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Telemedicine in India

The Future of Medical Practice?

October 2020



Telemedicine in India

The Future of Medical Practice?

October 2020

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1. Introduction

Telemedicine is the use of information and communications technologies to improve patient outcomes by increasing access to healthcare and medical information. The Indian Government has adopted the definition of telemedicine provided World Health Organization (“WHO”), as follows.

“*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*”

In the Indian context, telemedicine has the potential to increase access to quality healthcare for all Indians. India suffers from a low doctor to patient ratio with only one doctor for every 1,445 Indians.¹ This disparity is even more pronounced in the rural areas as many doctors prefer to practice in the cities. According to a study conducted by the WHO, 59.2% of all health workers are located in urban areas, where 27.8% of the population resides, and 40.8% of all health workers were in rural areas, where 72.2% of the population resides.² Telemedicine can help smooth over these inequalities by allowing doctors in urban areas consult the rural population, including providing specialized care as necessary.

The COVID-19 pandemic has only served to highlight the importance of telemedicine. Over the past few months, hospitals in India have been overwhelmed with COVID-19 patients and have not been able to make space for non-emergency consultations. Patients are also apprehensive of entering hospitals for fear of being infected with the Coronavirus. Telemedicine is the perfect alternative for such situations. It allows healthcare practitioners (“HCPs”) to provide remote consultations for such patients without either the patient or the HCP being concerned about hospital acquired infections. Telemedicine is also an effective way of treating minor cases of COVID-19 where hospitalization is not required. Patients can be tested from their homes and monitor their symptoms under the guidance of an HCP.

In this paper, we have outlined the legal and regulatory framework regulating telemedicine and provided our inputs on how we see this space evolving. The paper focuses exclusively on the practice of telemedicine by allopathic practitioners and does not deal with the regulations applicable to practitioners of traditional medicine such as Ayurveda, Homoeopathy, Unani and Siddha forms of medicine. We hope this paper serves as a primer for existing stakeholders in the telemedicine space (such as patients, HCPs, telemedicine platforms and investors) as well as those who are testing the waters.

1. <https://health.economictimes.indiatimes.com/news/industry/doctor-patient-ratio-in-india-less-than-who-prescribed-norm-of-11000-govt/72135237>
2. https://www.who.int/hrh/resources/16058health_workforce_India.pdf

2. Business Models

The following business models are prevalent in the telemedicine sector.

I. Consultation Over a Telemedicine Platform

Many telemedicine platforms have been launched in the past few years. These platforms are usually set up in the form of website or mobile applications. The platform connects patients with HCPs where consultation takes place over an app-integrated messaging or calling service. The platform may either provide patients with a list of doctors available on the platform and let the patient choose the HCP with whom to consult or directly connect the patient with the specific HCP. At the end of the consultation, the HCP may send a prescription online over the telemedicine platform on the basis of which the patient may purchase the required medicines. Alternatively, the HCP may also ask the patient to get certain tests done to be able to properly diagnose the underlying medical condition.

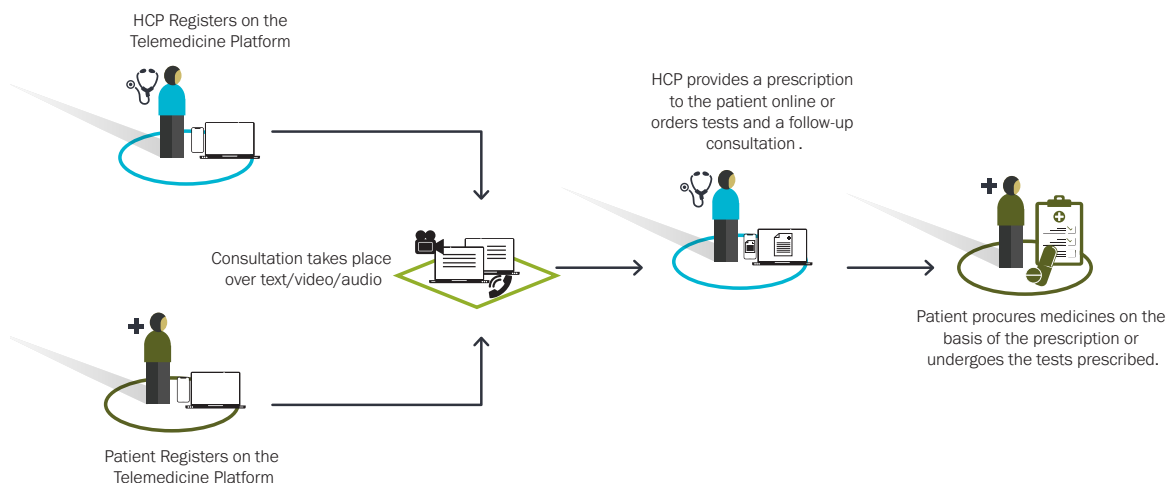


Chart 1: Consultation Over a Telemedicine Platform

II. Consultation Over a Messaging Platform

Patients and HCPs often consult informally over general messaging platforms. The messaging apps are distinct from telemedicine platforms as they are not specifically geared towards providing medical consultation or the collection or processing of health information. The consultation may be initiated by a patient by reaching out to the HCP and may take place over text messaging, call or video facilities provided by the messaging app. At the end of the consultation, the HCP may send a prescription online over the messaging app on the basis of which the patient may purchase the required medicines. Alternatively, the HCP may also ask the patient to get certain tests done to be able to properly diagnose the underlying medical condition.

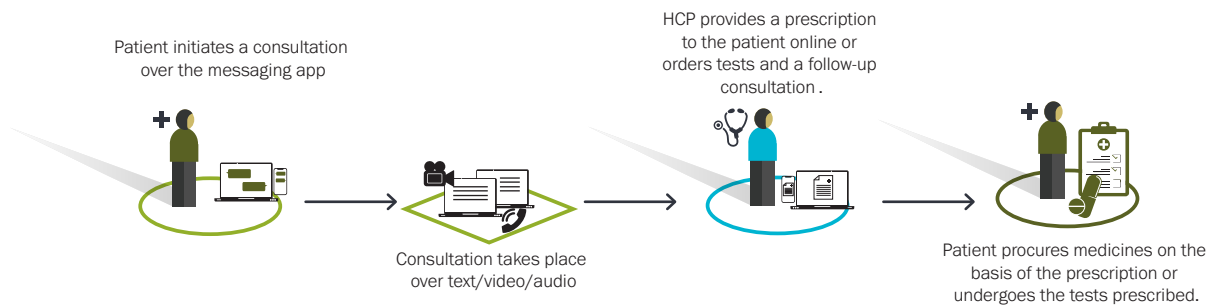


Chart 2: Consultation Over a Messaging Platform

III. Physician to Physician Consultations

As the name suggests, these consultations take place between two physicians when one physician (treating physician/referring physician) consults a specialist regarding a patient under the care of the treating physician. These consultations typically take place informally where the treating physician discloses patient information to the specialist to obtain the specialist’s inputs on the diagnosis or the course of treatment. The specialist typically does not interact with the patient themselves and any advice provided by the specialist is conveyed to the patient by the treating physician.

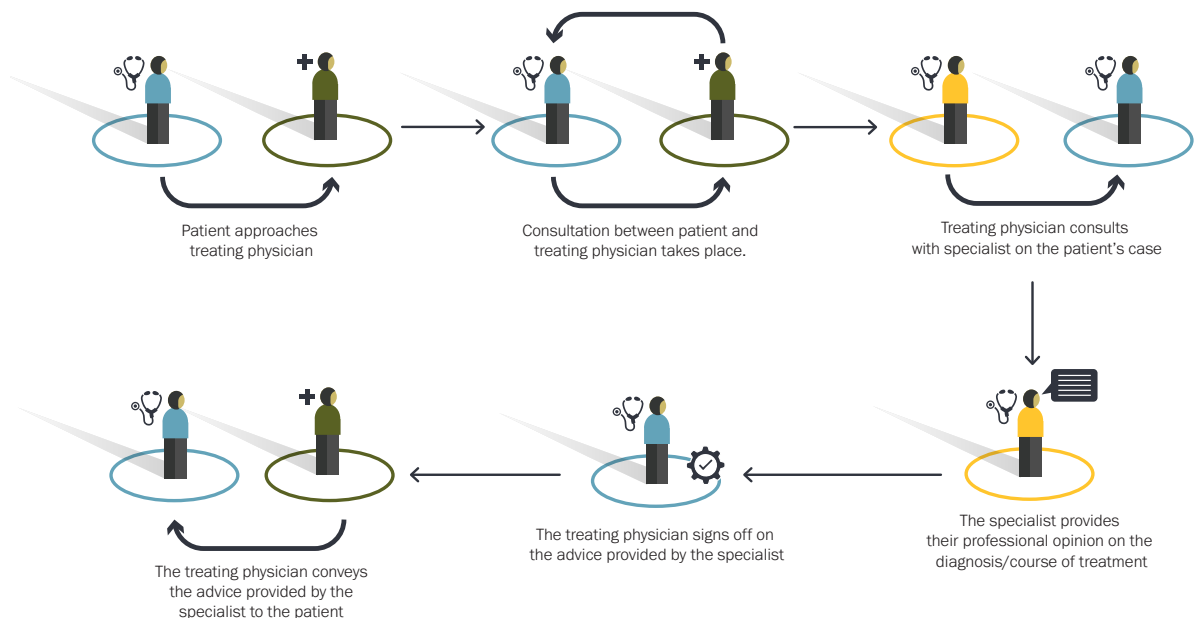


Chart 3: Physician to Physician Consultations

IV. Cross-Border Consultations

Cross-border consultations are a sub-set of physician to physician consultations. Cross-border consultations may take place in two ways:

i. A physician licensed to practice in India reviews medical information of a patient located abroad based on a referral made by a foreign physician. In this case, the foreign physician is the referring/treating physician while the Indian physician is the specialist. The specialist provides medical

advice to either to the patient directly (depending on whether the laws in the patient's country permit this), or provides their professional opinion to the treating physician who ultimately signs off on the patient's treatment plan.

ii. A physician licensed to practice in India consults a foreign physician on a specific case. In this case, the Indian physician is the referring/treating physician and the foreign physician is the specialist. The foreign physician reviews the medical information provided and recommends a course of action. The Indian physician ultimately signs off on this course of action as the treating physician.

3. Regulatory Framework Governing Telemedicine

The following regulations regulate the practice of telemedicine in India.

I. National Medical Commission Act, 2019 (“NMC Act”)

The Ministry of Health and Family Welfare (“**Health Ministry**”) notified the NMC Act in September 2020 as the primary legislation to regulate medical education and the medical profession in India. The NMC Act provides that only those persons who have a recognized degree in medicine and are registered with a state medical council have the right to practice medicine in India.

The NMC Act replaced the Indian Medical Council Act, 1956 (“**IMC Act**”) which regulated the medical profession prior to September 2020. The NMC Act contains transition provisions stating that rules and regulations published under the IMC Act continue to remain in force and operate till new standards or requirements are specified under the NMC Act.³ The rules and regulations are deemed to have been issued under the relevant provisions of the NMC Act itself.⁴ One of the standards framed under the IMC Act is the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (“**MCI Code**”) which lays down professional and ethical standards to be followed by doctors in their interaction with patients, pharmaceutical companies and within the profession. The MCI Code continues to remain in force and will be deemed to have been issued under the NMC Act unless a separate regulation on medical ethics is issued under the NMC Act.

II. Telemedicine Practice Guidelines (“TPG”) Issued under the MCI Code

The Board of Governors instituted by the Central Government for regulating medical education and the medical profession in India (in supersession of the Medical Council of India), issued the Telemedicine Practice Guidelines in partnership with the NITI Aayog. These guidelines have been made part of the MCI Code and are therefore binding on medical practitioners practicing allopathic medicine. The guidelines will remain binding and be deemed to have been issued under the NMC Act unless a new set of rules on this subject is issued under the NMC Act. The Telemedicine Practice Guidelines enable medical practitioners to practice telemedicine in any part of the country, provide guidance on the nature of care that may be provided and the manner of providing such care. For instance, it provides guidance on which mode of communication (audio/video/text) to use for which types of consultation (emergency/non-emergency/ medical practitioner to medical practitioner). The TPG also categorize medicines in List O, List A, List B and Prohibited List and specify which medicines can be prescribed in which situations (covered in detail in Section IV sub-heading 8).

3. Section 61(2) of NMC Act.

4. Proviso to Section 61(2) of NMC Act.

III. Drugs and Cosmetics Act, 1940 (“D&C Act”) and Drugs and Cosmetics Rules, 1945 (“D&C Rules”)

The D&C Act and D&C Rules regulate the manufacture, sale, import and distribution of drugs in India. In many foreign jurisdictions, there is a clear distinction between a drug that must be sold under the supervision of a registered pharmacist on the production of a valid prescription (signed by a registered medical practitioner) and those that can be sold by general retailers over-the-counter (“OTC”). OTC drugs have a different meaning in the context of Indian laws. The D&C Act requires that all drugs must be sold under a license. The D&C Rules clearly lay down which drugs can be sold only on the production of a prescription issued by a registered doctor, which implies that there is a distinction between prescription and non-prescription drugs. Drugs which can be sold only on prescription are stated in Schedules H, H1, and X of the D&C Rules.

The D&C Act states that no person can sell any drug without a license issued by the licensing authority. However, it provides for certain drugs, namely those falling under schedule K of the D&C Rules, to be sold by persons who do not have such a license. Hence, OTC drugs in the Indian context would mean only those drugs that are specified under schedule K. These broadly include drugs not intended for medical use, quinine and other antimalarial drugs, magnesium sulfate, substances intended to be used for destruction of vermin or insects that cause disease in humans or animals and household remedies, among others.

The D&C Rules also state that prescription drugs can only be dispensed on the production of a prescription which is in accordance with the provisions of the rules. For a prescription to be considered valid under the D&C Rules, it must be in writing, signed and dated by the doctor issuing the prescription.⁵ The prescription must also state the name and address of

5. Rule 65(10)(a) of the D&C Rules

the person for whose treatment it is given and also the quantity to be supplied.⁶

IV. The Information Technology Act, 2000 (“IT Act”), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 (“Data Protection Rules”) and the Information Technology (Intermediaries Guidelines) Rules, 2011 (“Intermediary Guidelines”)

Telemedicine involves a constant exchange of information between the patient and the service provider. The patient’s personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information⁷ (“SPDI”) under the Data Protection Rules. When a body corporate⁸ collects, stores, transfers or processes such information, certain requirements under the Data Protection Rules are triggered.

Broadly, the Data Protection Rules stipulate that the data should be collected and processed on the basis of

6. Rule 65(10)(b),(c) of the D&C Rules
7. Rule 3 of the Data Protection Rules defines Sensitive personal data or information of a person to mean such personal information which consists of information relating to (i) password; (ii) financial information such as Bank account or credit card or debit card or other payment instrument details; (iii) physical, physiological and mental health condition; (iv) sexual orientation; (v) medical records and history; (vi) Biometric information
8. Section 43A of the IT Act defines “body corporate” means any company and includes a firm, sole proprietorship or other association of individuals engaged in commercial or professional activities

and in accordance with the consent provided by the provider of information. The Data Protection Rules also require body corporates to put in place adequate security measures to ensure the data is stored safely.

The IT Act is set to be replaced by the Personal Data Protection Bill, 2019 (“**PDP Bill**”) as India’s primary data protection and privacy framework. The PDP Bill also considers consent as the basis for processing of data. However, the PDP Bill is more comprehensive in its approach to data protection compared to the IT Act. We have provided a detailed overview of the PDP Bill in our technology law analysis available [here](#).⁹

V. Government Policies Regulating Health Data

The Indian Government is currently in the process of establishing a national health system with the ultimate aim of storing the medical records of every Indian electronically. The process commenced with the release of the National Health Policy, 2017 which identified the attainment of universal healthcare and the establishment of a National Digital Health Ecosystem (“**NDHE**”) as one its goals. Subsequently, the NITI Aayog (the Indian Government’s think tank) and the Health Ministry have released various policies towards setting up the NDHE. These policies include the National Health Stack and the National Digital Health Blueprint Report which lay down the basic infrastructure and framework for the NDHE. On August 15, 2020, the Indian Government announced the launch of the National Digital Health Mission (“**NDHM**”) – a major digital health initiative which aims to provide a Health ID to every person in the country.¹⁰ Pursuant to this Health Ministry has also recently released the Health Data Management Policy (“**HDM Policy**”) under the NDHM for comments from the public. The HDM Policy covers the data

protection and privacy aspect of the health data and outlines the rights and obligations of all stakeholders involved in the collection and processing of digital health data i.e. patients, HCPs, clinical establishments, pharmaceutical companies, insurance providers etc.

The establishment of a NDHE is currently in the early stages of development. Once such a system is put in place, HCPs providing teleconsultation would have the option of accessing their patient’s electronic data quickly and easily. It should be noted, however, that both HCPs and telemedicine platforms may be required to undertake certain compliances to ensure that they handle patient data in compliance with the policies framed under the NDHE.

VI. Other Service Providers Regulations under the New Telecom Policy 1999 (“OSP Regulations”)

Service providers who render “Application Services” - which includes telemedicine services – using telecom resources provided by telecom service providers, are required to be registered as an ‘Other Service Provider’ (“**OSP**”) with the Department of Telecommunications.

Generally, the OSP registration requires the registration holder to comply with certain conditions as part of the license.

VII. Telecom Commercial Communication Customer Preference Regulations, 2018 (“TCCP Regulations”)

Telemedicine platforms may be required to send SMS to patients and users on the platform. Sending unsolicited commercial communications over voice or SMS are prohibited under the TCCP

9. New Data Protection Law Proposed in India, Nishith Desai Associates, available here: https://www.nishithdesai.com/fileadmin/user_upload/pdfs/NDA%20Hotline/Analysis_of_the_New_Data_Protection_Law_Proposed_in_India_.pdf (last accessed September 20, 2020)

10. Hindustan Times, What is the National Digital Health Mission, available at <https://www.hindustantimes.com/india-news/explained-what-is-national-digital-health-mission-and-how-it-will-benefit-people/story-qOKlv3rbkrvBoaR9ZQyvdk.html> (last accessed September 20, 2020).

Regulations. Promotional messages may only be sent to subscribers who have opted in for receiving such communications once registered with an access provider. However, there is no legal bar over sending transactional messages or voice calls. A transactional message is one which is triggered by a transaction performed by the receiver of the message provided the receiver is a customer of the sender and the message

is sent within 30 minutes of the transaction being performed and is directly related to it. For example, any information sent for OTP or purchase of goods and services would be identified as a transactional message. All other messages (even though directly connected with the delivery of goods) may only be sent as per a format registered with the access provider after obtaining the consent of the receiver.

4. Telemedicine Practice Guidelines

The TPG were issued in March 2020 to provide guidance to HCPs on the practice of telemedicine in light of the COVID-19 pandemic. Prior to the issuance of the TPG, the practice of telemedicine was governed in an ad-hoc fashion under applicable provisions of the IMC Act, MCI Code and the IT Act as covered above in the 'Regulatory Framework' section of this paper. While these legislations continue to apply, the TPG has plugged in the gaps in the erstwhile regulation and provided clarifications where necessary.

The stated purpose of the guidelines is to “assist the medical practitioner in pursuing a sound course of action to provide effective and safe medical care founded on current information, available resources and patient needs to ensure patient and provider safety”. Accordingly, the TPG provides a wide berth of discretion to the HCP to determine the correct course of action when consulting patients over telemedicine.

At the moment, the TPG are only binding on a registered medical practitioner (“RMP”) i.e. a person registered to practice with a state medical council as per the provisions of the NMC Act. The TPG will continue to be binding on RMPs unless fresh regulations on this subject are issued under the NMC Act.

The TPG do not apply to dentists or practitioners of traditional medicine e.g. Ayurveda, Unani, Siddha and Homeopathy. It may be noted that the Central Council of Indian Medicine (the body responsible for regulating practitioners of Ayurveda, Unani and Siddha) has released a separate set of guidelines regulating the practice of telemedicine for Ayurveda, Siddha and Unani practitioners. Separately, the Central Council of Homeopathy has released Telemedicine Practice Guidelines applicable to homeopathic practitioners.

As the TPG is binding only on RMPs, other stakeholders of telemedicine such as patients, telemedicine platforms, messaging apps, insurance providers etc. are not bound by these guidelines. Nonetheless, we expect telemedicine platforms to comply with these guidelines as it should encourage more RMPs to register on a telemedicine platform that is compliant with the TPG than one that is not.

We have covered the salient features of the TPG below.

I. Provides Legal Recognition to the Practice of Telemedicine

The TPG explicitly states that an RMP is entitled to provide telemedicine consultations from any part of India.

The formal legal recognition helps lay to rest legal ambiguities on whether RMPs are permitted to provide medical consultation over the telephone. Notably, a 2018 judgement by the Bombay High Court in the case of *Deepa Sanjeev Pawaskar And Anr v. The State of Maharashtra*¹¹ (“DSP Case”) had created uncertainty in the minds of RMPs on whether it was permissible for them to provide medical advice over the telephone. In the DSP Case, the Bombay High Court had rejected the anticipatory bail application filed by the applicant (Dr. Deepa) who apprehended arrest under Section 304 (culpable homicide) of the Indian Penal Code, 1860. While the decision of the Bombay High Court was reversed in appeal by the Supreme Court, many RMPs in India continued to remain apprehensive about providing medical advice over the phone.

In the DSP Case, Dr. Deepa, a gynecologist admitted Dnyanada to her clinic shortly after her initial discharge following a cesarean operation performed by Dr. Deepa. Dr. Deepa did not consult with the patient in-person as she was not present in the hospital but prescribed medicines over the telephone after discussions with the hospital staff. Over time, the condition of the patient deteriorated and eventually Dnyanada passed away. The Bombay High Court held that Dr. Deepa had prescribed medicines without arriving at a diagnosis which amounts to a case of culpable negligence. While the facts of the case do

11. Order dated July 25, 2018 in Criminal Anticipatory Bail Application No. 513 of 2018 passed by Justice Sadhana S. Jadhav of the Bombay High Court.

not deal with the legality of telemedicine specifically (the Bombay High Court at no point stated that it was not permissible for Dr. Deepa to prescribe medicines over the telephone), the observations of the court had nonetheless created confusion on whether telemedicine was permissible in India.

Prior to the DSP Case, the Supreme Court, in the case of *Martin F. D'Souza v. Mohd. Ishfaq*¹² had observed that prescriptions should not ordinarily be given to a patient without actual examination. They have also observed that the tendency to give prescriptions over the telephone should be avoided, except in cases of emergency.

Separately, there was also some ambiguity on whether an RMP registered with one state medical council would be entitled to practice in other Indian states. The MCI Act states that a person whose name is a part of the Indian Medical Register, which is a central register maintained by the MCI, is entitled to practice as a medical practitioner in any part of India, subject to any other conditions laid down under the MCI Act. However, certain state medical council legislations expressly prohibit the practice of medicine within the state unless the medical practitioner is registered with the relevant state medical council. The TPG have clarified that an RMP registered in any part of the country is entitled to practice nation-wide.

II. Specifically Excludes Non-Teleconsultation Aspects of Telemedicine

The TPG specifically excludes the following from its ambit.

- i. Specifications for hardware or software, infrastructure building and maintenance;
- ii. Data management systems involved, including standards and interoperability of such systems;
- iii. Use of digital technologies to conduct surgical or invasive procedures remotely;

12. (2009) 3 SCC 1

- iv. Other aspects of telehealth such as research and evaluation and continuing education of healthcare workers; and
- v. Consultations outside the jurisdiction of India.

To understand why the above has been excluded from the ambit of the TPG, one should keep in mind the circumstances under which the TPG was enacted. While the NITI Aayog and the Board of Governors have been working on regulating telemedicine for some time now, the release of the TPG was expedited in light of the COVID-19 pandemic.¹³ The guidelines are geared primarily towards providing guidance on the process of consulting remotely rather than the regulation of the consulting platforms themselves.

Nonetheless, the exclusions listed above are a key component of the broader concept of telehealth.¹⁴ The regulation of hardware or software specifications for telemedicine platform, standards for data management systems and the regulation of equipment used to conduct surgeries remotely is essential for the protection of patient health. Further, given the general inclination of the Indian Government to regulate digital health technologies, it is only a matter of time before specific tele-health technologies are also regulated.

III. Types of Telemedicine Consultation

The TPG classifies telemedicine consultations into the different types on the basis of mode of consultation, timing of information transmitted, the purposes of consultation and the person to whom advice is provided (patient, caretaker or RMP).

Each type of teleconsultation is further sub-divided in the following categories.

13. Sanchita Sharma, Telemedicine set to transform healthcare in a post COVID-19 world, Hindustan Times, available at: <https://www.hindustantimes.com/cities/telemedicine-set-to-transform-healthcare-in-a-post-covid-world/story-j79r1yEDFxYaE4nlcFNL3L.html> (last accessed September 10, 2020).
14. Tele-health has been defined under the TPG 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 communications technologies”.

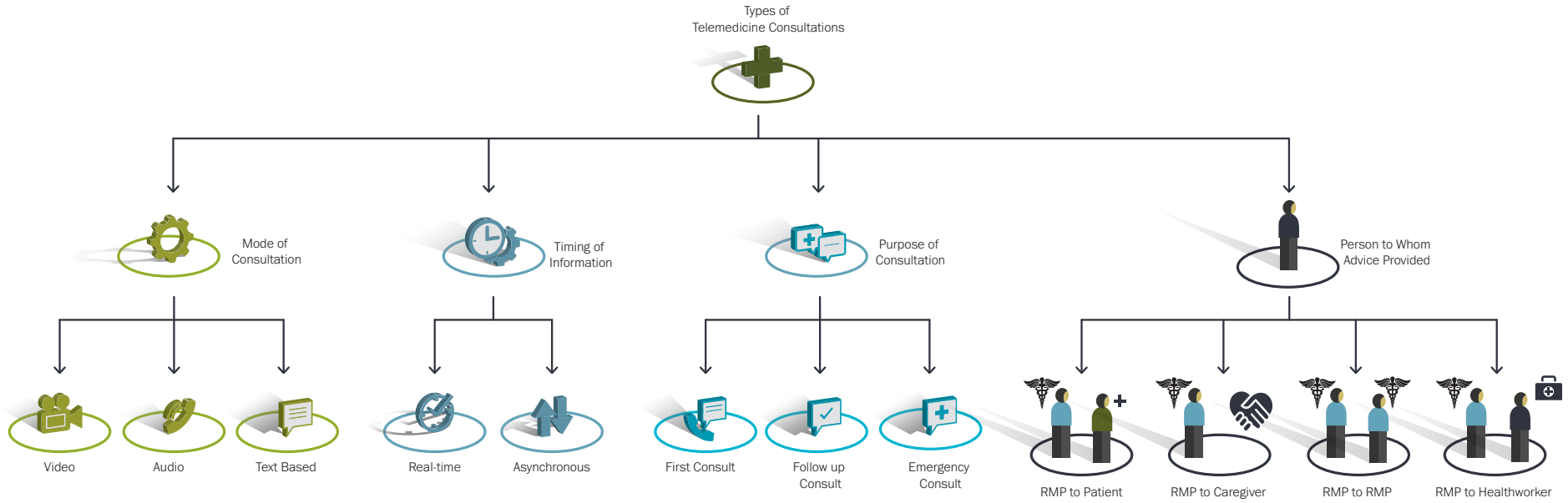


Chart 4: Types of Telemedicine

The TPG does not prescribe any type of telemedicine consultation. Rather, the TPG provide an overview of the advantages and disadvantages of each type of telemedicine consultation and gives discretion to the RMP on the type of teleconsultations best suited for achieving the intended purpose of the consultation.

IV. Situations Where Telemedicine is Permitted

The TPG states that the RMP should exercise their professional judgement to decide whether telemedicine is an appropriate method for providing consultation. The decision to consult by way of telemedicine should be made keeping in mind the following considerations:

- i. The mode/technology for consultation available i.e. if the RMP requires visual examination to arrive at a diagnosis (psoriasis or other skin conditions) and the only mode of consultation the patient/RMP has access to is through a phone call or text messaging, then the RMP should not arrive at a diagnosis or prescribe a course of treatment without physical examination.
- ii. The complexity of the patient's condition. At the start of the consultation, the RMP should inquire regarding the patient's medical history, past test reports or other information necessary. If the RMP believes that additional information or further tests are required for arriving at the diagnosis/treatment plan, the RMP should refrain from diagnosing the patient over telemedicine until such additional information/tests results have been obtained.
- iii. In emergency situations, the RMP may provide tele-consultation if this is the only means of providing timely care. In such situations, the RMP should provide consultation to their best judgement. If there are alternative methods available e.g. in-person care, the teleconsultation should be limited to first aid, life saving measure, counselling and advice on referral. The patient should be advised for an in-person consultation as soon as possible.

In all cases where advice is provided by way of telemedicine, the standard of care is the same as in-person care keeping in mind the intrinsic limits of telemedicine. Therefore, RMPs should ensure that they keep in mind the MCI Code even when providing advice by way of telemedicine.

V. Identification of the Patient and RMP Prior to Consultation

The TPG prohibits anonymous consultation on part of both the patient and the RMP. Each person should provide the following details at the start of the consultation.

Patient

- i. Name
- ii. Age
- iii. Address
- iv. Email ID
- v. Phone Number
- vi. Registered ID

RMP

- i. Name
- ii. Qualifications
- iii. Registration Number granted under the NMC Act (earlier IMC Act)

VI. Consultation to Minors

As stated above, the RMP is required to identify the age of the patient at the start of the teleconsultation. In the event the patient is a minor, consultation should be done in the presence of an adult whose identity should be verified in accordance with the parameters stated above.

VII. Patient Consent

The manner of obtaining patient consent depends on whether the teleconsultation was initiated by the patient, caregiver or by the RMP. In the event the teleconsultation is initiated by the patient, the consent is implied. In the event the teleconsultation is initiated by the caregiver, health worker or an RMP, the explicit consent of the patient should be recorded. The record may be maintained in the form of an email, text, audio/video message.

VIII. Prescribing Medicines

The TPG contains detailed provisions on which medicines may be prescribed in what circumstances as captured below.

A. Outcome of Telemedicine Consultations

In the event the RMP believes that the medical condition can be properly managed over telemedicine, the RMP may proceed with any (or all) of the below.

- i. *Provide Health Education:* The RMP may impart health promotion and disease prevention messages e.g. advice on diet, physical activity, prevention of contagious infections, immunizations, exercises, hygiene practices, mosquito control etc.
- ii. *Counseling:* This is advice specific to a patients' condition e.g. food restrictions, proper use of a hearing aid, home physiotherapy, etc. to mitigate the underlying condition. This may also include advice for new investigations that need to be carried out before the next consult.
- iii. *Prescribing Medicines:* The RMP may prescribe medicines over telemedicine if the RMP is satisfied that the RMP has gathered sufficient information regarding the patient's medical condition to arrive at a diagnosis and the prescribed medicines are in the best interest of the patient.

B. Manner of Prescribing Medicines

The TPG places limitations on the prescription of certain medicines depending upon the facts and circumstances of each case. Broadly, the TPG divides medicines into the following lists.

- i. List O: Medicines which are safe to be prescribed over any mode of teleconsultation. These include medicines for common conditions which are generally available 'over-the-counter' e.g. paracetamol, cough lozenges, ORS solution etc. or medicines necessary for public health emergencies.
- ii. List A: Medicines which may be prescribed over a first consult only in cases where the first consult is over video or as refills in a follow-up consultation. These include relatively safe medicines with low potential for abuse.
- iii. List B: Medicines which may only be prescribed refills during follow-up consultations provided the first consult where medicines were prescribed for the condition took place in person. The medicine may either be a re-fill or a new medicine for the same medical condition.
- iv. Prohibited List: Medicines which an RMP is prohibited from prescribing over telemedicine. This includes drugs specified in Schedule X of the D&C Act or listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985 (India's anti-drug legislation).

The categories of medicines that may be prescribed over telemedicine would be notified by the Government from time to time. As no list has been notified as of this writing, the general guidance provided by the lists would be applicable. The TPG provides an illustrative list of the medicines in each category above which has been provided in this paper as **Annexure A**.

The terms first consult and follow-up consult are defined under the TPG as follows.

- i. First Consult means that the patient is consulting with the RMP for the first time or the patient has consulted with the RMP earlier, but six months have passed since the first consultation or the patient has consulted with the RMP earlier but for a different condition.
- ii. Follow Up Consult means the patient is consulting with the RMP within 6 months of their previous in-person, and this consultation is for continuation of care of the same health condition. However, a consultation would not be considered to be a follow up consultation if there are new symptoms not in the spectrum of the health condition for which the first consult took place or the RMP does not recall the context of the previous treatment and advice.

C. Format of Prescription

The prescription issued by the RMP should be as per the requirements of the D&C Rules as well as the MCI Code. The prescription should specify the registration number granted to the RMP under the MCI Act.

The TPG have significantly streamlined the process of granting digital prescriptions. The TPG stipulate that a photo, scan or other digital copy of a signed prescription or an e-prescription issued to a patient over a messaging platform would be considered to be valid.

Prior to the release of the TPG, there was considerable ambiguity on the legitimacy of e-prescriptions. The D&C Rules require a prescription to be in writing and signed by a registered medical practitioner. Under the IT Act, a document that is required by law to be in writing would be deemed to be in compliance of such law if the same is made available in an electronic form and accessible in a way that it can be used for future references.¹⁵ Hence a prescription uploaded online would fulfill the first requirement of a valid prescription under the D&C Rules. However, the IT Act further states that where a law requires for a document to be signed (the law being the D&C Rules in this case), it would be deemed to be in compliance only if such information or matter is authenticated by means of an electronic signature.¹⁶ Affixing an electronic signature to any

document thus became essential for it to fulfil a legal obligation mandating a regular signature. Therefore, prior to the clarification provided by the TPG, uploading a scanned copy of a prescription may not have been recognized as valid under law.

The TPG also provides for a model prescription format provided below in **Annexure B**.

IX. Misconduct in the Telemedicine Context

The MCI Code provides some guidance on actions that constitute misconduct in general. For misconduct in the telemedicine context, one must turn to the TPG. The TPG states that the below actions would be considered to be misconduct. In the event an RMP is held guilty of misconduct, penalties prescribed under the MCI Act and the MCI Code would be applicable.

- i. Prescribing Medicines without an appropriate diagnosis/provisional diagnosis.
- ii. Failure to uphold patient privacy and confidentiality as required under the MCI Act.
- iii. Failure to comply with the MCI Act, MCI Code or other data privacy laws (such as the IT Act or the PDP Bill if enacted) for handling and transfer of medical information.
- iv. RMP insisting on telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation.
- v. RMP misusing patient images and data, especially private and sensitive in nature (e.g. RMP uploads an explicit picture of patient on social media)
- vi. RMP who prescribes medicines from the specific restricted list over telemedicine e.g. prescribing medicines from the prohibited list or prescribing medicines from List B during a first consult.
- vii. Soliciting patients for telemedicine through advertisements or inducements.

The TPG do not prescribe any specific penalty in the event of misconduct but rather refer to the MCI

15. Section 4 of the IT Act

16. Section 5 of the IT Act

Code for the same. The MCI Code authorizes state medical councils to decide complaints against RMPs. In the event the RMP is found guilty of misconduct, the state medical council may award punishment as the respective medical council deems fit. This may also include removal of the RMP's from the medical council register name (for a specified period of time or altogether) in effect barring the RMP from practicing medicine.

Separately, an action may be brought against an RMP by the aggrieved patient or their legal heirs before a court of law. Such cases may be civil or criminal in nature. Civil cases are typically filed by patients under India's consumer protection laws while criminal cases are initiated by filing a first information report (FIR) with the police.

X. Maintenance of Records

It is mandatory for the RMP to maintain the following records for teleconsultation.

- i. Log or record of telemedicine interaction e.g. phone logs, email records, chat/ text record, video interaction logs etc.
- ii. Patient records, reports, documents, images, diagnostics, data etc. (digital or non-digital) utilized in the telemedicine consultation.
- iii. In case a prescription is shared with the patient, the RMP is required to maintain the prescription records as required for in-person consultations.

5. Guidelines for Telemedicine Platforms

The TPG prescribe certain guidelines for telemedicine platforms. However, as the TPG have been issued as part of the MCI Code (and are therefore binding only on RMPs and not on telemedicine platforms), it is unclear how these guidelines would be enforced, or their violation penalized.

- i. Telemedicine platforms should ensure that patients are consulting with RMPs duly registered with MCI or respective state medical council.
- ii. Telemedicine platforms should provide the name, qualification, registration number granted under the MCI Act and contact details of every RMP listed on the platform.
- iii. In the event some non-compliance is noted, the telemedicine platform is required to report the same to the NMC so that the NMC may take appropriate action
- iv. Telemedicine platforms based on Artificial Intelligence/Machine Learning are not permitted to counsel patients or prescribe any medicines to a patient. However, technologies such as Artificial Intelligence, Internet of Things and advanced data science-based decision support systems may be used to assist and support the clinical decisions of the RMP. In all cases, the final prescription or counseling has to be directly delivered by the RMP
- v. Telemedicine platforms are required to ensure that there is a proper mechanism in place to address any queries or grievances that the patients may have.

In case any specific technology platform is found in violation, the NMC may blacklist the platform thereby discouraging RMPs from using that platform to provide telemedicine. However, no specific penalty has been prescribed for RMPs who continue to provide telemedicine services on a blacklisted platform.

6. Telemedicine Going Forward

The TPG provide a robust foundation on which to more comprehensively regulate telemedicine in the future. The TPG were issued to bring clarity to the process of telemedicine in light of the COVID-19 pandemic and have done an admirable job of clarifying some of the legal ambiguities regarding the status of telemedicine and providing a format for how teleconsultations should be conducted. That being said, there is room to expand the ambit of the TPG and to bring in changes to further consolidate the regulations governing telemedicine in India.

I. Limited Applicability

Issue: The TPG are applicable only to healthcare practitioners registered in accordance with the MCI Act and does not extend to dentists or other entities involved providing telemedicine services.

Background: As a result, the TPG apply only to RMPs. This definition excludes dentists or other health professionals e.g. dentists, nurses and community health professionals who may also provide medical advice over a telemedicine platform. Separately, the TPG also do not apply to other entities involved in providing telemedicine services i.e. telemedicine platforms which connect RMPs with patients and hospitals (in cases where the telemedicine platform is maintained by a hospital for its RMPs/patients) (collectively referred to as “**Telemedicine Service Providers**”).

Recommendation: To ensure that all aspects of the practice of telemedicine are regulated, the TPG (with the appropriate modifications) should be enacted in the form of an act (“**Telemedicine Act**”). The Telemedicine Act should specifically regulate the following.

- i. The types of care that each healthcare practitioner (which term should include nurses, healthcare workers, community health professionals etc.) is permitted to deliver over a telemedicine platform e.g. distinction between the medical advice that may be provided by an RMP as opposed to a community health worker.
- ii. Regulation of practices in addition to telemedicine consultations which are part of the telemedicine umbrella e.g. tele-ICU, tele-nursing, tele-radiology.
- iii. Software and security standards to be followed by Telemedicine Service Providers.
- iv. Regulation of data provided over a telemedicine platform including specific measures to protect the privacy of patients (explained below).
- v. Restrictions on providing care over platforms who are not equipped to ensure patient privacy.
- vi. Division of liability in the event harm is caused to the patient during or due to a teleconsultation.
- vii. Regulation of Artificial Intelligence (AI) and Machine Learning (ML) platforms as the TPG is not applicable to telemedicine platforms that use AI/ML to consult patients.

II. Patient Consent and Data Privacy

Issue: The TPG do not contain adequate guidance on obtaining informed consent from patients nor do they contain provisions on how the patient data may be used.

Background: The TPG consider patient consent as implied in instances where the patient initiates the telemedicine consultation and require the RMP to obtain explicit consent from the patient in cases the RMP has initiated the telemedicine consultation. However, the TPG do not account for the following when obtaining patient consent.

- i. The patient is not informed regarding the limits of teleconsultation prior to commencing the consultation unless such consultation is taking place in the presence of a health worker.
- ii. The patient is not informed regarding how the data they provide may be used. Generally, this information is contained in the terms of use and privacy policy of the telemedicine platform or of

the messaging app. However, patients may not be familiar with or even capable of understanding the privacy policy and therefore may not be in a position to give informed consent.

- iii. The patient may, when initiating a consultation over text, provide unsolicited information regarding their health. Currently, India's information technology and data privacy regulation does not provide guidance on the manner/level of protection this data would be granted as there is no privacy policy/terms of use regulating this data.
- iv. For patients consulting with an individual RMPs over informal messaging apps, it would be responsibility of the RMP to safeguard patient data as per India's data protection regulation. However, India's data protection regulation is not binding on individuals (and only on body corporates or sole proprietorships) due to which patient data provided to individual RMPs is virtually unprotected.

Recommendation: The following steps may be taken to remedy the issues highlighted above.

- i. The RMP should be required to specifically inform the patient regarding the process of the teleconsultation and the limits to telemedicine prior to initiating the consult. This would ensure that the patient has made an informed decision to obtain medical advice over telemedicine.
- ii. The RMP should be required to provide a brief on how patient data would be processed prior to obtaining any health data as part of the process for obtaining consent. To provide further protection, there should be specific provisions in the TPG ensuring a baseline level of data protection to health data provided during a teleconsultation. This would also ensure that in the event any unsolicited health information is provided by the patient, such information would also be granted adequate protection.

III. Protection to Minors

Issue and Background: The RMP is bound to consult minors only in the presence of an adult. However, this

may create issues for minors who wish to talk about sensitive subjects e.g. mental health/reproductive health consultations and are not comfortable discussing these issues in front of a parent/guardian.

Recommendation: Minors above a certain age should have the option of initiating teleconsultations without the presence of a parent/guardian if they so choose. Ideally, the parent/guardian would give consent to the teleconsultation and to the privacy policy but would not be present when the teleconsultation takes place.

IV. Restrictions on Prescribing Medicines

Issue: Medicines in List B can only be prescribed during a telemedicine consultation provided these medicines were first prescribed during an in-person consultation with the same RMP. However, there is no provision for an instance where the medicine was first prescribed during an in-person consultation with a different RMP than the one being consulted via telemedicine.

Background: Under the TPG a first consult means a consultation on a specific condition with an RMP for the first time or if more than six months have lapsed since an in-person consultation even though there were teleconsultations in the interim. A follow-up consultation is a consultation within six months of a first consultation. Some patients may have consulted an RMP on a particular condition prior to the COVID-19 lockdown in India but may not be able to consult the same RMP over telemedicine if the RMP is not available for teleconsultation. In other cases, six months may have elapsed between the last in-person consultation with an RMP due to the COVID-19 lockdown consequently changing the status of future consults from follow-up consults to first consults under the TPG. In all of these cases, patients may not be able to obtain treatment for their conditions or prescriptions for the drugs they require in the event those drugs are specified under List B of the TPG.

Recommendation: The definition of follow-up consultations should be modified to include first conditions in respect of a condition provided by any

RMP and not the specific RMP sought to be consulted over telemedicine provided the RMP who was consulted in-person has already arrived at a diagnosis of the condition and had previously prescribed a drug

listed in List B of the TPG. Further, the six-month time limit between in-person consultations should be removed keeping in mind the exigencies of COVID-19.

7. Conclusion

The release of the TPG is a watershed moment not only for the practice of telemedicine in India but digital health as a whole. One of the biggest obstacles to the adoption of digital health tools is the lack of specific regulation for these technologies. For instance, the Health Ministry has been in the process of regulating e-pharmacies for over two years now without much progress. On the data privacy front, COVID-19 has delayed the passage of the PDP Bill which was expected to provide more information and greater control to Indians over how their data may be used.

However, the passage of the TPG combined with the increased enthusiasm of the government in streamlining the storage and processing of health data, India appears to be at the cusp of the digital health revolution.

Annexure A

List of Medicines

List O

- **Common over-the counter medications such as**
 - Antipyretics: Paracetamol
 - Cough Supplements: Lozenges,
 - Cough/ Common-cold medications (such as combinations of Acetylcysteine, Ammonium Chloride, Guaifensin, Ambroxol, Bromhexene, Dextromethorphan)
 - ORS Packets
 - Syrup Zinc
 - Supplements: Iron & Folic Acid tablets, Vitamin D, Calcium supplements
 - 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 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
 - Local Ophthalmological drops such as: Ciprofloxacin 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: Salmeterol inhaler etc
 - Etc

List B









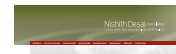
- **On follow-up, medications prescribed as 'Add-on' to ongoing chronic medications to optimize management such as for hYpertension: Eg, add-on of Thiazide diuretic with Atenolol**
 - Diabetes: Addition of Sitagliptin to Metformin
 - Etc

Annexure B

Sample Prescription Format

<p>REGISTERED MEDICAL PRACTITIONER'S NAME</p> <p>QUALIFICATION</p> <p>REGISTRATION NUMBER</p> <p>ADDRESS</p> <p>CONTACT DETAILS (EMAIL AND PHONE NUMBER)</p>																	
Date Of Consultation	<input style="width: 95%;" type="text"/>																
Name of Patient	<input style="width: 95%;" type="text"/>																
Address	<input style="width: 95%; height: 40px;" type="text"/>																
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CHIEF COMPLAINTS	DIAGNOSIS OR PROVISIONAL DIAGNOSIS																
RELEVANT POINTS FROM HISTORY	<p>Rx</p> <p>1. NAME OF MEDICINE (in capital letters only with generic name) drug form, strength, frequency of administration & duration.</p> <p>2. NAME OF MEDICINE (in capital letters only with generic name) drug form, strength, frequency of administration & duration.</p> <p>3. NAME OF MEDICINE (in capital letters only with generic name) drug form, strength, frequency of administration & duration.</p>																
EXAMINATION / LAB FINDINGS																	
SUGGESTED INVESTIGATIONS																	
SPECIAL INSTRUCTIONS																	
		RMP's Signature & Stamp															
<small>Note: This prescription is generated on a teleconsultation.</small>																	

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Our dedication to research has been instrumental in creating thought leadership in various areas of law and public policy. Through research, we develop intellectual capital and leverage it actively for both our clients and the development of our associates. We use research to discover new thinking, approaches, skills and reflections on jurisprudence, and ultimately deliver superior value to our clients. Over time, we have embedded a culture and built processes of learning through research that give us a robust edge in providing best quality advices and services to our clients, to our fraternity and to the community at large.

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As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparalleled mastery. Our TMT practice, IP practice, Pharma & Healthcare/Med-Tech and Medical Device, practice and energy sector practice have emerged from such projects. Research in essence graduates to Knowledge, and finally to *Intellectual Property*.

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