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Law Decoded for *Entrepreneurs*

Telemedicine: A Beginning of an Online Consultation Mechanism

A primer on Telemedicine guidelines notified on 25th march 2020

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DISCLAIMER:

This Primer is a combined work of Sarvaank Associates and Anicut Capital. Ajay Anand and Dhruv Ranjan from Anicut Capital has given his insight on the business prospects of telemedicine segment. The views expressed herein by the contributors are only for informational purposes. Nothing herein shall be deemed or construed to constitute a legal or business advice.

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"Effective use of technology is important to deliver healthcare. By leveraging technology, you can bring down lack of access and cost of healthcare."

-N.R. Narayana Murthy

Introduction

In today's world where we see technology advancement everywhere and in every sector, healthcare sector is one which is not left behind. Any advancement in healthcare sector is brought well-within the bracket and definition of Digital Health. World Health Organisation (the WHO) defined Digital Health as *"a broad umbrella term encompassing eHealth, as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence."* In simple words any tech advancement in healthcare sector will come under Digital Health.

One component of Digital Health is Telemedicine. In simple terms telemedicine means "the practice of medicine using remote access technology such as telephone, email, video conferencing etc. WHO defined telemedicine as *"the delivery of health care services, where distance is a critical factor by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities*¹."

Telemedicine have their own benefits like timely access to appropriate interventions which includes faster access to services that may not otherwise be available. In India we do not have proper health infrastructure because of which it gets difficult for the population especially rural population to get the proper and timely treatment as the proximity between the two hospitals is much. In such scenarios, telemedicine comes very handy as it is fast and cost effective. Secondly, if there is a situation where there is no requirement of patient to physically visit the medical practitioner like for regular, routine check-ups will reduce the burden of hospitals making it available instantly for emergency like situations. In this Primer, we aim to deal with the newly formulated telemedicine guidelines.

Regulatory Framework W.R.T Telemedicine

Till, 25th March, 2020 there was no clear guidelines regarding practice of telemedicine. Indian Medical Council Act, 1956 (the IMC), The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002, Drugs and Cosmetic Act, 1940 and rules, 1945, Clinical Establishment (Registration and Regulation) Act, 2000 and Information Technology Act, 2000 and Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 are presently the rules and regulations applicable on practice of medicine and Information Technology in India. There are no clear cut regulations which deals specifically with telemedicine. Even the Bombay High Court in its decision in *DeepaSanjeevPawaskar v. State of Maharashtra*² had created an ambiguity and uncertainty about the legitimacy of telemedicine because of absence of any regulations.

¹<https://www.mohfw.gov.in/pdf/Telemedicine.pdf>

²[DeepaSanjeevPawaskar v. State of Maharashtra, Criminal Anticipatory Bail Application No. 513 of 2018](#)



Taking absence of regulatory framework into considerations, the Board of Governors (the **BoG**) of Medical Council of India (the **MCI**) has issued Telemedicine Guidelines (the **Guidelines**) on 25th March, 2020 under the provisions of IMC. The Guidelines are formulated by NITI Aayog and the same is notified as Appendix 5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002.

The primary objective of the Guidelines is to give practical knowledge to medical practitioners to encourage them to consider usage of telemedicine as the part of their normal practice. The guidelines formulated by the government would help and assist medical practitioners in pursuing sound course of action to provide effective and safe medical care to the patients ensuring their safety and well-being. The Guideline provide norms and protocols relating to the physician-patient relationship, issues of liability and negligence, evaluation, management and treatment, informed consent, continuity of care, referrals for emergency services, maintenance of medical records, privacy and security of the patient records, fees.³

FUNDAMENTAL ASPECTS OF TELEMEDICINE GUIDELINES

I. Major Definitions

Guideline 1.1 of 2020 is the definition clause. It defines Telemedicine, Telehealth and Registered Medical Practitioner. The definition of telemedicine is the same as provided by WHO as stated above.

Telehealth is defined 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.

The difference between telemedicine and telehealth is that telehealth is the broader term which includes any usage of technology for health and health related services including telemedicine.

Registered Medical Practitioner (the RMP) is defined as a person who is enrolled in the State Medical Register or the Indian Medical Register under the IMC Act, 1956.

II. Exclusion

Things that are out of purview of these Guidelines are stated in Guideline 1.2. According to them, following aspects are excluded:

- Specifications for hardware or software, infrastructure building and 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 healthcare workers; and
- Does not provide for consultations outside the jurisdiction of India

III. Online Course for RMPs

RMPs can provide telemedicine consultations from any part of India. While practicing consultation by means of telemedicine, RMPs are expected to uphold the same level of professional and ethical norms and standards as applicable over them during traditional in-person care. Further, RMPs are also required to complete compulsory online course to be developed by BoG within 3 months of its

³ <https://www.mondaq.com/india/healthcare/928698/telemedicine-guidelines--a-review->



notification. In the starting phase, RMPs are required to follow the guidelines and once the course is developed, they can practice telemedicine consultation only after completing the course.

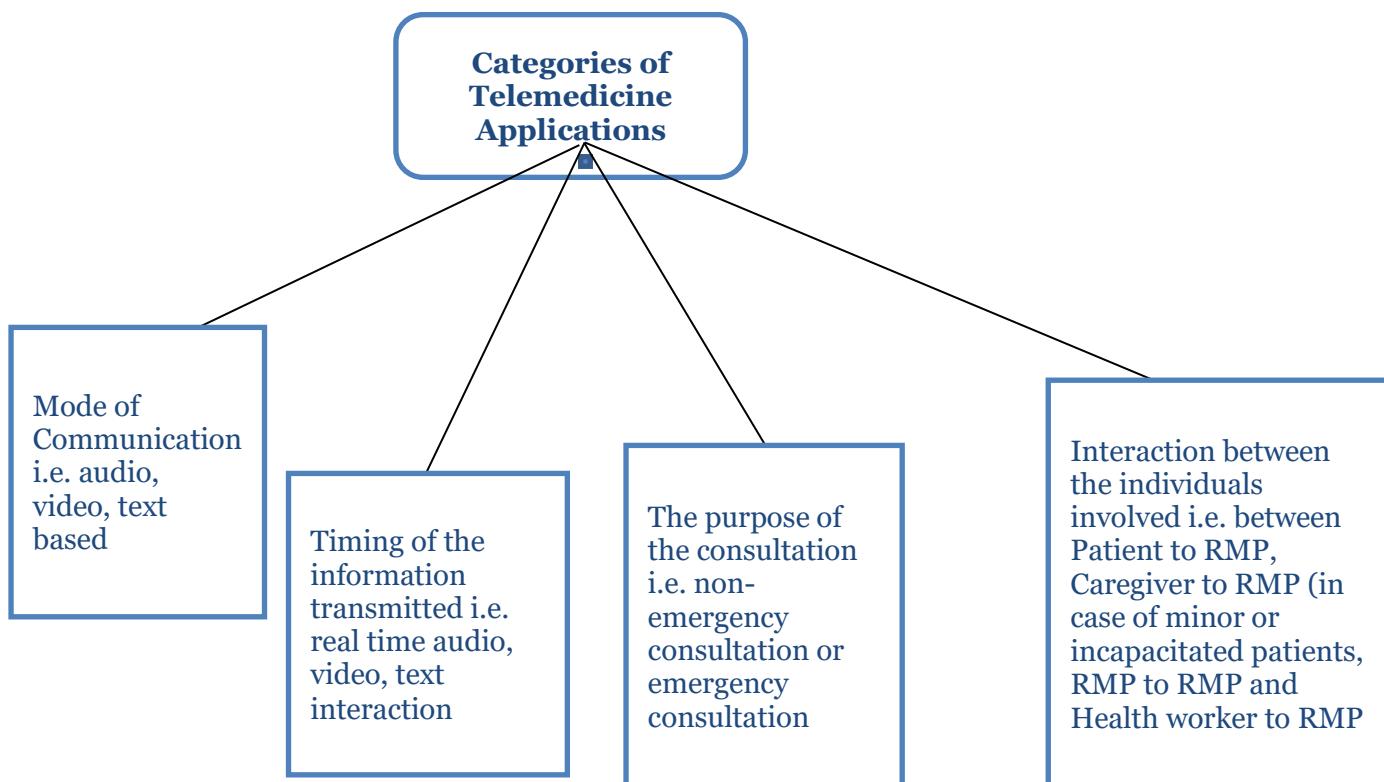
IV. Telemedicine Applications

Guideline 1.4 prescribes various tools that RMPs can use for carrying out technology based patient consultations, such as:

Technological Tools used by RMPs

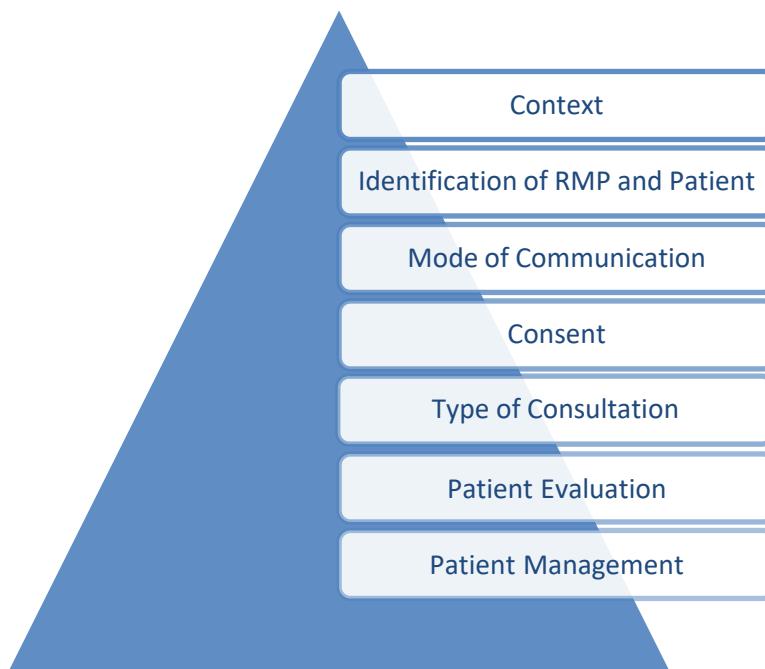
- Telephone
- Video
- Devices connected over LAN, WAN, Internet, mobile or landline phones
- Chat platforms like Whatsapp, Facebook Messenger etc.
- Mobile app or internet based digital platforms like Skype, email, fax etc.

Telemedicine applications are classified into 4 basic categories as enumerated below:



V. Guidelines for telemedicine in India

As stated Guideline 3, RMPs professional judgement should be the guiding principle for all the telemedicine consultations. The seven elements mentioned below to be adhered to at all cost before beginning any telemedicine consultation.



a. Appropriate and Sufficient Telemedicine as per Context

RMPs should exercise their professional judgement and expertise for deciding whether telemedicine consultation is sufficient and appropriate or traditional in-person is needed in interest of the patient. RMPs can decide the mode of consultation according to the availability and their adequacy.

b. Identification of Patient and RMP

RMP and Patient are mandatorily required to know each other's identity. RMP should before beginning telemedicine consultation verify and confirm the following information from the patient's to confirm their identity:

- Name
- Age
- Address
- Email id
- Registered id or any other identification as required

Apart from that, RMP should ensure every means by which patient can verify their credentials. While issuing prescription, RMP should make sure that they explicitly ask the age of patient and in case of any doubt regarding the age, RMP can ask for the age proof. RMP should provide the following details to the patient:

- RMP should inform the patient about his/ her Qualifications;
- RMP to make sure that the Registration Number accorded to them by State Medical Council or MCI is clearly visible on prescriptions, website and electronic communication like Whatsapp / Email etc.

c. Patient Consent



According to Guideline No. 3.4 patient consent is the condition precedent before taking any telemedicine consultation. The consent can be either express or implied depending upon the circumstances, such as:

- **Implied Consent** in case patient initiates the telemedicine consultation
- **Explicit Consent** is required in case a health worker, RMP or caregiver initiates telemedicine consultation. The consent can be recorded in any mode like audio, video and text. Consent can be given like "*Yes, I consent to avail consultation via telemedicine*".

d. Exchange of Information for Patient Evaluation

RMPs to ensure that they gather all the information related to its patient health including information like history, examination findings, investigation reports, past records etc. for exercising proper clinical judgement. The records so gathered should be maintained for each patient by the RMP.

In case the RMP is of the view that information received is inadequate, he/she can ask for some additional information from the patient which can be shared in real time or afterwards through email etc. as decided by the RMP and the patient.

Telemedicine has its own set of limitations. It cannot be used by doctors in every scenario. If the RMP through its expertise thinks that physical examination is necessary then in such scenarios RMP should not move further with telemedicine consultation until and unless physical examination is arranged through in-person consult.

e. Type of Consultation i.e. First Consultation/ Follow-up Consultation

The Guidelines categorizes consultation into two types such as First Consultation and Follow-up Consultation.

First Consultation includes the following:

- Consultation between the RMP and patient for the 1st time;
- The patient has consulted with RMP earlier, but more than 6 months have lapsed from the previous consultation; and
- The patient have consulted with RMP earlier for different health condition
- Follow-up Consultation includes the following:
 - The patient consults with the same RMP within 6 months of his/ her previous in-person consultation in continuation with the previous consultation for the same health condition.
 - If the patient develops new symptoms and the same is unrelated to the health condition for which the patient consulted RMP then the same would not come under the category of Follow-up.
 - If the RMP does not recall the context of previous treatment and advice then the same will also not fall under the category of Follow-up Consultation.

f. Patient Management: Health Education, Counselling and Medication

Depending upon the type of consultation, RMP can either educate the patient regarding his/ her health, provide counselling related to specific clinical condition or prescribe medicines.

RMP may prescribe medicines via telemedicine only when the RMP is satisfied that he/she has gathered adequate and relevant information regarding patient's health condition and the same is in the best interest of the patient. In case the medicines are prescribed without proper diagnosis, the same would be treated as professional misconduct on the part of RMP and will be dealt severely.



The guidelines have restricted prescription of medicines by RMP depending upon the type and mode of consultation. Medicines to be prescribed via telemedicine will be notified from time to time after consultation with the Central Government. Types of medicine to be prescribed via telemedicine are stated as follows:

List O	List A	List B	Prohibited List
<ul style="list-style-type: none">Medicines in this category are safe to be prescribed through any mode of consultation.It includes medicines used for common conditions and readily available over the counter, such as: paracetamol, ORS solution, cough Lozenges etc.	<ul style="list-style-type: none">This will include medicines which can be prescribed during First Consult through video consultation and which can be represcribed for re-fill, in case of follow-up.Medicines included in list A are those medicines which are safe with low potential of abuse.	<ul style="list-style-type: none">This is a list of medication which RMP can prescribe to a patient undergoing follow-up consultation in addition to those which have been prescribed during in-person consult for the same medical condition.	<ul style="list-style-type: none">MRP prescribing medicines via telemedicine cannot prescribe medicines in this list. It is because these medicines have a high potential of abuse and can harm the patient and society if not used properlyMedicines listed in Schedule X of Drug and Cosmetics Act and any narcotic and psychotropic and substance listed under NDPA Act.

While prescribing medicines by RMP via telemedicine, RMP needs to adhere to norms related to issue of prescription as per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations and should not contravene the provisions of Drugs and Cosmetic Act and Rules.

RMP is required to provide either a photo, scan or digital copy of signed prescription to the patient either by email or any messaging platform.

g. Duties and responsibilities of RMP

First and foremost responsibility of RMP is that he/she should at all cost abide by the principles of medical ethics which includes professional norms for protecting patient's privacy and confidential information about his/ her health as per the IMC Act. RMP would not be responsible for breach of confidential information if there is a reasonable evidence to believe that patient's privacy has been compromised by a technology breach or by a person other than RMP.

Misconduct

Any contravention of provisions by the RMP under the MCI Act will be treated as professional misconduct. Acts to be perceived as professional misconduct by RMP while dealing with telemedicine consultation are:

- RMPs insisting on telemedicine when the patient is willing to travel to a facility and/ or requests an in-person consultation
- RMPs misusing patient images and data, especially private and sensitive in nature



- RMPs who use telemedicine to prescribe medicines from the specific restricted list
- RMPs are not permitted to solicit patients for telemedicine through any advertisements or inducements

Penalties

As per IMC Act, ethics and other prevailing laws.

h. Maintain Digital Trail/ Document of Consultation

RMP dealing with telemedicine consultancy is mandatorily required to maintain the following records/documents for the period as prescribed from time to time, such as:

- Log or record of telemedicine interaction i.e. interaction either through 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 RMP.
- In case a prescription is shared with the patient, RMP is required to maintain the prescription records as required for in-person consultation.

i. Fee for telemedicine consultation

As per Guidelines 3.7.3, telemedicine is to be treated in a same manner as that of in-person consultations regarding fee. An appropriate fee may be charged by RMP for telemedicine consultation. Apart from that RMP should give a receipt/ invoice to the patient for the fee charged.

VI. Framework for Telemedicine

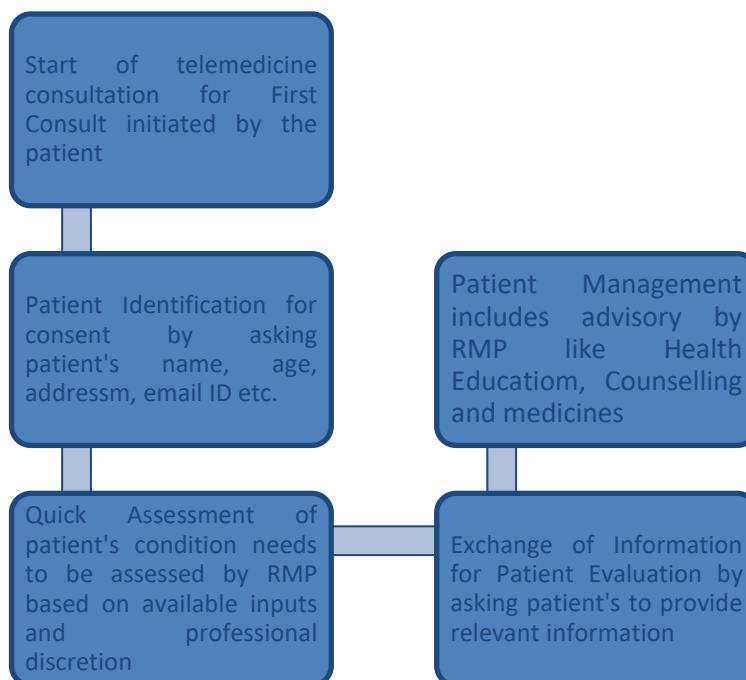
Guideline 4 lays out the framework for practicing telemedicine in 5 scenarios, such as:

1. Patient to RMP
2. Caregiver to RMP
3. Health-worker to RMP
4. RMP to RMP
5. Emergency situations

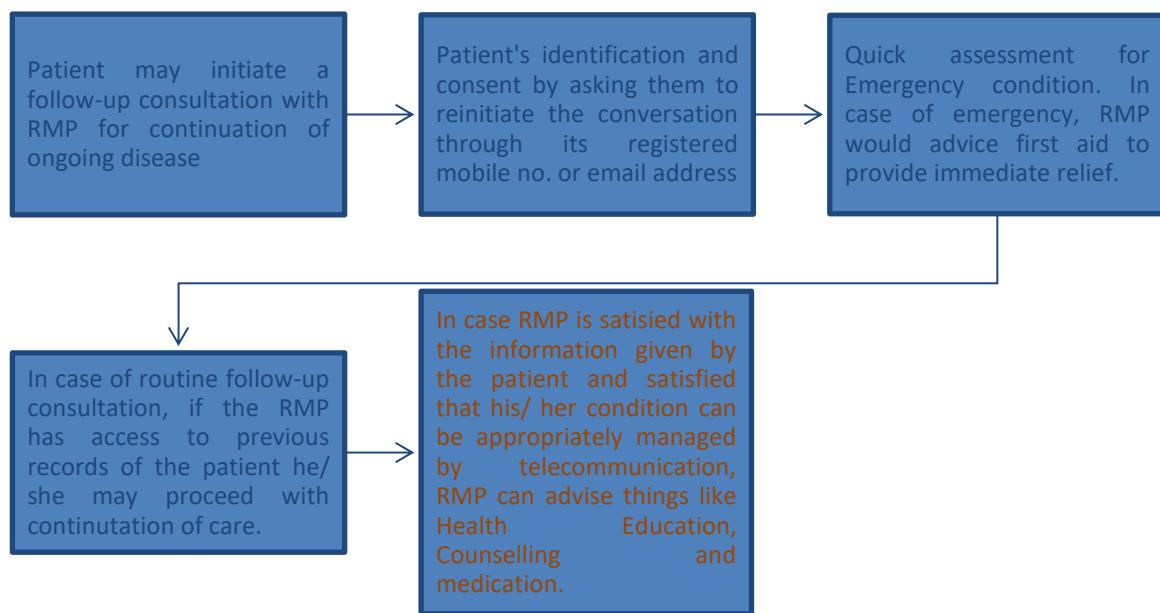
1. Consultation between Patient and Registered Medical Practitioner

This section deals with the key elements of a process of telecommunication to be used by the patient either during First consult or Follow-up consult with RMP.

For First Consult Patient to Registered Medical Practitioner- Process Flow



For Follow-up Consult Patient to Registered Medical Practitioner- Process Flow



2. Consultation between Caregiver and RMP

In case the patient is minor i.e. of 16 years of age or below or the patient is incapacitated due to reasons like physical disability or dementia, there might be a need of caregiver who can consult with RMP giving RMP the better information regarding the patient's health. Caregiver can be any family member, or any member authorized by the patient for representing the patient.

The Consultation process between RMP and Caregiver (with patient or without patient) will be in the same manner as that of Patient and RMP mentioned above which is either a First Consult or a Follow-up



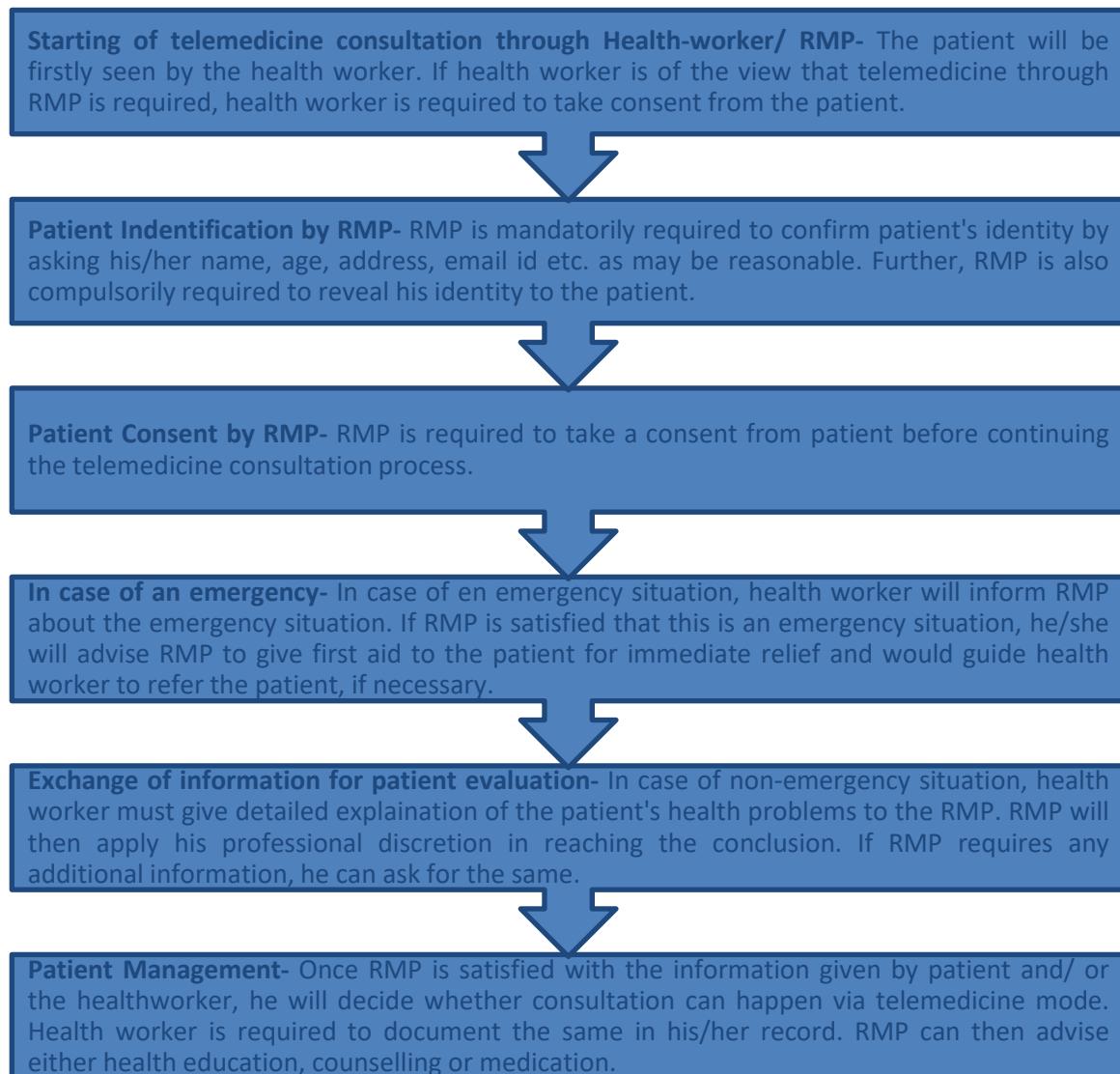
Consult.

3. Consultation between Healthworker and RMP

Health worker is defined in the Guidelines to include nurse, allied health professional, mid-level health practitioner or any other health worker authorized or designated by the appropriate authority.

Healthworker seeking consultation for a patient in a public or private health facility can seek help from RMP via mode of telemedicine.

For consultation between RMP and Healthworker- Process Flow



4. Consultation between RMP to another RMP/ Specialist

RMP can while treating a patient under his care take consultation with another RMP or specialist. Such consultation can be taken by RMP based on his professional discretion. RMP taking advice from another RMP will solely be responsible for treatment and other recommendations given to the patient.



VII. Guidelines for Technology Platforms enabling Telemedicine

- Technology platforms like mobile apps, websites etc. providing telemedicine services to consumers shall be obligated to ensure that customers are consulting with RMP duly registered with national medical councils.
- Technology platforms dealing with telemedicine is required to do proper due-diligence before listing any RMP on the telemedicine platform.
- In case of non-compliance of any of the guidelines, the platform can report the same to BoG, for appropriate actions.
- Technology platforms using mechanisms like Artificial Intelligence (AI), Machine Learning (ML) etc. are not allowed counsel the patients. Only registered RMP can counsel and communicate with the patient.
- Technology platform should keep in place the proper mechanism to address the queries and grievances that the end customer may have.
- In case any technology platform is found in violation, BoG may blacklist such technology platform and no RMP can use the platform to provide telemedicine.

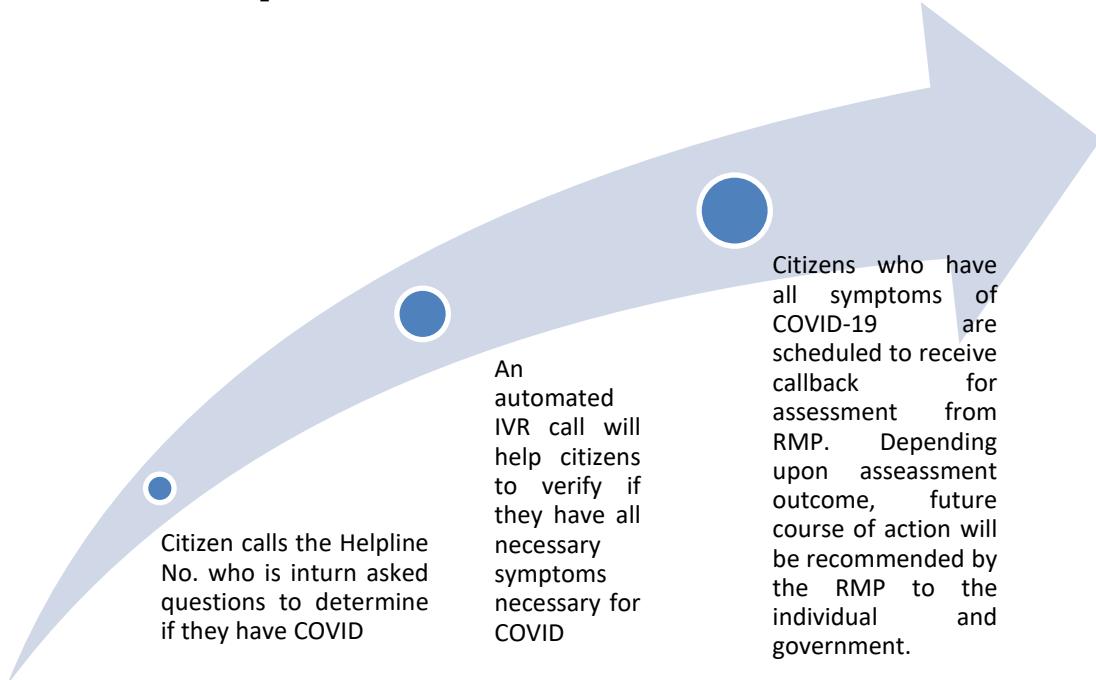
Business Perspective and Case Study

COVID-19 pandemic has led to the innovation of many technologies and one such technology is telemedicine. Since the government has notified the Guidelines w.r.t telemedicine, many start-ups have lend their hand and started working towards achieving the government's goal of maintaining health of every citizen without even going to hospitals. Through this we not only maintain hygiene of the citizen but also maintain social distancing protocol.

In this regard and to help the government in fighting with COVID-19, many start-up founders, doctors etc. have stepped up and created COVID Telemedicine Helpline with the name **StepOne**. StepOne uses very simple method like a person will call a helpline no. which will provide them with options to choose their symptoms which will be followed by a call from RMP in order to confirm the findings. Based upon the findings, RMP recommends the next steps to the individuals as well as the government. The USP of StepOne is that they have made the telemedicine facility available in vernacular language, i.e. in native dialect of the patient.



The Process flow of how StepOne works:



India has the advantage of low mobile phone data prices and high internet penetration. Leveraging the two attributes, telemedicine can vastly help in times of COVID to provide accessible healthcare to even the remotest parts of the nation. Here, we also have to take into consideration the affordability. India still is a nation where the allocation of spend in healthcare is relatively low. Any venture to build out a business in this space should keep in mind the price sensitivity surrounding it. At the same time, there should be emphasis of low cost of customer acquisition. Some ways for acquiring customers at scale at low cost could be:

- **Partnering with mobile carriers-** In today's times, the mobile operators are struggling to sustain their bottom line and are betting on other revenue streams such as OTT based video content. Here, telemedicine could be a hidden opportunity, any venture can partner with existing telecom operators to provide a built-in telemedicine app in a user's phone and come into a revenue share model with the mobile operator. The revenue to the mobile operator can either come on a per consultation basis or by charging a minimal amount to the telemedicine service provider for the app installation.
- **Partnership with private hospitals-** Telemedicine started in 2001 when the Indian Space Research Organisation (ISRO) began a pilot project, linking the Apollo Hospital in Chennai with the Apollo Rural Hospital at Aragonda Village in Andhra Pradesh. At present, Apollo TeleHealth runs about 700 healthcare centres in Public-Private-Partnership mode across India majorly spread across Andhra Pradesh, Himachal Pradesh, Uttar Pradesh and Jharkhand, touching more than 11.4 million. From the above, it is well clear that the private hospitals indeed have had a taste of scaling telemedicine in the remote rural areas of the nation. Any venture would gain immense value in terms of reach and a trusted partner brand which would help them to acquire



customers. This partnership will also help the telemedicine venture to get access to a very curated pool of doctors from the hospital.

The next and most important aspect of telemedicine is building the necessary ecosystem around it. At present lot of work is happening in terms of Artificial Intelligence (AI) which can address the generic queries of a patient, decipher the reports to give a conclusion and analyse the patient data set to suggest lifestyle changes. The problem is making the user trust an AI as talking to an anonymous doctor is challenging for a patient. Also, there is a dire need for a small offline tech enabled center which is equipped with DIY medical devices for the necessary tests and checks. The startups should ultimately move in the direction of setting up a hybrid model where, along with the pure mobile based telemedicine solution, there should be a low cost offline center which enables live consultation with the doctor who can instruct the patient to conduct tests using DIY med devices. Start-ups can also look for developing an app in vernacular language which can be used by telemedicine platforms for those users who lack knowledge of English or Hindi.

Conclusion

Telemedicine Guidelines issued by BoG can be summarized as step in a right direction. The Guidelines is very much within the contours of law and has finally accorded a legal status to telemedication. Going by the Guidelines, the doctor's liability is limited. He needs to show that there is consent and on the basis of such consent, the services have been provided by the doctor. In case the doctor is prescribing any medicines via teleconsultation, the doctor should ensure that the medicines prescribed should be legibly written. Because in case of illegible writing of the doctor, if patients take some medication which deteriorates the patient's health, doctors will have the direct liability.

In the event doctors are consulted directly without any intermediary then in such scenarios doctor will be liable directly in case of any data breach as it is mandatory under the Guidelines issued by BoG that doctor is required to keep his/ her patient's records. In case there is any intermediary i.e. there is one start-up who provides the platform through which doctor gives teleconsultation to the patients, then in case of any breach of data, the intermediary will be liable and not the doctors. In order to protect themselves from the liability arising due to data breach, the intermediaries will be required to ensure that they have adequate malware and other requisite protection.

In the current scenario, wherein not only India but the entire world is facing the havoc created due to COVID-19, this Telemedicine guidelines is serving as a protective cushion because at this juncture we are required to follow the social distancing protocol. From business point of view also telemedicine has brought with itself ample of opportunity for the whole lot of start-ups who can think of a venture by tagging along themselves by partnering with the mobile carrier and building a platform which can be used for teleconsultation.



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