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# Approach to Informed Consent in Telepsychiatric Service: Indian Perspective

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## ABSTRACT

Consent is an essential and important medico-legal prerequisite for a patient's treatment. This necessitates the service provider to participate in the informed consent process and discuss the risk-benefit of the proposed treatment, the best available treatment, engage in shared decision-making process, opportunity to convey their view and thereby limit chances of legal liability for all parties. The clinician should have ample knowledge and skill pertaining to the informed consent process and also have adequate understanding of medical ethics and law. This article provides an overview on informed consent pertaining to telepsychiatric services in India.

**Keywords:** Psychiatry, consent, telepsychiatry, India

**C**onsent is a process that allows for free expression of an informed choice by a capable person to par-

ticipate in a treatment or a study.<sup>1</sup> The motive of consent is to respect a person's autonomy and protect his/her right to choose by a rational decision-making process.<sup>2</sup> Informed consent is a process of communication between a patient and a doctor. The doctor gives the patient enough information so that the patient can make an informed decision regarding the proposed procedure, test, examination, or treatment; the patient makes an informed decision after reasonably foreseeing the consequences of the choice.<sup>3</sup> Informed consent is an important medical, ethical, and legal prerequisite for the treatment of a patient; failure to do so is an offense and a crime.<sup>4</sup> The informed consent has a legal connotation and focuses on the choice or free will of the individual to decide on the assumption that the person has the capacity to make treatment-related decisions. Consent is primarily based on

three guiding principles, autonomy, beneficence, and justice for participants.<sup>5</sup> Consenting procedure gained relevance and has played a vital role in the delivery of health care due to the rapidly changing approach of modern medical practice and the transition from a paternalistic care model to a collaborative care model.<sup>6</sup> This is also partly due to the evolving approach of treating healthcare seekers as service users and not just as patients. The introduction of newer technologies, innovation, data science, and artificial intelligence (AI) into modern medical technology has also brought a change.

The concept of informed consent is universally accepted and now constitutes Article 7 of the International Covenant on Civil and Political Rights of the United Nations. This also served as the basis for the multiple international conventions such as the United Nations International Covenant on Civil and Po-

litical Rights, the International Ethical Guidelines for Biomedical Research, and the Council for the International Organization for Medical Sciences (CIOMS); all have proposed ethical standards for informed consent.<sup>2</sup> Several medical associations, organizations, societies, and professional bodies have established a specific protocol for various invasive and non-invasive medical and surgical procedures, by examining the law of the land and the resolutions adopted by international conventions on consent procedures. Most guidelines recommend either implicit or explicit consent for any person-to-person medical interaction, and the same principles are applicable to telemedicine and virtual consultation.<sup>7</sup> Consent in medical practice in general and psychiatry, in particular, has an amplified legal importance, in patient care, treatment, and research. The consent process has several unique challenges, especially in persons with mental illness, since this depends on insight, psychopathology, and possible cognitive deficits, which hamper the person's capacity to consent.<sup>2</sup> In this regard, Australia, India, United Kingdom, and other high-income countries have separate laws regulating admission, discharge, rehabilitation, and capacity assessment.<sup>8</sup>

## Evolution of Consent in Telepsychiatry Practice

The concept of telepsychiatry draws its roots from "snail mail" correspondence therapy; Sigmund Freud corresponded with patients through letters. With easy access to a telephone, consultations over the telephone were done widely in the 1990s and early 2000s. The consenting process during the earlier years was unclear. Later in 1985, the American Psychiatric Association opined that therapy provided almost exclusively by telephone was "unusual, inappropriate, and not accepted medical practice".<sup>9</sup> As informed consent is required before providing any treatment, some professional organizations in the early 2000s noted the need for informed consent to e-therapy and other forms of cyber-medicine and telemedicine.<sup>10</sup> The consent process in multicentric clinical trials using telemedicine also presents a unique challenge. Although the process of obtaining

informed consent through telemedicine has become streamlined, there are still many challenges that require further attention from the electronic media.

However, the technological advancements in the last three decades, such as easy access to the internet at remote locations and the use of applications (e.g., email, teleconsultation, and conferences over the internet) and multimedia approaches (e.g., digital imagery and video), have made the information shared during consultation substantial enough to ensure a standard of effective healthcare delivery across the world. Studies on the effectiveness<sup>11</sup> acceptability, feasibility,<sup>12</sup> and satisfaction of telemedicine consultation are comparable to those conducted in person. In 2009, the World Medical Association guided the use of telemedicine for the provision of health care. In line with this, India, Malaysia, France, the United Kingdom, South Africa, and the state of California of the United States of America allowed telemedicine practice with informed consent.<sup>7,8</sup>

In India, the Indian Medical Council (IMC) published Telemedicine Practice Guidelines (TPG) in 2020, which allow for the legal practice of telemedicine.<sup>13</sup> The IMC has adopted the concept of telemedicine proposed by the World Health Organization<sup>14</sup> as "The delivery of health care services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities." The Indian Psychiatry Society, the Telemedicine Society of India, and the National Institute of Mental Health and Neuro Sciences (NIMHANS) have provided operational guidelines for telepsychiatry in India to give more clarity and for an easier interpretation.<sup>15</sup> Similarly, telepsychotherapy and telepsychiatric social work practice operational guidelines were brought out by their respective bodies of clinical psychology and psychiatric social work.<sup>16,17</sup>

## Type of Consent and Telepsychiatric Consultation

The process of consent will form the basis of the fiduciary relationship between a patient and a doctor.<sup>18</sup> Indian Medical Council, Professional Conduct, Etiquette and Ethics Regulations, 2002 (IMC regulations) discusses consent for various medical and surgical interventions.<sup>19</sup> It says that the consentee should be sufficiently competent to enter into a contract and should, therefore, be at least 18 years old, of sound mind, and not excluded by any statute. The Mental Healthcare Act, 2017 (MHCA) Chapter 1 Section 2(i) describes informed consent for a specific intervention, to be without any force, undue influence, fraud, threat, error, or misappropriation and obtained after providing adequate information, including the risks and benefits of, and alternatives to, specific intervention in a language and manner comfortable to the patient.<sup>20</sup> Consent is a must for each consultation, and it may be implied or explicit based on who initiates the consultation. If there are any changes in the mode, approach, or if a new health care worker is involved in telepsychiatric services, separate explicit consent is required.

## Implicit Consent

Implied consent is granted by the person and can be inferred from a person's behavior. In implied consent, clinicians can make certain assumptions based on human behavior and rational will. The treatment is provided in accordance with the principle of "best interest." An example of implied consent in a day-to-day medical procedure is when a person enters the consultation chamber by his or her own volition, and it may be deemed that the person has consented to the possibility of clinical diagnosis to be made. Consent to the instruction given by a doctor during the clinical examination may be inferred from the general submission of a patient.<sup>21,22</sup> As per IMC regulations<sup>19</sup> and TPG,<sup>13</sup> which allow the legal practice of telemedicine in India, one can draw a legal interpretation of implicit consent in the telepsychiatry practice when (a) any person voluntarily initiates the telepsychiatric consultation, and (b) any person voluntarily initiates email-

based asynchronous telepsychiatry follow up. Nevertheless, it is prudent to conduct an informal capacity assessment to know that the patients have the capacity to initiate the consultation.

## Explicit Consent

Consent is actively expressed by the person, either orally or in a written form.<sup>21,22</sup> Any consultation initiated by the service provider, a specific examination procedure, a major diagnostic procedure, general anesthesia, a surgical operation need explicit consent. If an invasive examination or procedure, such as an incision or surgery or when sampling of body fluids is required, the patient's written consent is ideally needed. There are three special circumstances where explicit consent may not be necessary:

1. **Necessity**—Circumstance in which serious harm or death is likely to occur without intervention, and there is doubt regarding the capacity of the patient (e.g., catatonia, Neuroleptic Malignant Syndrome, delirium, drug toxicity).
2. **Emergency**—If there is a danger to the life or danger from the patient (risk to self, risk to other, risk to public or personal property as described by the Sec 94 of MHCA, 2017).
3. Judicial order to examine and opine on the patient.<sup>20,21,23</sup>

As per IMC regulations<sup>19</sup> and TPG, which allow the legal practice of telemedicine in India,<sup>13</sup> the need for explicit consent is advised for the following situations: (a) Sending an email or SMS reminder or service provider contacting the patients regarding the next follow-up. (b) Psychiatrist transmitting the prescription directly to a pharmacy, (c) Family members participating in the consultation process, (d) Individual telepsychotherapy or telecounseling, (e) Telefamily therapy, (f) Any new healthcare worker involved in the treatment process of the patient, (g) Telegroup therapy, (h) Audio or video recording of consultation, (i) The second opinion from the medical specialist.

## How to Record and Store Telepsychiatry Consent

In India, many organizations or institutes offer a telepsychiatry-based fol-

low-up to previously enrolled and consenting patients in the organization. The earlier consenting procedure was to take an in-person consultation and would rely on consent forms, which were signed by the patient or the nearest relative or nominated representative (NR; if the patient has lost the capacity and nominated the NR as per MHCA, 2017) before the initiation of tele follow-up.<sup>20</sup> This strategy would eliminate the inherent disadvantages of securing consent while using the virtual medium. It also helps streamline patient suitability for telemedicine consultation, which can make virtual consultations healthier and improve clinician satisfaction and patient experience. This approach can be adopted in providing care to psychiatric patients after discharge.<sup>24</sup>

However, explicit consent can also be taken digitally, and TPG has laid out the same in India.<sup>13</sup> In this context, the clinician can use a virtual or digital forum or technology to share the telepsychiatry consent or specific procedure-related information via email or SMS or audio message or video message to the client. Those who have further doubts can use the helpline number or chatbot to discuss further the procedure or consultation. Once they have understood the information, one can check whether they received adequate and full information about the nature, purpose, rationale of telepsychiatric consultations, or the specific procedures. The risk and benefits involved, the alternative options available, the economic implication of decisions, all are part of the information to be understood. However, in-person assistance may have to be provided if the online discussion is found wanting,

After that, if the patient is able to process the information and can make decisions rationally, then consent to the procedure can be taken by sharing one time password (OTP) or via e signature, digital signature, or by clicking "Yes" in the online informed consent form. Those who want to opt-out of the procedure can do so by not completing the application or not sharing the OTP or e-signature or digital signature or by not clicking "Yes" in the online informed consent form. For those who agree to consent via OTP or e-signature or by clicking "Yes" in the

online informed consent form, an automatic consent form can be produced and stored in the patient database. The agreed consent form for virtual or telepsychiatry can be shared with the patient or family treatment in a portable document format or Hypertext Markup Language (HTML) formats via email or other asynchronous modes. The minimum duration of consent storage of consent form should be in accordance with the IMC regulations.<sup>19</sup> Even though consent was taken digitally, a copy of the explicit consent form should be kept as a hard copy for record and documentation purposes.

According to the TPG, 2020, a registered medical practitioners (RMP) "should abide by the IMC (Professional Conduct, Etiquette and Ethics) Regulations, 2002 and with the relevant provisions of the IT Act, data protection and privacy laws or any applicable rules notified from time to time for protecting patient privacy and confidentiality."<sup>13</sup> However, it exonerates the RMP of any responsibility for "breach of confidentiality if there is reasonable evidence to believe that patient's privacy and confidentiality has been compromised by a technology breach or by a person other than RMP. The RMPs should ensure that a reasonable degree of care while hiring such a service."<sup>13</sup>

## Assessment of Capacity to Consent for Telepsychiatric Consultation and Treatment

The assessment of capacity is an important legal component of informed consent, especially in psychiatry. Mental capacity is considered to be time- and task-specific and dynamic. According to the MHCA, 2017, capacity is assumed to be present in every person, including a person with mental illness (PWMI), and they can make a valid decision unless there are valid reasons to doubt the legal assumption.<sup>20</sup> The Mental Capacity Act of England and Wales of 2005 guidelines are more systematic and not based on a person's condition or behavior.<sup>25</sup> However, as per the Indian MHCA, Chapter II, and Section 4, capacity needs to be assessed on the following three principles: (a) the capacity to understand relevant information, (b) appreciation of reasonably

foreseeable consequences of a decision, and (c) communication of the decision by any means. Based on these broad principles, the expert committee formed by the Central Mental Health Authority of India has developed the guidance document to the practicing medical officers (MOs) and mental health professionals (MHPs) to assess the capacity. As per the guidance document and based on the principles of capacity assessment, certain conditions where the assessment of capacity done in quick time as one of the criteria is obviously not met are (a) certain occasions of violent behavior, (b) excitement, (c) catatonia, (d) a non-communicative confused patient, (e) delirium (when not in a lucid period), (f) substance intoxication, and many similar conditions. If not, then the MOs or MHPs can go ahead and assess the capacity. In this, the MHPs or MOs are expected to check for general orientation and the ability to follow verbal commands and then be able to appreciate his or her mental health condition. If it is a PWMI, depending on whether their ability to respond to the question correctly, MHPs or MOs proceed with the interview to check whether PWMI can assess the risk and benefit and make a decision after weighing the consequences. They may ask to seek further information if they have any doubts or queries before making a decision. Based on that, MHPs or MOs have to make a binary decision that he or she has the capacity for treatment decisions or not. If capacity is lacking, support from his or her NR will assist the person in making decisions; however, if the patient has made an advance directive, then the MHP is obligated to honour the same. The same principle applies to the MHPs or MOs while doing a tele-based capacity assessment for participation in telepsychiatry consultation, therapy, counseling, treatment, and discharge.<sup>26</sup> The consent may be either implied or explicitly based on existing guidelines laid down by the IMC regulations,<sup>19</sup> and TPG. The consent should be taken for the following: (a) consent to participate in audio- or video-based telepsychiatric services through the online open digital platform, (b) consent for telepsychiatry consultation or therapy or counseling based on who initiates the telepsychiatry consultation, and (c) consent

for sharing the e-prescription to the pharmacy directly. The consent process has to be recorded based on the TPG.<sup>13</sup>

## Components of Telepsychiatry Consent

1. Capacity to consent for telepsychiatric consent procedure.
2. Consent for telepsychiatric consultations over the face to face consultation or therapy
  - Nature, purpose, the rationale behind telepsychiatric consultations over the face to face consultation or therapy
  - Information about tele-psychiatric consultations, in case of therapy (how long, how many session)
  - Risk and benefit of telepsychiatric consultations over direct or in-person or face to face consultation
  - Reasonable alternatives to the type of teleconsultation (video conference is better than audio)
  - Economic considerations related to teleconsultation over direct or in-person or face to face consultation
  - Limitation about telepsychiatric consultations—emergency care.
3. Consent to sharing of e-prescription to the pharmacy.

## Approach to Telepsychiatry Consent in Special Situations

### Adults Lacking Capacity

In case of adults lacking capacity who are not in a position to give consent, MHPs need to check for Psychiatric Advance Directive (PADs) or NR. If he or she has not made NR or PADs in the past, immediate family members can act as NR as per MHCA, 2017. Before providing a proxy consultation, the clinician has to ascertain following things: (a) documented diagnosis of dementia, (b) severity as “moderate” or “severe,” (c) loss of capacity to consent by the patient, (d) a person seeking proxy consultation needs to have an authorization letter from the patient or if the clinician can recognize and confirm the identity of the family member, an authorization letter will not be necessary, and the clinician can proceed to provide telepsychiatry follow-up. An oral or written consent from the patient’s

NR has to be taken while delivering telepsychiatric consultation to the patient.

## Minor (Children and Adolescents)

In the case of minors, who are less than 18 years of age, parents act as NR. The clinician has to ascertain the following things: (a) identity document with proof of age, which shows the person is less than 18 years and (b) documented proof that he or she is the parent of the child or the clinician can recognize the parents (without a documented proof). The oral or written consent from the parents needs to be taken while delivering telepsychiatric consultation to the patient.

## Emergency Care

The telepsychiatric consultation or counseling is not suitable during a psychiatric emergency. However, RMP can consult psychiatrist or specialist through technology to provide emergency psychiatry care. Legal liability of care lies with the RMP, who initiated the consultation with the specialist.

## Family Member in Consultation

To take clear oral or written consent from the patient and ask if he or she feels safe and comfortable with the presence of family members to discuss and share his or her disease and confidential information.

## Group Therapy

To take clear oral or written consent from the patient and ask if he or she feels safe and comfortable with the presence of other group members to discuss and share his or her disease and confidential information.

## Family Therapy

It is necessary to take a clear oral or written consent from the patient and family members and ascertain if the patient is comfortable with having family members in the meeting wherein confidential details of their illness maybe discussed.

## Consultation Through Health Care Worker

The health care professional or worker can facilitate a telepsychiatric consul-

tation for a patient with a psychiatrist. The health care professional or worker should be qualified and designated from an organization for providing the telepsychiatric services. Health care professionals should take an explicit written or oral consent from the patients to take a history, examine the patient, and convey the findings to a psychiatrist.

## Telepsychiatry and Consent During COVID-19 Pandemic

The restrictions imposed to control the pandemic helped to accelerate the uptake of telemedicine in India as elsewhere. It has also brought its own unique challenges. The use of telepsychiatry has predictably increased, not only for the outpatient consult but is also being employed for consultation and liaison with other medical specialties. China has used online platforms successfully for screening and treating mental disorders during COVID-19. Technology has been used to facilitate emergency mental health interventions while offering access to online psychological therapies such as cognitive-behavioral therapy and self-help programs.<sup>27</sup> In Karnataka, India, in places which are designated as COVID-19 treatment facilities, telemedicine modalities are being utilized to offer mental health care for needy people who are infected with SARS-CoV-2 and isolated. However, a pandemic should not preclude the consent process, and service providers need to respect the privacy and autonomy of the user and adhere to a good consenting procedure.

## Unique Advantages, Challenges, and Legal Aspect of Telepsychiatry Consent

An ideal informed consent in a face to face or telepsychiatry setting requires an array of factors to come together. Informed consent has four essential elements—capacity, voluntariness, decision-making, and knowledge.<sup>28,29</sup> “Capacity” is the ability of the service user to understand the nature of the treatment, the consequences of the treatment, or not taking it. “Voluntariness” is the willingness to undergo the treatment or re-

fusal of the treatment and is to be free of coercion. Coercion is the intentional overriding of one person’s known preferences or actions by another person, where the person who overrides justifies the action by the goal of benefiting or avoiding harm to the person whose preferences or actions are overridden.<sup>30,31</sup> Coercion in telepsychiatry would be a new challenge for both service users and providers. Service providers must guard against using implicit or explicit coercive practices; they need to empower the user to make decisions that are in the best interest of the user. A study has shown that although most psychiatrists considered coercion as a caring, protective, and safe attitude, they did acknowledge its potential negative impact on patient dignity and therapeutic relationships.<sup>32</sup>

One way of empowering the user is by providing adequate knowledge about the treatment, procedure, or other related aspects. Knowledge includes sufficient information given to the patients to understand the nature and consequences of the treatment or the lack of it. It usually involves the nature of the proposed treatment, the risks and benefits of the proposed treatment, and the available alternatives. Decision-making means the ability to make decisions weighing the pros and cons and communicating the same to the treatment provider. A legally valid consent will involve all these factors.<sup>6</sup>

Teleconsent differs from traditional informed consent by removing the in-person and pen-to-paper signature components and instead has a video interaction between the participant and the provider followed by authentication via OTP or photo-based or handwritten e-signature or by clicking “Yes” in the online informed consent form. The teleconsent and other consent modalities are distinct. The standard for the consent process, which remains a face-to-face discussion with the patient, will be constrained by the need for travel on the part of the patient. Teleconsent procedure may require the participants to have access to a telephone, fax machine, or email, scanner, and a printer to be able to send and receive the consent form, which may not be available among rural and disadvantaged communities.

This also overcomes the transportation and technological barriers by minimizing the requirements to a computer connected to the internet. In India, smartphone usage has been on the rise, and smartphones often replace the reliance on computers. The medium of teleconsult relies heavily on a good internet connection and often adds its challenges to the consenting process.

Another challenge during the teleconsultation process is the requirement for sustained attention from the patient, provider, or researcher. During a video conversation or when digitally sending the consent forms, one may argue that the participants may not be as cognitively attentive compared to the traditional face-to-face interaction between the two parties. This also makes the clinician job of confirming the extent of patients’ understanding challenging.<sup>33</sup>

The telepsychiatry consultations offer the convenience of consulting the professional at their convenience. Another challenge is the privacy and confidentiality of the consultation; patients and clinicians may need time to get used to the software, which stores the information in the server. There is a chance of data leakage due to poor encryption of data in the server. There is the potential risk of patients bringing in the bias of convenience over the inherent weakness of teleconsult, to consent for the same. During the consenting process, the physician needs to explain the shortcomings, bearing in mind the patient’s potential bias toward a teleconsult due to the inherent convenience. It is also important to ensure that the patient is sufficiently comfortable with the new medium before introducing the nuances of informed consent, even if this involves multiple sessions.

## Future Directions and Way Forward

With further advancement in technology, in future consent process could partly be automatized with the help of AI chatbot. A chatbot is an artificial intelligent software application that can mimic a human conversation via text or text to speech methods. The component of providing adequate information about the nature, purpose, rationale of the teleconsultation

or a specific procedure, risks, and benefits of the same, reasonable alternatives, economic implications, and limitations could be done by AI, which gives all the relevant information to the user. It can perhaps even check if the user has understood the information and help with answering any questions regarding the same in an FAQ format. The AI program can direct the user to a human service provider if the user wishes to or has queries that the software is inept to handle.

Augmented reality (AR) and virtual reality (VR) are already being used in medical education and healthcare.<sup>34</sup> Similarly, AR and VR applications can be developed, which can provide enhanced user experience and improve the teleconsenting process. One of the major drawbacks of telepsychiatry consultation has been the loss of empathy; perhaps with VR technology, one can bring back the empathy component to the satisfaction of both the mental health user and the service provider.

Consent for procedures like electro-convulsive therapy (ECT) can be automatized, and the AI program can customize and provide information like the number and frequency of sessions to the individual user based on the available good practice guidelines and the latest evidence. Similarly, consent for capacity assessment and admission can also be automated. With the inclusion of AI chatbots and related technology into the consent process, especially admission, ECT, and starting specific medication, there could be a significant advantage by making it easy, thorough, and seamless. This has the potential not just to enhance user experience but prevent healthcare provider burnout. However, the client has to meet the service provider for the final consent agreement. The service provider may keep a signed hard copy of the consent form in the client record for recording and documenting purposes.

## Conclusion

Telepsychiatry is a growing field, and the need to streamline the operational guidelines is much needed. The *Telepsychiatry Operational Guidelines* published recently is a step in the right direction. In telepsychiatry, consent holds an important aspect in the delivery of psychiatric services as it involves more non-human

interfaces such as information and technology. The consent should not only be limited to telepsychiatry consultation services but also include the explicit consent about sharing of prescription to the pharmacy and sending a reminder for future consultation. There is also a need to work further on developing implementable record-keeping for teleconsults in line with the data protection laws of the land and compliance with the data safeguarding agencies. The streamlining of the telepsychiatry consenting process will safeguard both the treating team and the patient.

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# Telepsychiatry Netiquette: Connect, Communicate and Consult

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## ABSTRACT

Globally, telepsychiatry has been around since the 1950s. It is in the COVID era that it has gained the relevance and much-needed momentum amongst mental health care professionals. Given the restrictions imposed by the global lockdown owing to the fear of contracting the virus, the ease of access and safety offered by telepsychiatry makes it both appealing and “the new normal.” Despite some hesitation from

mental health professionals, there is adequate research to support the role of telehealth services in the management of various mental health disorders. As with any formal system, the practice of telepsychiatry is regulated by professional guidelines to show the way forward to both health provider and seeker. The manuscript examines the ways telepsychiatry is redefining our virtual conduct. It emphasizes the evolving “netiquette” needed to navigate online consultations.

It also elucidates the challenges faced by health professionals, and possible ways of maneuvering and circumventing the same. Telepsychiatry, a dynamic process which is interactive and personalized, adds a third dimension to the practice of modern medicine. It is here to stay. So, it is not a question of “if” instead “how soon” we can adapt to and get conversant with this revolutionary mode of connection, communication, and consultation, which will make all the difference.