**Title:** Telemedicine & Ethics: Missed Opportunities in India

**Abstract**: The unfurling of COVID- 19 pandemic in gigantic form in such a short span of time has brought the whole world to a complete standstill burdening the existing healthcare industry tremendously. Presently, all nations are making stupendous efforts to control and curb this highly contagious virus transmission. Enhanced risk of exposure, infection and propensity to become super-seeders are just the tip of iceberg ubiquitously being faced by frontline medical and paramedical personnel. Hence, telemedicine has suddenly become one of the favored ways utilized by healthcare workers to continue provision of health care and simultaneously diminishing risk of exposure. Prior to this pandemic telemedicine was seen as an upcoming modality of diagnosis and treatment and was marred by inadequate guidelines and legislations. The current pandemic has made it prudent for policy makers to set forth new guidelines worldwide for ease of operations. The Government of India along-with Medical Council of India has also made an initiative to set up desired directions and regulations to reduce ambiguity and lifting restrictions as a measure to consolidate and simplify Telemedicine Act, 2003. Herein, we briefly describe the recently notified Telemedicine Practice Guidelines of 2020 (Government of India) and bring to the notice the pertinent ethical concerns surrounding the teleconsultation process in our country.

**Keywords**: Telemedicine, Guidelines, India, Ethics

**Introduction**:

The concept of provision of telemedicine or telehealth is not new to India and efforts have been made in the past too. Telemedicine in India saw its birth with ISRO’s (Indian Space Research Organization) Telemedicine Pilot Project in 2001 which linked Chennai's Apollo Hospital with the Apollo Rural Hospital at Aragonda village in the Chittoor district of Andhra Pradesh (1). Thereafter, many institutes came up with telemedicine services like notable telepsychiatry services provided by PGIMER (CDSS) which is being used to provide standardized ways of diagnosing and managing psychiatric disorders (2). Project ECHO (extension for community healthcare outcomes) developed in New Mexico has been integrated by NIMHANS to train Tobacco Cessation Counselors and in the management of addictive disorders (3).

These applauding initiatives and projects were unable to bridge the gap that still exists between research evidence and practical utility of telemedicine. Its progress and acceptability were largely hindered by lack of sufficient resources, tardy process of policy making at the national level as well as state level, poor acceptance by the patients as well as medical professionals, and a range of pertinent medico-legal issues which were not addressed adequately by the existing legislations (4). The Indian laws applicable to telemedicine are those governing the medical profession and information technology namely Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945, the Indian Medical Council Act, 1956, Information Technology Act, 2000 (IT Act), Telemedicine Act, 2003, the Clinical Establishment Act, 2010, and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (5). The Telemedicine Act of 2003 also fell short of addressing the various deficiencies and did not support the growth of this field of medicine.

Now, to somewhat support medical fraternity to combat the ongoing pandemic of novel Corona Virus Disease-2019 or the SARS-nCoV-19 and clear the haze, the Board of Governors in super session of the Medical Council of India notified an amendment to the Medical Council Act, 1956 (102 of 1956) and brought forward the “Telemedicine Practice Guidelines” under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations of 2002. The Government of India subsequently notified these guidelines with effect from 12th May 2020 (6). The amendment, which was a long-awaited requirement of the medical fraternity, aims at provision of easily accessible and affordable health care. We will use only guidelines hereafter to denote the Telemedicine Practice Guidelines.

Firstly, as per the guidelines ‘The purpose of these guidelines is to give practical advice to doctors so that all services and models of care used by doctors and health workers are encouraged to consider the use of telemedicine as a part of normal practice. These guidelines will 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’.

Secondly, the guidelines provide a definition for “Telemedicine” which is the same as provided by the World Health Organization (WHO) i.e. ‘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.’ (7). It also provides for the definitions of “Telehealth” and “Registered Medical Practitioner”. The former 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” (8). In comparison to telemedicine, telehealth is considered to be a broader term and encompasses not only provision of the consultation but also the means (i.e. digital technology) through which the purpose of teleconsultation is fulfilled. Further, a registered medical practitioner is described as “a person who is enrolled in the State Medical Register of the Indian Medical Register under the Indian Medical Council Act 1956’ (9). The guidelines further lay the protocol to provide telehealth services to the masses under various sections and sub-sections. Without discussing the details of the guidelines, we here try to highlight some of the major ethical concerns which are not addressed in these guidelines.

1. **Informed consent**: Informed consent is a safeguard which protects the rights of patients as well as is a shield for the doctor to any future litigations and accusations for breach of patient’s rights. It must include full description of all therapeutic procedures, risks, alternative approaches, and process through which procedure can be cancelled by patient at any time. The telemedicine guidelines recommend that consent must be sought prior to providing any medical consultation (6). Further, if the patient initiates it, then the implied consent is considered and during video consultation, the RMP is supposed to seek an explicit consent from the patient. The guidelines also recommend that the RMP must record patients’ consent in his/her records. The guidelines further clarify that medico-legal value of informed consent is applicable in a similar way to telemedicine services as well. However, though patient has the right to seek treatment, but it’s the RMPs prerogative if he believes that consultation can be provided on telephonic platform or a face to face consultation is required. Hence, the RMP may close a consultation in situation which deems a face to face consultation like in emergency situations. This is a welcome step which partly protects the doctor’s rights and his judgment rather than only emphasizing on the need of the patient. So far, it seems that the guidelines address the issue of informed consent. However, the guidelines are silent if the whole conversation with the patient is to be recorded or not, rather it only recommends logging of the calls made by the RMP. Also, an informed consent without the signatures of the parties involved does not carry any meaning in a court of law as a legal document. There also is an overlooked grey area in case of teleconsultation initiated by an RMP with another RMP/specialist (referral). In such cases the patient may have provided consent for treatment only to primary RMP, who further seeks opinion of another RMP or specialist. Therefore, the patient may consider it to be a boundary violation in case a procedure is performed on the patient through referral tele-consultation and hence consent is mandated in both the scenarios. Ben Stanberry (10) has authoritatively written on this aspect of telemedicine as well as other related medico-legal and ethical issues. The author highlights the issue of remotely performing an invasive procedure especially related to healthcare of the seafarers who may at times need specialist services which are not easily accessible onboard.

Although the guidelines bar from performing any surgical or invasive procedure remotely through the use of digital technology, but the vision has been very narrow in outlining this clause. It is reminded that even suggestion of an injectable medicine from RMP to RMP for a patient may be lifesaving in certain emergency situations, but it will be considered as breach of violation of the privacy of the patient if he has not consented for it and the act may be construed as misconduct as per the guidelines.

1. **Standard of care**: The guidelines recommend that a standard of care at par with the face-to-face consultations must be established and maintained in telemedicine services as well. Standard of care by definition is that which a minimally competent physician in the same field would do under similar circumstances (11). With respect to telemedicine it would depend upon the specialty of the physician and mode of communication. The recent guidelines only empower the doctors to provide counseling, prescribe a selected list of drugs and first aid. Any surgical or invasive procedure done remotely is excluded from it. Furthermore, the provision of emergency services through the means of telemedicine may not be completely feasible. The guidelines only recommend that an RMP should identify an emergency condition and advice for first aid and refer the patient. However, it has been left to the judgement of the physician to identify the emergency conditions. But the failed judgements in such scenario have been harshly punished in past such as in case of State of Maharashtra vs Deepa Sanjeev Pawaskar and Sanjeev Pawaskar, 2018 (12). As the field of medicine is so subjective that judgement of a physician may not be same with another and often a serious complication may be overlooked as a common adverse effect. Hence, in the absence of any evidence base it will be impossible to provide same standard of care in telemedicine.
2. **Doctor-Patient relationship**: Establishment of doctor patient relationship is the key ethical component of medical practice and laws and also the main way to appropriate diagnosis and treatment. It includes, gathering information, therapeutic relationship and communication and depends upon mutual trust between patient and doctor developed through time. Telemedicine may be useful in follow up consults on the background of already established good doctor patient relationship. However, during first consults the lack of traditional practice of physical/systemic examination may lead to erroneous diagnosis. This relationship also holds true for referring and referred doctor wherein any interruption of flow of information may make them both liable (13, 14).
3. **Confidentiality:** The issue of confidentiality deepens with telehealth and telemedicine wherein breach of security is an eminent threat. All the documents, records including call logs are to be maintained and stored by the doctor. The situation may worsen when maintaining the personal health records of patients, the storage of data in various digital formats is outsourced to private entities including at times the insurance companies. It may be impossible in the present scenario to establish such a system which is resistant to hacking or for some sceptics to protect from governmental surveillance (15, 16). Another related issue is the accessibility of the full data to the patient. There are two caveats for this aspect- 1. Regarding the ownership of the medical records and 2. Access to the medical records. Although the information provided by the patient belongs to him, but the medical records compiled by the doctor are his property (15). Some contend that the patient may have a right to access his medical records maintained by the doctor/hospital. However, there are no legislations in India which guide us on this contentious subject. Examples have been set in the UK, where the Access to Medical Reports Act, 1988 and the Access to Health Records Act, 1990, grant patient access to their teleconsultation records (10, 15). Further, the British Medical Association also encourages the doctors to provide complete access to their medical records except in the situations where such records are believed to be deleterious to the health of patient or the confidentiality of other people is compromised (also contained in the aforementioned legislations; 10, 15). Some institutes in India provide digital access to only the laboratory investigations or a very limited personal health records for the sake of protection of misuse of such data in inappropriate hands. Also, there are no standardized protocols for ensuring data privacy across various countries, so, a lot of work needs to be done in this arena. Further, the latest telemedicine guidelines partly address the later issues, as international consultations are not allowed using the present telemedicine guidelines and in case there is provision of tele-consultation services, then the doctors are liable to be managed by the ethics and laws of respective country whose citizen have sought tele-consultation.

Also, the present guidelines do not provide any input on ‘specifications for hardware or software, infrastructure building & maintenance’ and has excluded it conveniently. The only progressive development is that the doctor may not be held responsible for breach of confidentiality if there is a reasonable evidence to believe that patient’s privacy and confidentiality has been compromised by a technology breach or by a person other than himself. Legally speaking, even the specialist whom the RMP consults for a patient as well as all the members of the teleconsultation team who are involved in the healthcare, are also duty bound to maintain the confidentiality of the patient. Even it has been contended, that information obtained from other sources about the patient such as medical records or investigation reports will also come under the purview of confidentiality. In such cases, even the third party which provides any medical information about the patient is also duty bound to maintain the privacy of the patient. However, it still remains questionable that to what extent the non-medical professionals engaged in delivery of the tele-consultation services are responsible for ensuring the confidentiality of the patient health records.

1. **Recording of teleconsultations**- Although, the guidelines do not recommend the recording of teleconsultations in India and only maintenance of log of calls is suggested, it also goes on to state that besides the prescription shared with the patient, other records, reports, documents, images, diagnostics, data etc., be it digital or non-digital, shall not be retained by the RMP. However, some professionals and academic/non-academic institutes may be interested in recording the tele-consultations for the purpose of audit, research and teaching. But the guidelines have also excluded the area of research from the guidelines in its present form. So, it would be prudent to seek consent for storing the recorded consultations as well. Another, issue related to this aspect which remains unattended, specifically in certain cases of mental illnesses, is wherein the patient is already pursuing some case in a court of law and produces the recorded consult as an evidence to support his/her claims. The Telemedicine Practice Guidelines of 2020 does not provide any legal framework to address this issue and only states in a passing reference that the RMP must adhere to the relevant provisions of the IMC Professional conduct, Etiquette and Ethics Regulations of 2002 and various provisions of the IT Act, 2000.
2. **Transmission of data**: A major concern in many digital platforms to provide tele-consultation is the encryption of data which is transmitted (17). Again, to highlight, the Telemedicine Practice Guidelines of 2020 have conveniently excluded the issues of specifications for hardware or software, infrastructure building and its maintenance, data management systems involved, their standards as well as interoperability. This issue cannot be brushed aside with an excuse of urgency. The recent example of questions raised on one of the prominent teleconference platforms which was highlighted by many leading media houses and newspapers in India, led to release of advisory from the government of India to not use one such platform that did not provide end to end encryption. Further, there is another interesting caveat to this. If an encrypted content is available in public domain then its decryption is not considered as a breach of privacy and confidentiality and various court rulings in this regard have been available internationally. Furthermore, though the state provides for privacy acts under the Information Technology Act 2000 (India), but what about the safeguards in cases of governmental surveillance. Lately, even the Aarogya Setu application launched in India to fight the COVID-19 pandemic has been criticized by skeptics for its possible breach of privacy of the citizens.
3. **Miscellaneous:** There are certain other issues pertaining to the prescription of certain category of drugs only as well as exclusion of the Schedule X drugs from the prescribed list of drugs in the guidelines. From the perspective of a patient, for example who is suffering from a terminal illness and undergoing through severe pain or an injectable drug user who is already on opioid substitution therapy from a government approved center, cannot avail the benefit of telemedicine to seek a refill of medications from the category of opioids and other Schedule X drugs. Further, although the Insurance Regulator and Development Authority of India (IRDAI) has recently recommend the inclusion of telemedicine in the health insurance benefits, but this issue is still left ambiguous in the recent guidelines with no clarity for the doctor as well as patient. Currently, no health insurance in India covers telemedicine for litigations, claims and reimbursements. Also, though the guidelines have eased seeking teleconsultation for a dependent child or an incapacitated elderly patient, however, without seeing and identifying such a patient may seldom lead the healthcare worker to end up in the claws of legal system. Hence, care must be observed by the doctor in provision of health care services to proxies of the patients. Lastly, the guidelines also provide few recommendations for the technology platforms that enable telemedicine in India, however, it mainly relates to the enrollment of the RMP, verifying their credentials etc. But, various aforementioned ethical concerns which are also aptly applicable to the telehealth providers have been overlooked in the guidelines.

**Conclusion**

The recent effort by board of governors and MCI would provide an impetus to make adequate health services available to remotely accessible peripheral areas in coming times. The provision of an online course on telemedicine to RMPs would also assist them in adapting to its concept and getting in depth knowledge as well overcoming their ethical dilemmas. We may soon see its presence and incorporation in undergraduate course as well in future times. However, the predominant emphasis of the guidelines seem to be the provision of a legal framework to enable telemedicine to address the healthcare issues in this tough battle with COVID-19 pandemic.

The issues of informed consent, doctor-patient relationship, confidentially and privacy, standards of care, and the management of the data so generated have still not been amply addressed. Utilization of telemedicine in performance of any invasive procedures remotely may at times be life saving for a patient, but they have been outrightly banished. It is always prudent to have methodologically sound, evidence-based, and ethically appropriate guidelines for delivering telemedicine services. Although the Telemedicine Practice Guidelines in its present form make the provisions of services very easy for the health care provider as well as the health seeker. However, a lot of work is still needed to address the various ethical and legal aspects of telemedicine in India.

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