

National List of Essential Medicines 2022 of India: Perspectives from Psychiatrists

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The National List of Essential Medicines (NLEM) is a dynamic list of medicines consisting of agents used to manage diseases that are of public health importance in a country. Recently, India launched its fifth edition of the NLEM in September 2022, after revising the last NLEM published in 2015.¹ The first three editions were published in 1996, 2003, and 2011. The current edition chose to comprise medications that target public health conditions, are cost-effective with proven efficacy and safety profile, and are aligned with the current national practice guidelines. All medications included in the list are approved by the Drugs Controller General of India and are recommended by the respective national programs. Care has been taken to trim the list; while choosing an agent from a broad class of medications (e.g., antidepressants), preference is given to an agent that is effective in other conditions, too (e.g., Fluoxetine is one of the two antidepressants chosen because it works in OCD also). This enables the list to be concise



but cater to wide range of psychiatric disorders. The current list consists of 384 drugs, growing from 348 in NLEM 2011 and 376 in NLEM 2015. Thirty-four drugs from the previous list have been dropped, and 26 new drugs have been added.

Medicines Used in the Treatment of Psychiatric Disorders

Continuing the trends of NLEM 2011 and NLEM 2015, the current list has 27 sections depicting the medications endorsed for a certain group of disorders (e.g., psychiatric disorders, neurological disorders) and also proposes what preparation of a certain drug (i.e., injection, tablets, or syrup) is to be kept and at what level of healthcare (primary, secondary, and tertiary). In NLEM 2022, 16 medications have been mentioned under the section “Medicines used in the treatment of Psychiatric Disorders” (section 23). Though fixed-dose combinations of drugs have been generally avoided in the list, in this section, the combination of buprenorphine and naloxone has been listed. Fluoxetine is the only drug that has been listed in two subsections (as an anti-obsessive and as an antidepressant drug). No drug has been dropped from the section on psychiatric disorders, but three have been added under

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the newly created subsection of “Medicines used in disorders due to psychoactive substance abuse.” **Table 1** summarizes the changes in NLEM for the various psychotropic drugs. **Table 2** compares Indian NLEM 2022 with WHO Essential Medicine List (EML) 2021.²

New Additions

The additions include buprenorphine (0.4 mg) sublingual tablets, buprenorphine+naloxone sublingual tablets (0.4+0.1 mg and 2+0.5 mg), and nicotine gum (2 and 4 mg). There have been calls to include these medications in the list, keeping in mind the rising burden of substance use in India.^{3,4} The authors of the NLEM 2022 have taken care to include both 0.4 mg and 2 mg of buprenorphine in the list to cover the use of the medication as an acute withdrawal management agent and a long-term maintenance agent.

It is a welcome step to include a fixed dose combination of buprenorphine and naloxone as an essential medicine, considering that such a combination helps reduce the diversion of the medicine.⁵ It is more important given the COVID-19 pandemic leading to the practice of providing take-home dosages of this medicine across different settings.⁶

TABLE 1.
Drugs for Psychiatric Disorders Mentioned in Various NLEMs.

		NLEM 2011	NLEM 2015	NLEM 2022
Psychotic disorders		Haloperidol	Haloperidol	Haloperidol
		Chlorpromazine		
		Olanzapine		
			Clozapine	Clozapine
			Fluphenazine	Fluphenazine
			Risperidone	Risperidone
Mood disorders	Depressive disorders	Amitriptyline	Amitriptyline	Amitriptyline
		Fluoxetine	Fluoxetine	Fluoxetine
		Imipramine		
	Bipolar disorders		Escitalopram	Escitalopram
		Lithium	Lithium	Lithium
		Sodium valproate	Sodium valproate	Sodium valproate
			Carbamazepine	
Anxiety and sleep disorders		Alprazolam		
		Diazepam		
			Clonazepam	Clonazepam
			Zolpidem	Zolpidem
Obsessive compulsive disorder & panic disorder			Clomipramine	Clomipramine
	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine
Substance use disorders				Buprenorphine
				Buprenorphine + Naloxone
				Nicotine gum

NLEM: National List of Essential Medicines.

TABLE 2.
Comparison of NLEM 2022 with WHO EML 2021.

Disorder Category as per NLEM	NLEM 2022	WHO EML 2021
Psychotic disorders	<ul style="list-style-type: none"> • Clozapine (Tablet 25/50/100 mg) • Fluphenazine (Injection 25 mg/ml) • Haloperidol (Tablet 2/5/10/20 mg, Oral liquid 2 mg/5ml, Injection 5 mg/ml) • Risperidone (Tablet 1/2/4 mg, Oral liquid 1 mg/ml, Long-acting injection 25/37.5 mg) 	<ul style="list-style-type: none"> • Chlorpromazine (Injection 25 mg/ml in 2 ml ampoule, oral liquid 25 mg/5 ml, tablet 100 mg) • Fluphenazine (Injection 25 mg in 1 ml ampoule) • Haloperidol (Injection 5 mg/1 ml ampoule, Tablet 2/5 mg) • Paliperidone (Prolonged release injection (25/50/75/100/150 mg) • Risperidone (Oral 0.25 mg to 6.0 mg) <p>Complementary list</p> <ul style="list-style-type: none"> • Chlorpromazine (Injection 25 mg/ml, Oral liquid 25 mg/5 ml, Tablet 10/25/50/100 mg) • Clozapine (Solid oral dosage form 25 to 200 mg) • Haloperidol (5 mg/ml injection, oral liquid 2 mg/ml, solid oral dosage 0.5/2/5 mg)
Depressive disorders	<ul style="list-style-type: none"> • Amitriptyline (Tablet 10/25/50/75 mg) • Escitalopram (Tablet 5/10/20 mg) • Fluoxetine (Capsule 10/20/40/60 mg) 	<ul style="list-style-type: none"> • Amitriptyline (tablet 25/75 mg) • Fluoxetine (solid oral dosage form 20 mg) (therapeutic alternatives: citalopram, escitalopram, fluvoxamine, paroxetine, sertraline)
Bipolar disorders	<ul style="list-style-type: none"> • Lithium (Tablet 300 mg) • Sodium Valproate (Tablet 100/200/400 mg, Modified release tablet 300/500 mg) • Carbamazepine (Tablet 100/200/400 mg, Modified release 200/400 mg, Oral liquid 100 mg/5 ml) 	<ul style="list-style-type: none"> • Lithium (Solid oral dosage form 300 mg) • Valproic acid (Tablet enteric coated 200/500 mg) • Carbamazepine (Tablet 100/200 mg)

(Table 2 continued)

(Table 2 continued)

Disorder Category as per NLEM	NLEM 2022	WHO EML 2021
Generalized anxiety and sleep disorders	<ul style="list-style-type: none"> Clonazepam (Tablet 0.25/0.5/1 mg) Zolpidem (Tablet 5/10 mg) 	<ul style="list-style-type: none"> Diazepam (Tablet 2/5 mg)*
Obsessive compulsive disorders and panic attacks	<ul style="list-style-type: none"> Clomipramine (Capsule 10/25/75 mg) Fluoxetine (Capsule 10/20/40/60 mg) 	<ul style="list-style-type: none"> Clomipramine (Capsule 10/25 mg)**
Disorders due to psychoactive substance use	<ul style="list-style-type: none"> Buprenorphine (Tablet SL 0.4 mg) Buprenorphine+Naloxone (Tablet SL 0.4+0.1 mg and 2+0.5 mg) Nicotine (nicotine replacement therapy oral dosage 2/4 mg) 	<ul style="list-style-type: none"> Bupropion (Tablet 150 mg sustained release) Nicotine replacement therapy (Chewing gum 2/4 mg, Transdermal patch 5-30 mg/16 hours, 7-21 mg/24 hours) Varenicline (Tablet 0.5/1 mg) <p>Complementary list</p> <ul style="list-style-type: none"> Methadone (Concentrate for oral liquid 5 mg/ml, 10 mg/ml, oral liquid 5 mg/5 ml, 10 mg/5 ml) Therapeutic alternative: Buprenorphine

NLEM: National List of Essential Medicines, WHO EML: World Health Organisation Essential Medicine List.

*medicine for anxiety disorder as per the WHO EML.

**medicine for obsessive compulsive disorders as per the WHO EML.

It is also praiseworthy that all these medications are recommended for availability at primary, secondary, and tertiary levels. This implies that managing opioid and tobacco dependence can be and should be done at the primary healthcare level. Until now, such management only existed in specialized psychiatric or de-addiction centers or substance use treatment centers such as OST and tobacco cessation centers.

Carbamazepine was included in the NLEM 2015 as an antiepileptic/anticonvulsant but not for any psychiatric indications. The WHO EML contains carbamazepine as an essential medicine for bipolar disorders. The NLEM 2022 lists carbamazepine in the bipolar disorders section also, along with its previous neurological indications, keeping in line with the current treatment guidelines for bipolar disorders management.

Other Observations

The inclusions are largely in line with the WHO EML.² The NLEM 2022 now includes medications for all major common and severe mental disorders medications. Most of these are to be available at the primary healthcare level (except for clozapine [only the tertiary healthcare level] and lithium [at the secondary and tertiary levels]). By comprehensively listing medicines for SUD and common and severe mental disorders, the NLEM 2022 provides an opportunity to deliver psychiatric management at the primary care level and strengthen our commitment to reduce the wide treatment gap that exists for various psychiatric disorders.

TABLE 3.

Levels of Healthcare for Various Drugs Included in NLEM.

Disorder	Drug	NLEM 2015	NLEM 2022
Psychotic disorders	Clozapine	T	T
	Fluphenazine	S, T	P, S, T
	Haloperidol	S, T	S, T
	Risperidone	P, S, T	P, S, T
Depressive disorders	Amitriptyline	P, S, T	P, S, T
	Escitalopram	S, T	P, S, T
	Fluoxetine	P, S, T	P, S, T
Bipolar disorders	Lithium	S, T	S, T
	Sodium valproate	P, S, T	P, S, T
	Carbamazepine	Not included	P, S, T
Generalized anxiety and sleep disorders	Clonazepam	P, S, T	P, S, T
	Zolpidem	P, S, T	P, S, T
OCD and panic attacks	Clomipramine	S, T	P, S, T
	Fluoxetine	P, S, T	S, T
Psychoactive substance use	Buprenorphine	Not included	P, S, T
	Buprenorphine+Naloxone	Not included	P, S, T
	Nicotine (nicotine replacement therapy)	Not included	P, S, T
Dementia	Donepezil	Not included	S, T

P: Primary, S: Secondary, T: Tertiary, NLEM: National List of Essential Medicines.

Although clozapine has been included in the NLEM for long, the level of healthcare has been restricted to tertiary. As the need for clozapine in treatment-resistant schizophrenia is indisputable, this may be modified in the future. Clozapine may also be allowed to be used at the secondary healthcare levels, considering the availability of District Mental Health Program psychiatrists in all districts.

In contrast to the WHO EML, NLEM 2022 contains donepezil (added in

NLEM 2015). This is also an important inclusion, considering the rising public health burden of dementia in India.⁷

NLEM 2022 mentions that fluoxetine (for OCD management) and haloperidol (for psychosis management) can be used only at secondary and tertiary healthcare levels. Similar discrepancies also existed in the previous NLEMs (Table 3). For example, in NLEM 2015, clomipramine (for OCD) was mentioned to be used only at secondary and

tertiary levels, while fluoxetine (for OCD) was mentioned to be used at all healthcare levels. There is no particular reason why these drugs cannot be used at the primary healthcare level. Also, fluoxetine (for depression) and clomipramine (for OCD) have been mentioned to be used at all levels. ***All other antipsychotics (except clozapine) are also mentioned to be used at all levels. Thus, the future NLEMs may modify this to allow the use of fluoxetine and haloperidol at all healthcare levels.

Important Oversights

There are certain essential drugs for psychiatric disorders, such as drugs for acute withdrawal management and long-term maintenance of alcohol dependence which have not been included in this list. Other drugs such as varenicline and bupropion, listed in the WHO EML 2021 for tobacco dependence, have also been overlooked in NLEM 2022. Benzodiazepines' role in alcohol withdrawal management is unequivocal. Considering that alcohol use is a major public health issue⁸ and that delirium tremens can be life-threatening, these drugs should be featured in future NLEMs. Naltrexone is another drug very useful in the management of both alcohol and opioid use disorders, and its inclusion can be effective in dealing with these disorders.

Similarly, the addition of memantine can also be considered, given the increasing burden of major neurocognitive disorders due to Alzheimer's disease. The inclusion of these drugs will further strengthen the NLEMs.

Conclusion

NLEM 2022 covers psychiatric medications comprehensively. This will help strengthen the care and treatment for psychiatric disorders across the country and may help reduce the treatment gap for these conditions. We welcome the addition of buprenorphine, buprenorphine+naloxone, and nicotine replacement therapy and hope to see medications for alcohol dependence in the future NLEMs.

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