old whose has foreskin does not retract back	7 yrs old fell has pain and swelling in left side of scrotum
50 yrs old diabetic who has frequent Urination	50 yrs Old Diabetic with right flank pain, dysuria and fever
35 years old male asthmatic has needs a refill of his medication – Puff and tablets	35 years old male asthmatic who has run out of medication and has cough along with breathing problems

2. Identification of RMP and Patient

NO Anonymous Tele-consult Allowed

Patient's Identity	Doctors Identity
 Why important – To ensure that there is No impersonation- Wrong prescription should not be transmitted Minor For Home Healthcare – fraud claims 	Why Important – WHO 2016 report states that 57% doctors practicing allopathic medicine in India are NOT qualified

3. Mode of Telemedicine – RMP should decide best suitable consult



Hybrids - Apps allow Choices of All platforms including Payments

Login & Register

E- Appointments

E-History (facilitates review and referral)

Upload documents, images and Videos (Reports, photos, X-rays, USG ...)

E-Consent

E- Consult

E-prescription

E-payment





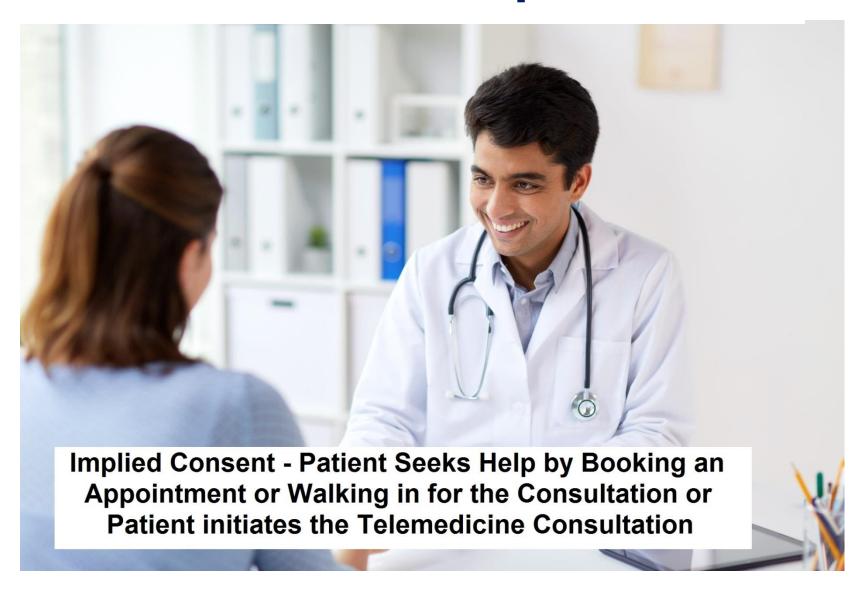




Mode of Telemedicine



4. Consent – Implied



4. Consent – Explicit

The RMP must RECORD Consent in his patient records & preserve the DOCUMENTS



How to Take and Record an Explicit e-Consent?

"Caregiver"- could be a family member, or any person authorized by the patient to represent the patient



- **A. Verbally** informing the rights and duties to the patient
- B. (SMS or Email or Video) with a mandatory need to reply e.g. "Yes, I consent to avail consultation via telemedicine"
- C. Interactive Consent Form by mail or web link Mostly by Checking clicks & Submit

Explicit Consent - Case Scenarios

Explicit Consent	Consenting Process
Mother seeking Tele-consult for a child	Consent from child is not necessary as long as there is proof she is the mother
RMP or Caregiver seeking tele-consult on behalf of patient with RMP but patient incapacitated and unable to provide consent	 Don't do Tele-Consult if you are not sure. Suggest they go for in person consultation If there is a prior relationship with RMP or caregiver, you may proceed with caution If you don't know the RMP or caregiver and there is an absolute emergency - can do it for first aid, or for life saving measure only Do document this type of consult more elaborately

5. Types of Tele-consultation







Ref-TPG – 1.4.2.2 According to timing of information transmitted & 1.4.2.3 - According to the purpose of the consultation

5. First Consult & Follow-Up Consult



Patient is consulting with the doctor for the first time

- or Patient has consulted earlier, but more than 6 months have lapsed since the last consult
- or the patient has consulted earlier, but it was for a different condition or if a new symptoms appear
- or the doctor cannot recall earlier consult.

Types of Consultations - Follow-Up Consult

Follow-Up Consult(s) means-

- The patient is consulting for same condition within 6 months of previous in person consultation
- For this consults other than video consults possible



6. What is Required for Patient Evaluation in Tele-Consultation ?

Similar to Face to Face consultation

Principle – Do no Harm if you can't do good - Non-maleficence

- All possible information like history, examination, investigation, past records, supplemented if required by speaking to a healthcare worker or family member and by any information supported by technology-based tools.
- If PHYSICAL EXAMINATION IS CRITICAL JUDGEMENT, he should suggest such an examination by another RMP or in-person consult.
- If information is inadequate the RMP can request for additional information from the patient and PAUSE the consult and RESTART when such info is available or suggest a face to face consultation.

Safety, safety & More Safety for patient is of utmost importance in making a judgment for Tele-consult or not

In Emergency Situation - Can You offer Telemedicine Services?

Yes it is possible to save a Life – But Role is Limited

 Best for an in-person interaction with an RMP at the earliest

 However <u>IF THIS IS NOT POSSIBLE</u> assistance like Giving First Aid advice or Control bleeding using tourniquet



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Fee for Telemedicine Consultation

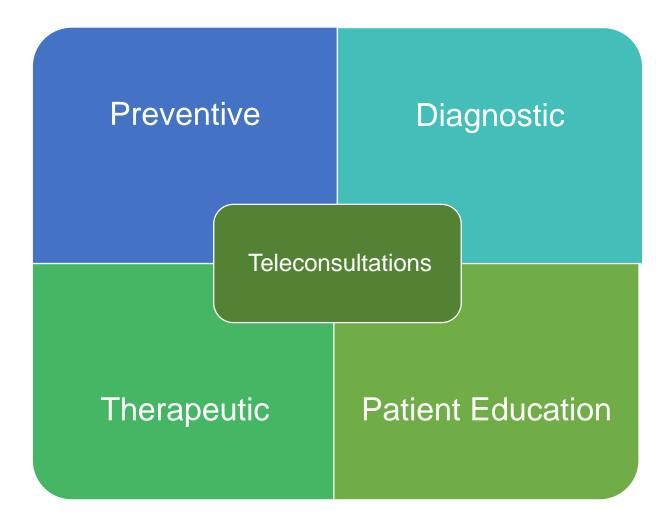
Fees & Reimbursement – Allowed like in-person consultations

Receipt - A receipt / invoice for the fee charged for providing teleconsult should be provided.

Direct Costs Indirect Costs a) for the patients and their families: a) for the potients and their families The lost of a working day Travel costs The lost of a school day b) for the organizations and the system: b) for the organizations and the system. Occupation of physical space and material resources consumption of Consultation Prices, contracted by both involved Hospitals the Hospitals Greater pressure on administrative and clinical services Overload of the specialty's appointment schedule

Health Insurance companies will soon start looking at reimbursement for tele-consults

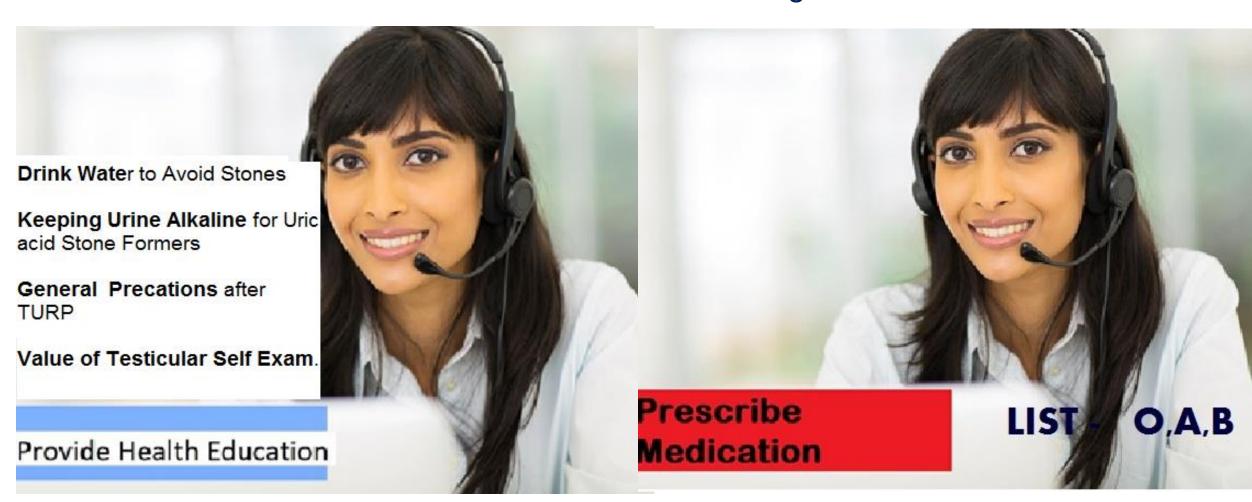
Common Forms of Teleconsultations



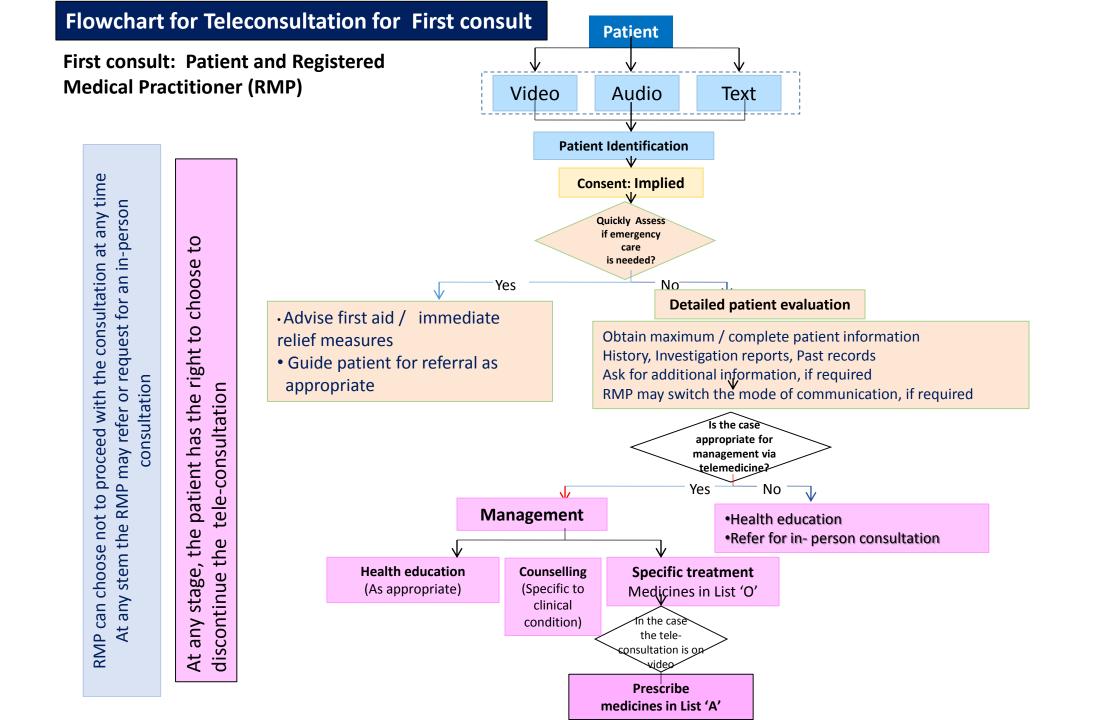
Ref- TPG -1.4.2.3 According to the purpose of the consultation

Patient Management

RMP can decide what is best suited under a given circumstances



Ref- TPG - 3.7.1 According to the purpose of the consultation



TELEMEDICINE PATIENT CONSENT / REFUSAL FORM – A Sample Form

PATIENT DETAILS	
PATIENT NAME: Ram Singh	DATE OF BIRTH: 18/12/1960
ADDRESS: 144, House on Mathura Gate	
Chennai, Pin code - 600010	

•PURPOSE. The purpose of this Consent Form is to obtain your consent to participation in telemedicine consultation in connection with the following procedure (s) and/or service (s):

[insert details] - Hematuria

Symptom or Condition

- •NATURE OF CONSUL.. During the telemetricine consultation, the following may be sought or undertaken:
 - 1.Details of your medical history, examinations, x-rays, and test will be discussed with other health professionals through the use of interactive video, audio, and telecommunications technology.
 - 2. Your physical examination may take place.
 - 3.A non-medical technician may be present in the telemedicine center to aid in the video transmission.
 - 4. Video, audio and/ or photo recordings may be taken of you during the consult.
- •All existing laws regarding your access to medical information and copies of your medical records apply to this telemedicine consultation. Note that dissemination of any identifiable images or information for this telemedicine interaction to other researchers or other entities shall not occur without your consent.
- •Reasonable efforts have been made to eliminate any confidentiality risks associated with this telemedicine consultation.
- •You may withdraw or withhold your consent to the telemedicine consultation at any time without affecting your right to future care or treatment or risking the loss or withdrawal of any benefit to which you would otherwise be entitled.

Undertaking

I have been advised of all the potential risks, consequences and benefits of telemedicine. My registered medical practitioner has discussed with me the information cited above, and I have understood the terms of this telemedicine consultation.

I agree/ do not agree to participate in telemedicine consultations for the procedures/ s and or service /s discussed above.

Signature: _____ Signature of Patient or Caregiver

RMP DETAILS

RMP NAME: Kaml Jeet RMP Registration No.: TNC-35621

Contact Details: 98 3321-67891

Privacy Issues

Confidentiality Issues

Tele-Consult & Prescribing Medications

SHOULD BE DONE WITH UTMOST CAUTION & DISCREETION

The Rule States:

'Prescribing without Diagnosis or provisional diagnosis will amount to a professional misconduct.'

'RMP may prescribe medicines via telemedicine only when RMP is satisfied that he/ she has gathered adequate and relevant information about the patient's medical condition and prescribed medicines are in the best interest of the patient'.

E-Prescription Making Health Care Efficient

Prescription Medication – Four Lists

List O

- Common over-the counter medications such as
 - o Antipyretics: Paracetamol
 - Cough Supplements: Lozenges,
 - Cough/ Common-cold medications (such as combinations of Acetylcysteine, Ammonium Chloride, Guaifensen, Ambroxol, Bromhexene, Dextromethorphan)
 - ORS Packets
 - o Syrup Zinc
 - Supplements: Iron & Folic Acid tablets, Vitamin D, Calcium supplements
 - o Etc
- 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 B

- On follow-up, medications prescribed as <u>'Add-on'</u> to ongoing chronic medications to optimize management such as for hYpertension: Eg, add-on of Thiazide diuretic with Atenolol
 - Diabetes: Addition of Sitagliptin to Metformin
 - o Etc

List A

- First Consult Medications (Diagnosis done on video mode of consultation) such as
 - Ointments/Lotion for skin ailments: Ointments Clotrimazole, Mupirocin, Calamine Lotion, Benzyl Benzoate Lotion etc
 - o Local Ophthalmological drops such as: Ciprofloxacillin for Conjunctivitis, etc
 - Local Ear Drops such as: Clotrimazole ear drops, drops for ear wax etc...
 - Follow-up consult for above medications
- Follow-up medications for chronic illnesses for 're-fill' (on any mode of consultation) such as medications for
 - Hypertension: Enalapril, Atenolol etc
 - Diabetes: Metformin, Glibenclamide etc
 - Asthma: Salmetrol inhaler etc
 - o Etc

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- Following Medicines shall be added to list A of Medicine Lists after the existing entries:
 - Drugs used in Psychiatry practice such as Phenobarbitone, Clobazam and Clonazepam as first consult and as well as follow up.

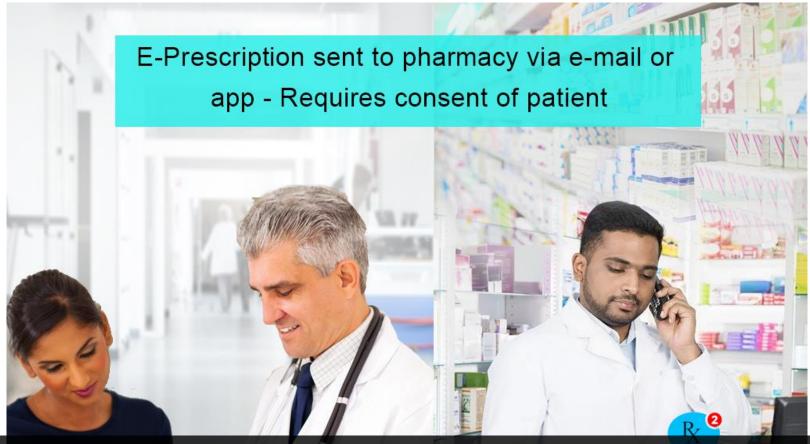


Prohibited Medications - Schedule X Drugs, Narcotics and Psychotropic drugs

Ref – TPG- 3.7.4 Prescribing Medicines &

https://mciindia.org/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Modification%20in%20Medicine%20Iists%20in%20Telemedicine%20Practice%20Guidelin.pdf

How to Issue an E- Prescription and Transmit



RMP shall provide photo, scan, digital copy of a signed prescription or e-Prescription to the patient via email or any messaging platform A sample format of prescription will be available on the ministry's website

Sample E-Prescription in the Guidelines

PRESCRIPTION

REGISTERED MEDICAL PRACTITIONER'S NAME:	CHIEF COMPLA	AINTS: DIAGNOSIS/PROVISIONAL
QUALIFICATION: REGISTRATION NUMBER: ADDRESS:	RELEVANT POI	MEDICATIONS : INAME OF THE
CONTACT DETAILS Mobile: Email:	FROM HISTORY	MEDICINE (III capital letters with
Date of consultation:	EXAMINATION/ FINDINGS:	frequency of administration and
Name of the Patient:: DOB /Age : Gende	r:	duration)
Address: (\	Vhere applicable)	
Height:	SUGGESTED	
Weight:	INVESTIGATION	•
LMP:		

RMP'S Signature & stamp

Note: This prescription is generated on a teleconsultation

e-Prescriptions – Precautions



Suspect Minor:

- Seek age proof
- Don't Prescribe

Basic Phone: (low bandwidth)

Dictate directly to Patient or Chemist the detailed drug information - Check understanding by asking the patient or pharmacist to repeat

Breach Due to Technology

Data Breach of Patient information will be one of the biggest challenges as we go forward RMPs should ensure that reasonable degree of care is undertaken when **hiring such services**.



Ref- TPG - 3.7.1.3 – RMP will not be held responsible for breach of confidentiality... https://uk.norton.com/internetsecurity-how-to-8-ways-to-protect-your-private-information-online.html

Breach Due to Technology – How to Minimize Risks



What Precautions Can You Take?

- Use websites that have a Security Key that Begin with HTTPS and NOT HTTP
- Be Wary of using Free Public Wi Fi
- Use 'Passcode' on your Mobile in Case it is lost



Medical Ethics, Data Privacy & Confidentiality

Medical Ethics - Protect patients privacy & Confidentiality esply. in Video consults **Data Privacy & Confidentiality** - Required to fully abide by -

- Indian Medical Council Regulations of 2002 on Professional conduct, Etiquette & Ethics)
- Relevant provisions of the IT Act,
- Data protection and privacy laws

And any other law notified from time to time for protecting patient privacy and confidentiality and regarding the handling and transfer of such personal information regarding the patient.

Medical Ethics - Examples of Misconduct

DO NOT Solicit or Advertise or give inducement for tele-consults

RMPs insists on Telemedicine, when the patient is willing for in person consult

- Misuse of patient images and data, especially private and sensitive in nature e.g. RMP uploads an explicit picture of patient on Social Media
- Prescribe medicines from the restricted list

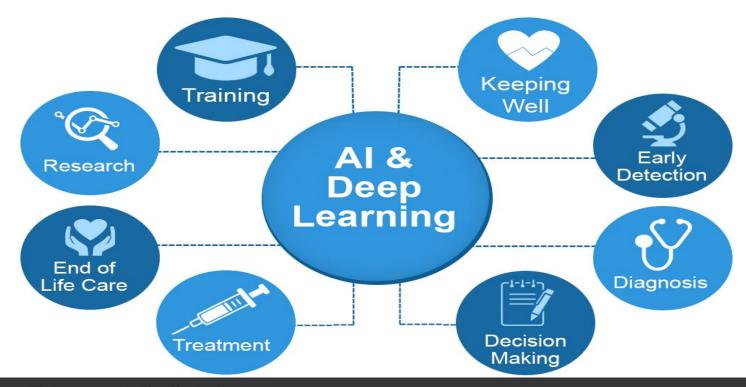
Penalties: As per IMC Act, ethics and other prevailing laws

Maintain Digital Trail & Documentation of Consultation

It is incumbent on RMP to maintain the following records & Hard copy of the documents for the period as prescribed from time to time

- Telemedicine interaction Record or Log Phone logs, email records, chat or text record or video interaction logs including consent
- Patient Records Reports, documents, images, diagnostics, data etc. (Digital or non-Digital) utilized in the tele-consult should be retained by the RMP.
- **Prescriptions** All prescription record that is shared with the patient like in-person consultations.

Is There a Role of Al & Machine Learning for Tele-consults?



Can Be used for Decision Support System
But 'NOT to counsel the Patients or Prescribe any Medicines' automatically to
the patient

Summary of the Telemedicine Practice Guidelines

- Telemedicine and Tele-health practice now allowed in India
- Registered Medical Practitioner empowered to decide the form of consultation appropriate for the patient
- Diagnosis and treatment can be administered using telemedicine technology via Internet

Telemedicine Practice Guidelines

Enabling Registered Medical Practitioners to Provide Healthcare Using Telemedicine



Thank You

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