**Title:** Telemedicine & Ethics: 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 Board of Governors (in supersession of the Medical Council of India) notified an amendment to the Medical Council Act, 1956 and brought the Telemedicine Practice Guidelines of 2020 to lay a framework of provision of telemedicine in our country. This is a very much welcome step that was awaited for many years by the medical fraternity and shall provide medico-legal background to assist in delivery of online health services. However, the guidelines, in its present form, partly address the ethical aspects pertinent to telemedicine in India. Herein, we briefly describe these guidelines and bring to the notice the relevant ethical concerns surrounding the teleconsultation process in our country. We also suggest possible solutions to these ethical issues surrounding the practice of telemedicine.

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

**Introduction**:

The concept of provision of telemedicine or telehealth though not non-existent, yet is still naive to India. 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 Post-graduate Institute of Medical Education and Research (PGIMER) which developed a computerized diagnostic support system (CDSS) that 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 National Institute of Mental Health and Neurosciences (NIMHANS) to train Tobacco Cessation Counsellors (TCCs) and in the management of addictive disorders (3).

However, these applauding initiatives and projects were unable to bridge the gap existing between research evidence and practical utility of telemedicine. Lack of sufficient resources, tardy process of policy making at the national as well as state level, poor acceptance by the patients as well as medical professionals, and a range of pertinent and unaddressed medico-legal issues are some of the attributing factors (4). A major reason is confounding Indian laws applicable to telemedicine that govern both 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).

Telemedicine saw an impetus recently with the advent of pandemic of novel Corona Virus Disease-2019 or the SARS-nCoV-19 when the Board of Governors in supersession of the Medical Council of India notified an amendment to the Medical Council Act, 1956 (102 of 1956) bringing forward the “Telemedicine Practice Guidelines” under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations of 2002. The Government of India (GOI) 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. 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 though touched, yet not fully covered by the guidelines. We also purpose the possible solutions to address these ethical issues via the mechanism of bringing out them in form of a revised telemedicine act or rules.

1. **Informed consent**: The concept of an informed consent is verified, however, surge of digitisation in 21st century warrants an altered guiding principle for the same. Though the principle of an informed consent has been grounded on an ethical and legal framework which provides autonomy and a voluntary choice to the patient in routine medical practice or research; it also keeps in consideration the cultural values of an individual. In a traditional form of signed paper consent, the medical professional discloses the relevant information about an investigation or treatment or a new research drug/intervention (for research trials) and discusses this with the patient face to face (10). The patient is expected to take an informed decision after a proper understanding of the available choices and authorizes the medical professional to go ahead. However, in addition to clinical aspects, telemedicine affirms the addition of few other issues in informed consent. Before elaborating further, we highlight one of the medico-legal cases pertaining to telemedicine. In 2005, Dr. Christian Hageseth, a psychiatrist, provided a prescription of fluoxetine (an anti-depressant) to a patient who consulted from the state of California, USA. The prescription was provided on the internet after the patient fulfilled the diagnostic criteria for moderate depression on a questionnaire. Unfortunately, the concerned patient committed suicide after a month. Interestingly, the online teleconsultation company operated from outside USA and Dr. Hageseth was licensed to practice in the state of Colorado, USA. Eventually, in the absence of record of patient consent, Dr. Hageseth was sentenced to 9-months prison as the court pronounced punishment considering him being not licensed in the state of California (11; 12). It is however very difficult to predict the altered course of action with presence of informed consent.
2. **So, when and how to seek informed consent?**: Informed consent is a safeguard which protects the rights of patients as well as the doctor from any future litigations and accusations for breach of patient’s rights. The telemedicine guidelines has made following recommendations in this regard (6):

* Consent must be sought and recorded prior to providing any medical consultation.
* If initiated by patient (most common scenario), implied consent is considered.
* During video consultation, the RMP is supposed to seek an explicit consent from the patient.
* Medico-legal value of informed consent is applicable in a similar way to telemedicine services as well.
* Providing consultation on telephonic platform or face to face is RMP’s prerogative. Hence, the RMP may close a consultation in situation which deems a face to face consultation like in emergency situations.

Till now, in our routine clinical practice we do not seek consent from the patient to provide healthcare service and it is a kind of implied consent. The same is applicable to the teleconsultation format if one is to go according to the guidelines. Even at our centre where we provide telemedicine services in accordance to the guideline, we seek an oral consent from the patient before providing a consult but we do not video record the consent. Some of the third party platforms which provide teleconsultation to the patients do get an explicit consent to seek their services in form of getting a box ticked to agree to the terms of conditions of their services. However, the same format of seeking consent may not be acceptable here as the patient might not have completely understood the concept of a tele-consult and consequent treatment advised thereupon (13). Although, Kotsopoulu et al., suggested that consent can be written or oral depending upon circumstances, either recording of consent or insertion of electronic patient consent may be prudent and beneficial for both doctors as well as patients (14).

1. **Informed consent in case of reference to another RMP**: An overlooked grey area in case of teleconsultation that looms is when it is initiated by a RMP with another RMP/specialist (referral). In such cases the patient may have provided consent for treatment only to primary RMP. Therefore, a case of boundary violation may arise in case a procedure is performed on the patient through referral tele-consultation. Ben Stanberry (15) 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 current 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 and misconduct if not consented for. We propose that some of the minor procedures which may be lifesaving at times must be allowed to be undertaken by the means of telemedicine after seeking a proper written informed consent. Furthermore, it is also recommended that it is the obligation of the primary RMP to seek a written informed consent in this regard and the same must be provided to the RMP being consulted.
2. **Information and Communication Technology (ICT) component of informed consent in telemedicine**- Electronic or a digital informed consent encompass the issues of reading through the whole content of information provided online, comprehension of the information, the issues surrounding the maintenance of electronic records, their encryption, de-identification etc. Kaplan and Litewka (2008) rightly pointed out that “What actually should constitute an informed consent in telemedicine” (16). The authors acknowledge the common ethical concerns such as privacy, security, information accuracy and confidentiality as the common issues. But in addition, they also suggest that the involvement of new technologies would embark new hidden risks, hence giving consent implies also consenting to these unseen risks including emotional or psychological. Hence the informed consent must also include the encryption process for protection of privacy, the timeframe for conservation of patient’s data and ways to deal problems associated with the lack of face to face interaction inherent in certain forms of electronic communication (e.g. email, chat). Besides, Schairer et al., (2018) raise a pertinent issue surrounding the commercial terms of use as well as privacy policies for informed consent process (17). The informed consent sought by some of the tele-health platforms and mobile health systems include the finer details of whole process akin to that being followed in most of the online consumer services (banking, online shopping). We believe it to be a painstakingly tedious task to read through those micro prints and therefore often patients tick the box in a cursory manner. Secondly, the protection of this data from data mining is essential. Few countries have established laws which guide through the process of collection and dissemination of the health related data such as the Health Insurance Portability and Accountability Act (HIPAA) followed in the US or the Data Protection Act of UK which is used by the National Health Service (NHS). In the Indian context, telemedicine is partly guided by the Information Technology Act, 2000 (IT Act) and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011. The IT Act and the Rules, consider the medical history and records, physical, physiological and mental health condition, and sexual orientation in addition to other details as sensitive personal data which is to be protected by the third parties with utmost sincerity. The Act also lays down rules for securing such data, their maintenance, security and transfer. However, the definition of sensitive data was criticised and at certain instance some of the provisions were even overridden by other terms and the major lacuna was that it kept the government offices out of its purview. To allay these apprehensions, the Supreme Court of India held the right to privacy as a fundamental right protected under the article 21 of the Indian Constitution. Consequent upon this, the GOI has brought the Personal Data Protection Bill in 2018 which is presently with the parliamentary standing committee and stuck due to the current pandemic. In addition, the GOI has also constituted a National Health Authority which will work upon building the information technology infrastructure in the health sector and aim at bringing all the stakeholders under its domain. Recently, in his Independence Day speech, the Indian Prime Minister launched the National Digital Health Mission and as a pilot project it will be taken up in 5 Union Territories of India. This ambitious project will bring the Indian health delivery sector at par with some of the best developed health sectors in the world and open new avenues in teleconsultation.
3. **Format of informed consent in telemedicine**:

Shore (2013) provides a framework of seeking informed consent in the field of telepsychiatry which emphasises on not only just provision of a psychiatry consultation but making the patient understand the whole process of provision of teleconsultation, its limitations in respect of maintenance of confidentiality, logistic issues which may arise as well as the alternative options available (18). He has also provided a useful video teaching guide for the process of informed consent (https://www.youtube. com/watch?v 1⁄4 zWBJDj9owv0&feature 1⁄4 youtube). In the same line, some recent researchers have developed electronic modules of seeking informed consent for teleconsultation as well as participation in clinical research trials. One such example involves the MyHeart Counts study application (19, 20). Another group of researchers at the Yale University had developed an interactive virtual tool to seek informed consent which utilizes virtual coaching, used multimedia elements to educate the patient and enhance their comprehension and understanding of the whole process of informed consent (21). Gianfranco and colleagues (2019) recommend that the informed consent must indicate that data is being collected, the purpose & method of treatment, the subjects with whom data may be shared, identification of the details of the holder of data as well as the methods used to protect data (22). Similar views are presented by another researcher, who has suggested the following recommendations for a good quality consent process (23):

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| **Table No. 1 Components of Informed Consent for telemedicine** (*Cvrkel, 2018*) | |
|  | Deliver information in at least two of the methods namely, written, video or live conversation. |
|  | Use of simple language to explain the top to bottom process of data collection & storage |
|  | Specify the risk of potential breach of data (or becoming public) in neutrally-phrased manner |
|  | Discuss the unexpected consequences, findings or research possibilities |
|  | Provision of an option to withdraw consent and retrieve personal data |
|  | Ownership of data, accessibility and profit agreements |

In the same line we recommend that it must be mandatory to seek an informed consent prior to start of teleconsultation in every case, rather than relying on just implied consent as it may partly protect the RMP from any future litigations. However, the method of seeking an informed consent may vary amongst different teleconsultation set-ups.

1. **Telemedicine and autonomy of patient:** There are two components of telemedicine with different implications for patient autonomy. In one wherein the patient is monitored by means of smart wearable sensors (SWS) which are commonly used for monitoring self as well as remotely by a team of health professionals and the other wherein the patient seeks a one-time medical help. The first case is beyond the scope of this paper as this has not been discussed in the guidelines. In the second case, it will not be wrong to say that the whole process of a teleconsultation starts with due care and respect for the autonomy of the patient (i.e. end user). On one hand, patient has liberty to choose the health-care set-up and on the other RMP may work to build a good doctor-patient relationship by providing a personal dimension of care through video consults. Some authors have reported that face-to-face consultation are valued more by the doctors as well as their patients (24) and is also observed by us in our routine practice of telemedicine since the lockdown. Autonomy of the patients may also be strengthened by increasing their health literacy. Though it is a complex issues, and sceptics have raised doubts about what level of medical knowledge should be shared with the patients for a smooth delivery of healthcare, enhancing health literacy vis a vis the process of various aspects of handling their health records must be performed. It has been purported that by engaging the patients in their own care through the means of telemedicine and telehealth empowers the autonomy of the patients.
2. **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 (25). With respect to telemedicine it would depend upon the specialty of the physician and mode of communication. The recent guidelines only permit the doctors to provide counseling, prescribe a selected list of drugs and first aid. Also a 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 (26). 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. Another aspect of care is the continuity of care. The guidelines recommend when deemed to be seen face-to-face, the physician must ask the patient to visit the doctor. However, we believe that it should not be done in a way of abandoning the patient by just referring to a local centre/hospital. In the best case of continuity of care, the RMP/telemedicine team must have a collaborative system in place by means of which a patient may be referred to a centre wherein communication may be made and relevant health information may be shared. Though, the National Digital Health Mission of India envisages this paradigm also by means of generation of unique health ID card. But a lot of effort, research and practice would be required from the policy makers and the executioners for this digital innovation. As there will be differences in maintaining the standard of care across specialties, so, each specialty must bring out their own practice guidelines which shall be approved by the GOI so that a standard format may be followed across the country.
3. **Doctor-Patient relationship**: The establishment of a doctor-patient relationship is crucial as it influences the patient satisfaction, understanding of the health condition, compliance to treatment and thus outcome of treatment and even psychological well-being (27). This in turn is often influenced by the medium of consultation too. Some authors are skeptical that technology in health will lead to reduction of the humanistic qualities of this profession and that it will lead to depersonalization in delivery of health (28). This increase in psycho-social distance between the doctor and patient may eventually adversely impact the health outcomes. However, few others believe that some specific group of patients such as in psychiatry, may feel less inhibited, stigmatized and intimidated, in comparison to face-to-face consult, and thus provide better avenues for health care (29). Doctors must now be trained to not only seek medical information from the patient, but also be able to provide a comfortable and warm environment with minimal distractions during the process of teleconsultation. Another aspect of a face-to face consult which is lost in telemedicine is the non-verbal behavior of the patient and the lack of touch (physical and emotional). It might be of much importance in certain branches of medicine such as psychiatry where the diagnosis is often based upon the non-verbal behavior and affective responses of the patient (30). Doctor-patient relationship may be also be influenced when a consultation is made between one RMP and other. On one hand, the primary practitioner (nurse or an RMP) may supplement medical information, provide findings of physical examination, and non-verbal cues and co-ordinate execution of instructions vis a vis treatment (31). But on other hand, the relationship may be marred in view of a range of factors such as socio-demographic factors, cultural and linguistic background, variance in the levels of medical training, more keenness to obtain medical information on part of the specialist tele-consultant (often ignoring other psycho-social aspects of care) or the nursing practitioner/RMP, who seeks opinion for a patient, may even get intimidated by the stature of a specialist etc. Another variable to doctor-patient relationship in the field of telemedicine, which has not been addressed in the guidelines, is the maintenance of dignity of the such an encounter. In our practice, we have often observed that patients do not follow the decorum of seeking a medical consultation from a doctor through the means of telemedicine. The use of language, posture, dressing, improper selection of a room during the consultation and surrounding disturbances, violations of boundaries (of a professional relationship) have often led to distasteful doctor-patient relationship which is seldom seen in a formal face-to-face consultation in an office/hospital setting. Though the guidelines provide recommendation for the doctors in this regard, but no such provision has been made for the conduct of behavior. We, therefore, propose that to enhance proper utility of telemedicine by the masses in our country, proper training of doctors/health staff at various levels and patient literacy in this context shall form a necessary component.
4. **Technical aspects of telemedicine & ethics**: The technical aspects of telemedicine practice form its basic tenant. Ackerman and others (2010) have provided an overview of the process of developing the technology of telemedicine in keeping with the perspectives of various stakeholders namely the patients, the practitioners, researchers, the providers of healthcare services, professional societies, the healthcare industry and policy makers (32). We here highlight some of the issues which have been only been partly addressed (in some form) in the guidelines at present but are essential in strengthening of the practice of telemedicine in India.
   1. **Confidentiality/ privacy and ownership of the data:** The issueof confidentiality deepens with telehealth and telemedicine wherein breach of security is an eminent threat. 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 (33, 34). 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 (33). 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 ReportsAct, 1988 and the Access to Health Records Act, 1990, grant patient access to their teleconsultation records (15, 33). 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; (15, 33)]. Furthermore, 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 argued 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. Another major concern here is the encryption of data which is transmitted (35) and 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. The solutions to these issues lie in the proposedPersonal Data Protection Act (2018) that provides for the structural framework of various online consumer services, protection of their data, procedures, requirement of the software and hardware, setting up authorities to handle the violation and even penalties in such cases.
   2. **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. Even the telemedicine portal designed by the Ministry of Health & Family Welfare, GOI which is available as eSanjeevaniOPD (<https://esanjeevaniopd.in/>) does not have any provision for the health professional to keep the patient data with them. However, some professionals and academic/non-academic institutes may be interested in recording the tele-consultations/maintaining the patient data for the purpose of audit, research and teaching. But the guidelines have excluded the area of research in its present form.
   3. **Design of telemedicine services**: The primary ethical issues to be considered are the usability and user friendliness of the modality of telemedicine. It must be suitable to different environments (home, office) and different populations intended to use the technology (such as geriatric patients, rural population). Design of these modalities is also influenced by software engineers developing them and marketing strategies. Hence conflict may arise related to the final outcomes promised and desired by the patient.
5. **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.

**Future directives:**

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.

It is always prudent to have methodologically sound, evidence-based, and ethically appropriate guidelines for delivering telemedicine services. We have tried to summarize them in a tabular form for better understanding of the readers (Table No. 2). 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.

**Table No. 2:** Framework to address the ethical issues pertaining to Telemedicine Practice Guidelines, 2020

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| Sr. No | **Ethical concern** | **Recommendation** |
| 1. | Informed consent |  |
|  | 1. When and how to take informed consent | To be taken before every consultation. It can be either oral or electronic. Recording the consent is favoured for prevention of future litigations. |
|  | 1. Referral | Primary RMP obligated to take written informed consent from patient before consulting a specialist. The same should be provided to the referred RMP. This consent would be a safeguard for both the medical professionals and patient. |
|  | 1. IT component informed consent | 1. End to end encryption process for protection of privacy 2. Timeframe for conservation of patient’s data (including sensitive information) 3. To bring out Telemedicine Rules which may incorporate the recommendation of Personal Data Protection Act (pending) to the telemedicine practice guidelines. 4. Establishment of National Health Authority for development of an improvised IT infrastructure would alleviate many of the privacy/security issues. |
|  | 1. Autonomy | Increase health/digital literacy of users/patients to promote self- care |
| II | Standard of care | Only recommended treatment module is provision of counselling, certain drugs and first aid. Affiliation with local centre for dealing with emergency situations is purposed. National Digital Health Mission and creation of single ID may smoothen it. |
| III | Doctor patient relationship | Training of doctors/allied medical personnel in social and communication skills that will enhance a cordial doctor-patient relationship. On part of the user, health literacy and etiquettes of using telemedicine services shall also be undertaken. |
| IV | Technical aspect | Mode of consultation should be user friendly and multiple platforms to seek healthcare facilities may be developed. End to end encryption should be ensured. |
| V | Confidentiality | The informed consent must include the data holders name and confidentiality clause should be added in agreement with software developers. The same clause should be added in job descriptions and work agreements of other staff indulged in health provision.  Personal Data Protection Act (when comes in force) for the structural framework of various online consumer services, protection of their data, setting up authorities to handle the violation would be beneficial.  More laws are required to acknowledge dispersal of information and health records stored in hospitals when patients seek them. |
|  | Research | Research guidelines pertaining to recording of patient data, reports and other documents must be established. |
|  | Insurance | Telemedicine services must be included in insurance and indemnity claims. |

**References**:

1. ISRO Telemedicine Initiative (Internet). Available from:<http://www.televital.com/downloads/ISRO-Telemedicine-Initiative.pdf>. *(Last accessed on 16-06-2020).*
2. Chakrabarti S. Usefulness of Telepsychiatry: A critical evaluation of vidoconferencing-based approaches. *World J Psychiatry 2015*; 5(3):286-304. doi: 10.5498/wjp.v5.i3.286.
3. Chand P, Murthy P, Gupta V, Kandasamy A, Jayarajan D, Sethu L, et al. Technology enhanced learning in addiction mental health: developing a virtual knowledge network: NIMHANS ECHO. In: IEEE Sixth International Conference on Technology for Education, Clappana, 2014:29-32. doi: 10.1109/T4E.2014.14.
4. Gorea RK. Legal aspects of telemedicine: telemedical jurisprudence. *JPAFMAT* 2005;5.
5. Ateriya N, Saraf A, Meshram VP, Setia P. Telemedicine and virtual consultation: The Indian perspective. *Natl Med J India* 2018; 31(4):215-8. DOI: [10.4103/0970-258X.258220](https://doi.org/10.4103/0970-258x.258220)
6. Telemedicine Practice Guidelines: Enabling registered medical practitioners to provide healthcare using telemedicine. Ministry of Health and Family Welfare. Telemedicine Practice Guidelines [Internet]. New Delhi. Available from: <https://mciindia.org/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Final_FAQ-TELEMEDICINE%20%206-4-2020..pdf>. *(Last accessed on 16-06-2020).*
7. Telemedicine. Opportunities and developments in member states. Available from: [*www.who.int/goe/publications/goe\_telemedicine\_2010.pdf*](http://www.who.int/goe/publications/goe_telemedicine_2010.pdf)*. (Last accessed on 16-06-2020).*
8. Tuckson RV, Edmunds M, Hodgkins ML. Telehealth. *N Engl J Med.* 2017, 377(16):1585-92. doi: 10.1056/NEJMsr1503323.
9. The Indian Medical Council Act, 1956. Accessed from: [www.mciindia.org/documents/theIndianMedicalCouncilActs/Complete-Act-1.pdf](http://www.mciindia.org/documents/theIndianMedicalCouncilActs/Complete-Act-1.pdf). (Last accessed on 16-06-2020)
10. Grady C. Enduring and emerging challenges of informed consent. *N Eng J Med.* 2015;372(22):2172. doi: 10.1056/NEJMc1503813.
11. Becker CD, Dandy K, Gaujean M, Fusaro M, Scurlock C. Legal perspectives on telemedicine Part 1: Legal and regulatory issues. *Perm J*. 2019;23:18-293. https://doi.org/10.7812/TPP/18-293.
12. Fields BG. Regulatory, legal and ethical considerations of telemedicine. *Sleep Med Clin* 2020;15(3):409-16. <https://doi.org/10.1016/j.jsmc.2020.06.004>.
13. Recupero PR, Rainey SE. Informed consent to e-therapy. *Am J Psychother.* 2005, 59(4), 319-31. <https://doi.org/10.1176/appi.psychotherapy.2005.59.4.319>
14. Kotsopoulou A, Melis A, Koutsompou VI, Karasarlidou C. E-therapy: The ethics behind the process. *Procedia Comp Sci*. 2015;65:492-9. Doi:10.1016/j.procs.2015.09.120.
15. Stanberry B. The legal and ethical aspects of telemedicine. *J Telemed Telecare* 1998; 4:95-7. DOI: [10.1258/1357633981931632](https://doi.org/10.1258/1357633981931632).
16. Kaplan B, Litewka S. Ethical challenges of telemedicine and telehealth. *Camb Q Healthc Ethics* 2008;*17(4)*:401-16. <https://doi.org/10.1017/S0963180108080535>
17. Schairer CE, Rubanovich CK, Bloss C S. How Could Commercial Terms of Use and Privacy Policies Undermine Informed Consent in the Age of Mobile Health?. *AMA J Ethics* 2018, 20(9):E864-72. <https://doi.org/10.1001/amajethics.2018.864>
18. Shore JH. Telepsychiatry: videoconferencing in the delivery of psychiatric care. *Am J Psychiatry,* 2013; 170(3):256-62. <https://doi.org/10.1176/appi.ajp.2012.12081064>
19. Hershman SG, Bot BM, Shcherbina A, Doerr M, Moayedi Y, Pavlovic A, et al. Physical activity, sleep and cardiovascular health data for 50,000 individuals from the MyHeart Counts Study. *Sci Data* 2019;6(1):24. <https://doi.org/10.1038/s41597-019-0016-7>.
20. Grady C, Cummings SR, Rowbotham MC, McConnell MV, Ashley EA, Kang G. Informed consent. *N Eng J Med.* 2017; 376(9):856-67. DOI: [10.1056/NEJMra1603773](https://doi.org/10.1056/nejmra1603773).
21. Abujarad F, Alfano S, Bright TJ, Kannoth S, Grant N, Gueble M, et al. Building an informed consent tool starting with patient: The patient-centered virtual multimedica interactive informed consent (VIC). *AMIA Annu Symp Proc*. 2017; 374-83.
22. Gioia G, Salducci M. Medical and legal aspects of telemedicine in ophthalmology. *Rom J Ophthalmol. 2019;63(3)*:197-207.
23. Cvrkel T. The ethics of mHealth: Moving forward. *J Dent.* 2018;74(S1):S15-S20. <https://doi.org/10.1016/j.jdent.2018.04.024>
24. Sabesan S, Allen D, Caldwell P, Loh PK, Komesaroff P, Talman M, et al. Practical aspects of telehealth: Doctor-patient relationship and communication. *Int Med J*. 2014;44(1):101-3.doi: 10.1111/imj.12323.
25. Moffet P, Moore G. The standard of care: Legal history and definition: The bad and good news. *West J Emerg Med* 2011;12(1):109-12. PMCID: [PMC3088386](http://www.ncbi.nlm.nih.gov/pmc/articles/pmc3088386/)
26. Deepa Sanjeev Pawaskar And Anr vs The State of Maharashtra, aba513.18.doc, 2018. Available at: <https://indiankanoon.org/doc/160266477/>. Last Accessed on: 16-06-2020.
27. Miller EA. Telemedicine and doctor-patient communication: a theoretical framework for evaluation. *J Telemed Telecare*. 2002;8(6):311-8. DOI: [10.1258/135763302320939185](https://doi.org/10.1258/135763302320939185).
28. Evans HH. High tech vs ‘high touch’: the impact of medical technology on patient care. In: Clair JM, Allman RM, eds. Sociomedical Perspectives on Patient Care. Kentucky, MA: University Press of Kentucky, 1993:83-95.
29. McLaren P, Ball CJ, Summerfield AB, Watson JP, Lipsedge M. An evaluation of the use of interactive television in an acute psychiatric service. *J Telemed Telecar.* 1995;1(2):79-85. DOI: [10.1177/1357633X9500100203](https://doi.org/10.1177/1357633x9500100203).
30. Miller EA. The technical and interpersonal aspects of telemedicine- effects on doctor-patient communication. *J Telemed Telecare*. 2003;9:1-7. Doi:10.1258%2F135763303321159611.
31. Gelber H, Alexander M. An evaluation of an Australian videoconferencing project for child and adolescent telepsychiatry. *J Telemed Telecare.* 1999;5(S1):21-3. DOI: [10.1258/1357633991933297](https://doi.org/10.1258/1357633991933297).
32. Ackerman MJ, Filart R, Burgess LP, Lee I, Poropatich RK. Developing next-generation telehealth tools and technologies: patients, systems, and data perspectives. *Telemed J E Health*. 2010; *16*(1):93-5. <https://doi.org/10.1089/tmj.2009.0153>
33. Stanberry B. The legal and ethical aspects of telemedicine. 1: Confidentiality and the patient’s rights of access. *J Telemed Telecare* 1997;3:179-87. DOI: 10.1258/1357633971931101
34. Lustgarten SD, Colbow AJ. Ethical concerns for telemental health therapy amidst governmental surveillance. *American Psychologist*, 72(2):159-70. <https://psycnet.apa.org/doi/10.1037/a0040321>.
35. Stanberry B. The legal and ethical aspects of telemedicine. 2: Data protection, security and European Law. *J Telemed Telecare*. 1998;4(1):18-24. doi: 10.1258/1357633981931236.