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# Prescribing Psychotropics: Perspective From Telepsychiatry Operational Guidelines 2020

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## ABSTRACT

As telemedicine gained both importance and momentum following COVID-19 pandemic, Telemedicine Practise Guidelines (TPG) March 2020 was notified by the Central Government of India. Following the above, the Indian Psychiatrists Society, Telemedicine Society of India (TSI) and National Institute of Mental Health and Neurosciences (INI), Bangalore came together to address the specific needs of Psychiatrists practicing tele consultations, there by releasing Telepsychiatry Operational Guidelines 2020. This article discusses the guidelines outlines in the above documents with respect to prescribing psychotropics. We have discussed the thought process behind formulation of Telepsychiatry Operational guidelines, the challenges that may arise while following the above guidelines with possible solutions.

**Keywords:** Telepsychiatry Operational Guidelines, Telemedicine Practice Guidelines, online prescriptions, e-pharmacy

Telemedicine in psychiatric care has opened avenues for individuals in need of psychiatric services ranging from consultation, obtaining medications, and obtaining nonpharmacological interventions. In the recent past, the Government of India has notified guidelines for telemedicine practice, *The Telemedicine Practise Guidelines—March*

2020 (TPG).<sup>1</sup> In lines with the above document, *Telepsychiatry Operational Guidelines—2020* was brought forth to tailor the use of Telemedicine in psychiatric practice. In this article, we would discuss the guidelines concerning psychotropic medications. “Psychotropic drug” is defined as any drug that can cause a change in mood, emotion, or behavior.<sup>2</sup> We will discuss the pros and cons of the guidelines, about writing an online prescription, on how to ensure that medications reach patients following a telepsychiatry consultation, and the ethical issues involved in all of the above.

During a teleconsultation, the psychiatrist has the responsibility of prescribing appropriate medications to the patient wherever required. Although the rules of Narcotic and Psychotropic Substances Act, Drug and Cosmetic Act 1940, and Rules 1945 apply while prescribing any medication similar to a traditional in-person consultation,<sup>3</sup> still some differences need to be understood while prescribing during a telepsychiatry consultation. Although there are some restrictions as to what drugs can be prescribed online and in what context, the same clinical practice guidelines that are applicable for in-person consultation also apply here. Telepsychiatry Operational Guidelines

describe the process involved in prescribing medication, that is, psychotropics from a psychiatrist’s perspective following a psychiatry teleconsultation.

## Prerequisite Before Prescribing Psychotropics Online

Prerequisite before prescribing psychotropic medication online is that the psychiatrist should arrive at a provisional or final diagnosis following a consultation; the mode of consultation can be audio/video/text. During a teleconsultation, if a psychiatrist is unable to arrive at a diagnosis, then an in-person meeting needs to be considered.

Prescribing medication following telepsychiatry consultation depends upon the following factors:

- Type of consultation: first or follow-up consultation
- Mode of consultation: text/audio (telephonic consultation)/videoconferencing
- The appropriate list of medicines suitable for a prescription will depend on the above two criteria

It is important to note that psychotropic medications should be written in generic names.<sup>4</sup>

The Board of Governors in Supersession of the Medical Council of India with previous sanctioning from the Central government of India notifies the list of medications in various categories from time to time.<sup>1</sup> Groups of drugs that can be prescribed following a teleconsultation are as follows:

- List O:** This includes over-the-counter drugs (OTC) that need to be readily and easily available to the general public and can be dispensed without a prescription, for example, paracetamol, antacids, ORS, vitamin supplements, tincture iodine, and cough lozenges. In times of public health emergencies such as epidemics and pandemics, this list will also include all the necessary drugs relevant to the health emergency situation.<sup>1</sup> List O does not contain any psychotropic medications. Any individual cannot procure psychotropic drugs without a valid prescription.<sup>5</sup>
- List A:** Drugs in list A are relatively safe and have a very low risk of abuse. These can be prescribed after the first consultation on video only and on subsequent “follow-up telepsychiatry consultations,” which may be audio/video/text-based for re-fill prescriptions.
- List B:** This includes drugs that can be used as an “add-on” for the ongoing psychiatric prescription and are needed to optimize the treatment. The psychotropics in this list can be prescribed on “follow-up consultation” only, which can be via text/audio/video mode. The drugs in this list may change from time to time, depending upon the notification from the Governing Bodies representing the Government.
- List C:** This includes drugs that “cannot be prescribed” after a tele-consultation. This list includes Schedule X drugs of the Drug and Cosmetic Act 1940 and Rules 1945, and drugs that come under the purview of narcotic and psychotropic substances listed in the Narcotic Drugs and Psychotropic Substances Act 1985, for example, methadone, ketamine, zolpidem, codeine, and benzodiazepines.

Following the notification of the Telemedicine Practice Guidelines, it remained to be clarified how a psychiatric consultation and prescribing psychotropics should be carried out and which psy-

chotropic should figure in which of the list of drugs. It was in this scenario that various professional bodies took up the responsibility to segregate the psychotropic medications into the lists. The Indian Psychiatric Society (IPS), Telemedicine Society of India (TSI), and National Institute of Mental Health Neurosciences (NIMHANS), Bangalore, came together to create a separate guidance document on telepsychiatry practice guidelines.<sup>6</sup>

Although the task of deciding the drug list appeared to an easy job, multiple factors needed consideration. The main goal was to populate the lists so that it would bring clarity for the prescribing telepsychiatrist while at the same time ensuring the benefit for patients and also ensuring compliance with other legal statutes. Therefore, the authors took two approaches which are described in **Table 1**.

TABLE 1.

### Approaches to Deciding the Psychotropics in the Various Drug Lists of the Operational Guideline

	Approach 1: Including All First Line Treatments for Various Psychiatric Disorders in List A	Approach 2: To Include Essential Drugs in List A and Rest in List B
Pros	<ul style="list-style-type: none"> <li>Psychiatrist will have the advantage and ease of following treatment guidelines.</li> <li>Psychiatrist can make a treatment decision in collaboration with the client, which would allow the client to take decision after understanding the details of the drug: its mechanism of action, adverse effects with the available evidence.</li> </ul>	<ul style="list-style-type: none"> <li>Only those with a firm diagnosis will receive prescription.</li> <li>Where the diagnosis cannot be arrived or when psychiatrist perceives the need to evaluate in more detail, he/she can insist on in-person consultation before considering giving out prescription based on the limited information available.</li> <li>A RMP or health worker following collaborative consultation with a psychiatrist online can make psychotropics available to the patients.</li> <li>Any RMP who has undergone DMHP training in primary care psychiatry can prescribe psychotropic drugs, since essential drugs need to be made available in all health care settings, it would be easier for the RMP to prescribe without the patient facing difficulty in procuring psychotropic drugs.</li> <li>All the basic psychotropic drugs are available in peripheral health settings.</li> </ul>
Cons	<ul style="list-style-type: none"> <li>First-line psychotropic drugs will vary depending on multiple factors, such as predominant symptomatology, age of the patient, presence of comorbidities, special population such as pregnancy and lactation.</li> <li>There are numerous guidelines/protocols available for psychiatric illness management.</li> <li>All drugs may not be available and cost of drugs varies from each other; therefore, choosing few drugs over the other may create bias.</li> <li>List A drugs should be safe and low potential for abuse, which cannot be ensured for all psychotropic drugs.</li> <li>As per TPG, RMPs can prescribe list A drugs in the first visit, if many psychotropics are included in list A, Medical Officers with DMHP training alone may find it challenging to choose a drug from a very elaborate and lengthy list A.</li> </ul>	<ul style="list-style-type: none"> <li>Psychiatrist might feel constrained with the list containing only few drugs.</li> <li>Drugs which a client can benefit in the first consultation—the psychiatrist may have to wait till follow-up consultation to consider particular drug.</li> </ul>

TPG: Telemedicine Practice Guidelines, RMP: registered medical practitioner, DMHP: District Mental Health Program.

**TABLE 2.**  
**Psychotropics Drugs in Each Category of Drugs<sup>6</sup>**

Category	Antidepressants	Antipsychotics	Sedative Hypnotics/ Benzodiazepines	Other Oral Psychotropic Medication	Injectable
List A	Imipramine Escitalopram Fluoxetine	Haloperidol Risperidone Olanzapine	Clonazepam <sup>a</sup> Clobazam <sup>a</sup>	Mood stabilizer Lithium carbonate Carbamazepine Sodium valproate Antiepileptic drugs Phenobarbitone, Diphenyl- hydantoin Anticholinergic drugs Trihexyphenidyl	Inj. fluphenazine Inj. haloperidol Inj. promethazine
List B	Sertraline, paroxetine, desvenlafaxine, mirtazapine, citalopram, duloxetine, venlafaxine, doxepine, clomipramine, nortriptyline, bupropion, amitriptyline, fluvoxamine, and other antidepressants	Aripiprazole, quetiapine, clozapine, lurasidone, ziprasidone, chlorpromazine, paliperidone, iloperidone, amisulpiride, asenapine, zuclopendixol, flupentixol, etc.		Mood stabilizers Oxcarbazepine Lamotrigine Divalproex sodium and other drugs Anticravings and aversive drugs Disulfiram Topiramate Baclofen Naltrexone Acamprosate and other anticraving agents Anti-dementia drugs Donepezil Rivastigmine Memantine and other drugs used in the treatment of Dementia Anti-ADHD drugs <sup>b</sup> Atomoxetine Clonidine Modafinil and other drugs	<sup>c</sup> Injectables prescription for depot Inj. zuclopendixol Inj. flupentixol
<sup>d</sup> List C	–	–	Zolpidem Diazepam Lorazepam and other sedative hypnotic drugs	Methadone Buprenorphine Ketamine Morphine Tramadol Codeine	

Source. Adapted from *Telepsychiatry Operational Guidelines-2020*, Indian Psychiatric Society and Telemedicine Society of India in collaboration with National Institute of Mental Health and Neurosciences (Institute of National Importance), the list has in turn been adapted from Essential drug List of MHCA 2017.<sup>7</sup>

The above list broadly consists of the psychotropic drugs notified by the central government. The drugs in various categories may vary from time to time depending on the amendments and modifications put forth by the Board of Governors, Medical Council of India. <sup>a</sup>Benzodiazepines: clonazepam and clobazam were included in list A after amendment by MCI. <sup>b</sup>Anti-ADHD drug methylphenidate cannot be prescribed via teleconsultation neither in first consultation nor in follow-up. <sup>c</sup>Injectable prescription is to be given only after Collaborative Consultation with an Registered Medical Practitioner or health worker. <sup>d</sup>List C drugs can never be prescribed by a psychiatrist after a teleconsultation—first/follow-up consultation.

After much deliberation in the professional bodies like TSI, IPS and NIMHANS, Bangalore, the authors thought it logical to include all the essential psychotropic drugs (enlisted under MHCA 2017) in list A and the rest in list B. This approach seeks to ensure that psychotropics so included in list A will be of the safe type, having a low potential for abuse, and of ready availability and accessibility. The list, however, is not the final one and would be revised from time to time, depending on the notifications by the Medical Council of India or other Governing Bodies. **Table 2** broadly lists various drugs in list A, B, and C

## Strengths of the List of Drugs in Telepsychiatry Operational Guideline 2020

The Telepsychiatry Operational Guideline is the first of such guidelines for any single specialty, catering to specific needs and requirements of psychiatry. The categories and list of drugs provide a clear idea about which drugs can be prescribed by a psychiatrist online and which cannot be, thereby preventing indiscriminate prescription of drugs and providing a legal safety net to the psychiatrist when a particular medication is not prescribed.

The categorization is simple and easy to follow. The medications in list B being exhaustive allow the psychiatrist to choose a psychotropic from a wide range of psychotropics in follow-up teleconsultations. List B includes most classes of psychotropics that are usually prescribed for treatment of psychiatric illness for both common mental disorders and severe mental disorders. Depot antipsychotics have considerable benefits in the treatment of schizophrenia, especially in ensuring treatment adherence.<sup>9</sup> Antipsychotic drugs in list B include depot antipsychotics (e.g., fluphenazine decanoate in list A; zuclopendixol decanoate

and flupenthixol decanoate in list B) also, thus enabling the psychiatrist more choice to choose from.

## Areas Where There Is Scope for Further Deliberation

List A consists of only three antidepressant drugs: imipramine, escitalopram, and fluoxetine. Among the tricyclic antidepressants (TCA), amitriptyline is the commonly prescribed TCA,<sup>10,11</sup> which is currently notified under list B (which means a psychiatrist can prescribe it only in follow-up). Being a widely prescribed antidepressant, including it in the list A would be beneficial to patients.

Prescription patterns of benzodiazepines show that clonazepam is the most commonly prescribed benzodiazepine, followed by lorazepam and diazepam.<sup>10,12</sup> Current guidelines restrict prescription to clonazepam and clobazam only. Diazepam and lorazepam are the essential drugs that are supposed to be available in all government health establishments.<sup>7</sup> Therefore, prohibition on prescribing diazepam and lorazepam through teleconsultation needs to be relooked at, especially when telepsychiatry collaborative consultation is carried out with a registered medical practitioner (RMP) or a health care worker from a primary care setting. The above described are a few areas where there is scope to add more psychotropic medications in list A. More such additions and revisions in the lists may be required as the number telepsychiatry consultations increase that will enable to draw evidence from experience, which would make it possible to put forth the felt need to the governing bodies to make the necessary changes in the lists of medications (list A, B, or C).

## Methods of Generating and Issuing a Prescription

Whenever a prescription is issued (in whatever manner it is), the rules of Indian Medical Council Regulations 2002 should be adhered to.<sup>13</sup> A prescription can be either handwritten or digitally generated. It should contain the generic name of the drugs in clear legible handwriting, preferably in capital letters, with the signature of the psychiatrist when it is handwritten. If it is a digitally generated prescription, then the generic name of the drug should be mentioned in capital

letters along with a digital signature. The psychiatrist's signature should be accompanied by his/her name, designation, and affiliation. Then, the prescription so generated can be sent either as a photo or as a scanned copy through appropriate communication mode, which can be either via email or via WhatsApp or similar platform. It is prudent to document the phone number/email (to which the scanned copy of the prescription is sent) in the consultation notes. Then, the patient can approach the pharmacy of his choice to obtain the prescribed medications.

## Ethical Issues of Prescribing Medications and Dispensing Medications

As per the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (Amended on 2016)," registered medical practitioners are not supposed to run an open shop for the sale of medications other than those prescribed by himself. Despite this, in India, many clinicians prescribe and dispense medicines by themselves.<sup>14</sup> When the same person prescribes and dispenses drugs, it can lead to a conflict of interest. The conflict is between adhering to the best possible practice guidelines and the financial gains of the clinician. This practice has been reducing in metro cities, but it is still widely prevalent in rural and semi-urban areas.<sup>15</sup> Another probable issue is the availability of only certain psychotropic medications in the patient's location wherein the psychiatrist has minimal choices and may need to prescribe the drug that is readily available and accessible for the patient.

With the government giving the nod for telepsychiatry practice, the above-mentioned ethical issues will take a newer shape with newer ethical conflicts. When a psychiatrist prescribes medications to a patient residing in a metro or semi-urban area, he/she will have multiple pharmacies where they can approach and get the drug. If the patient is from a rural area, then obtaining prescribed medications will be an additional task for which he/she will have to travel to an urban place, which will defeat the main purpose of telepsychiatry. Few psychiatrists might prefer to send the medications through parcel services to their patients and collect the medication fee; this arrangement

can be considered in the current situation of pandemic (lockdown). Still, otherwise, this is akin to doctor selling medications by himself as in in-person consultation. This invites a similar conflict of interest, where the psychiatrist dispenses a particular brand of psychotropic medicines directly to the patient by taking payment for monetary profit.

## E-Pharmacy

E-pharmacy is an Internet-based service, where the patient can upload his/her prescription to the E-pharmacy website and then E-pharmacy will deliver the medication to the specified address. E-pharmacies have been in the Indian market since 2015 when the Indian Internet Pharmacy Association formed. E-pharmacies are supposed to adhere to the Drug and Cosmetics Act 1940, Drugs and Cosmetic Rules 1945, Pharmacy Act 1948, the Indian Medical Act 1956, and Information Technology Act 2000.<sup>3</sup> Of late, there has been a surge of E-pharmacy websites, and it is expected to grow by nearly five times by 2022.<sup>16</sup> After the telepsychiatry guidelines have been released, E-pharmacies have assumed a greater role in the delivery of medications to patients. In India, E-pharmacies are not governed by any specific law or regulatory body, whereas developed countries like the USA, Canada, and Australia have legal, regulatory organizations like the National Association of Boards of pharmacy to regulate E-pharmacies. These regulatory bodies help customers in identifying real and fake E-pharmacies, and hence a need for such a statutory authority in India.<sup>3</sup> There is a potential conflict of interest area here as well: if the E-pharmacist ties up with a specific manufacturer and keeps the products of only that manufacturer, it would mean no option for the patient to choose from, which we strongly discourage. Another conflict of interest zone is when the drug manufacturer himself/herself opens an online portal for the delivery of prescribed medications. Doing so might break the rules of Pharmacy Act 1948, which mandate that only licensed pharmacists can sell the medicines.<sup>15</sup> However, these issues can be curtailed by (a) doctors prescribing only generic medication, which is also a mandate by the Medical Council of India,<sup>4</sup> (b) E-pharmacy providing list of all brands, and its cost. A "one drug one price" policy is another way

to solve this problem. All drugs may be brought under “Drug Price Control” too.

## Privacy Issues

Section 23 of the Mental Health Care Act 2017 speaks about the “Right to confidentiality” of the patient, but TPG mandate mentioning of diagnosis on the prescription guidelines. Writing the diagnosis on the prescription will mean revealing the patient’s illness to anyone who comes across it even by chance. Therefore, while generating a prescription psychiatrist should not violate both legislations mentioned above and mentioning the ICD or DSM code of the diagnosis is a suggested solution. With the ongoing integration of technology into health care delivery, there is the possibility of integrating electronic health records with E-pharmacy soon. When that happens, the option will arise of directly sending the prescription to the E-pharmacy companies with the patient’s concurrence for dispensing the medication.

## Conclusions

Newer opportunities, challenges, and ethical issues arise with the official notification of Telemedicine and telepsychiatry. The opportunities include making health care accessible even to a person staying in the most remote of the places, obliterating the logistics barrier. The main challenge lies in ensuring that not just the psychiatrist’s opinion reaches the patient but also the required medications, especially to those who are living most remote place. The main ethical issue that might arise is psychiatrists selling medicines or foreign pharma companies selling pills or pharma companies venturing into the area of selling their drugs directly to patients. Our recommendation is to have a regulatory body to supervise activ-

ities of E-pharma companies and protect the interests of the patients.

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