

**Indian Psychiatric Society**  
**Addictive Disorder Specialty Section**



# **Guidelines**

## **Treatment of Opioid Dependence using Opioid Agonists (Buprenorphine)**

*with focus on operational procedures*

**August 2019**

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**Coordinator: Dr. P. D. Garg**

## **Authors:**

**Dr. Atul Ambekar**

Professor, NDDTC, Department of Psychiatry, AIIMS, New Delhi. [atul.ambekar@gmail.com](mailto:atul.ambekar@gmail.com)

**Dr. Ashwin Mohan**

Senior Consultant, Chandigarh. [ashwinpsych@gmail.com](mailto:ashwinpsych@gmail.com)

## **Reviewers:**

1. Dr. Abdul Maajid, SKIMS, Srinagar
2. Dr. M. Suresh Kumar, Senior Consultant Psychiatrist, Chennai
3. Dr. P. D. Garg, GMC, Amritsar
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7. Dr. Shilpa Adarkar, SGS Medical college & KEM Hospital, Mumbai
8. Dr. Shrigopal Goyal, SPMC, Bikaner

## **List of Abbreviations**

**ADSS: Addictive Disorders Specialty Section**

**AIIMS: All India Institute of Medical Sciences**

**COWS: Clinical Opiate Withdrawal Scale**

**IPS: Indian Psychiatric Society**

**MAT: Medication Assisted Treatment**

**MATOD: Medication Assisted Treatment of Opioid Dependence**

**NDDTC: National Drug Dependence Treatment Centre**

**OAT: Opioid Agonist Treatment**

**OATOD: Opioid Agonist Treatment for Opioid Dependence**

**OOWS: Objective Opioid Withdrawal Scale**

**OPT: Opioid Pharmacological Treatment**

**OST: Opioid Substitution Treatment**

**PGIMER: Post Graduate Institute of Medical Education & Research**

**SOP: Standard Operating Procedures**

**SOWS: Subjective Opioid Withdrawal Scale**

**WHO: World Health Organization**



# INDIAN PSYCHIATRIC SOCIETY

**Headquarters** : Plot 43, Sector 55, Gurgaon, Haryana 122 003, India  
**Phone:** +91-124-4006750, **Email:** ipssecretaryoffice@gmail.com  
**Secretariat** : NC -116, SBI Officers Colony, Kankarbagh, Patna – 800020, India  
**Mobile:** +919431011775, **Email:** dr.vinaykr@gmail.com  
**Websites** : www.indianpsychiatricsociety.org • www.indianjpsychiatry.org

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## Dr. Mrugesh Vaishnav President

Samvedana Happiness Hospital  
3rd floor, Satya One Complex  
Helmet Circle, Memnagar  
Ahmedabad - 380006, Gujarat  
**T :** +91 79-26764350  
**M :** +91 9825767565  
**E :** drmrugesh@rediffmail.com

## Dr. P. K. Dalal Vice President

Professor & Head, Department of  
Psychiatry, K. G. Medical University,  
Shah Mina Road, Chowk,  
Lucknow - 226003, Uttar Pradesh  
**T :** +91 522 241 8529  
**M :** +91 9415025665  
**E :** docpkdalal@gmail.com

## Dr. Vinay Kumar Hon. General Secretary

NC-116, SBI Officers' Colony  
Kankarbagh,  
Patna - 800020, Bihar  
**T :** +91 612 2353882  
**M :** +91 9431011775  
**E :** dr.vinaykr@gmail.com

## Dr. Mukesh P. Jagiwal Hon. Treasurer

101, 'Shriji Niwas', A to Z Bldg.  
Opp. Dhiraj Sons  
Mansukh Tower Lane, Athwagate  
Surat - 395001, Gujarat  
**T :** +91 6352779966  
**M :** +91 9879521795  
**E :** mukeshjagiwala@yahoo.co.in

## Dr. Om Prakash Singh Hon. Editor

AA 304, Ashabari Apartments  
O/31, Baishnabghata  
Patuli Township,  
Kolkata - 700094, West Bengal  
**T :** +91 8768781046  
**M :** +91 9434013231  
**E :** opsingh.nm@gmail.com

## EXECUTIVE COUNCIL (2019-20)

### Imm. Past President

**Dr. Ajit V. Bhide**  
**M :** +91 9243115266

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**M :** +91 9830055235

### Imm. Past Hon. Treasurer

**Dr. Mukesh P. Jagiwal**  
**M :** +91 9227926688

## DIRECT COUNCIL MEMBERS

### Dr. Abdul Majid

**M :** +91 9419071771

### Dr. Harpreet Singh

**M :** +91 7702486770

### Dr. Kishor Gujar

**M :** +91 9922501577

### Dr. Neelanjana Paul

**M :** +91 9433831692

### Dr. Abhay Matkar

**M :** +91 9448450565

### Dr. M. Aleem Siddiqui

**M :** +91 7607358897

### Dr. Laxmikant Rath

**M :** +91 9823077550

### Dr. Savita Malhotra

**M :** +91 9872000894

### Dr. Shashi Rai

**M :** +91 9415007076

## ZONAL REPRESENTATIVES

### Central Zone

#### Dr. Rajeev Jain

**M :** +91 9826097055

#### Dr. Vipul Singh

**M :** +91 9415051675

### Eastern Zone

#### Dr. Srikumar Mukherjee

**M :** +91 9830029598

#### Dr. Tophan Pati

**M :** +91 9437064922

### Northern Zone

#### Dr. B. S. Shekhawat

**M :** +91 9414069655

#### Dr. Parshotam Dass Garg

**M :** +91 9872622889

### Southern Zone

#### Dr. Gunapalli Suresh Kumar

**M :** +91 9848608604

#### Dr. Laxmi Naresh Vadlamani

**M :** +91 9348039580

### Western Zone

#### Dr. Arun V. Marwale

**M :** +91 7588402283

#### Dr. Vivek C. Kirpekar

**M :** +91 9822200689

Dated: 8<sup>th</sup> August 2019

## Message from President, Indian Psychiatric Society

Opioid Use Disorders are among the most formidable public health challenges being faced in India. Many members of the Indian Psychiatric Society (IPS) are striving to find solutions to address this problem, the most important of which is provision of evidence based treatment. A number of regulatory hurdles are encountered in making this treatment available to millions of affected Indians and a need of guidelines focusing on procedural and regulatory issues is being felt for a long time.

In order to enhance the capacities of mental health professionals in India, the IPS has been developing and disseminating a number of tools. The Addictive Disorder Specialty Section (ADSS) of IPS is proud to present one more tool aimed at providing the required guidance to the Psychiatrists as well as to the government agencies involved in the much needed regulation on controlled pharmaceuticals.

It is my pleasure to present this document to all the members of IPS.

Best wishes,

*M. J. Varshney*

**Dr. Mrugesh Vaishnav**

President

Indian Psychiatric Society



# INDIAN PSYCHIATRIC SOCIETY

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**M** : +91 9825767565  
**E** : drmrugesh@rediffmail.com

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**M** : +91 9415025665  
**E** : docpkdalal@gmail.com

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**T** : +91 612 2353882  
**M** : +91 9431011775  
**E** : dr.vinaykr@gmail.com

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Opp. Dhiraj Sons  
Mansukh Tower Lane, Athwagate  
Surat - 395001, Gujarat  
**T** : +91 6352779966  
**M** : +91 9879521795  
**E** : mukeshjagiwal@yahoo.co.in

## Dr. Om Prakash Singh Hon. Editor

AA 304, Ashabari Apartments  
O/31, Baishnabghata  
Patuli Township,  
Kolkata - 700094, West Bengal  
**T** : +91 8768781046  
**M** : +91 9434013231  
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**M** : +91 7588402283

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**M** : +91 9822200689

Dated: 8<sup>th</sup> August 2019

## Message from Hon. General Secretary, Indian Psychiatric Society

Indian Psychiatric Society (IPS) is committed to improve the standards of mental health care in India through enhancing the capacities and ensuring continuing professional development of all mental health professionals. In the series of many activities to achieve this noble goal, I am pleased to note that the Addictive Disorder Specialty Section (ADSS) of IPS has developed this document which will serve the purpose of guiding the Indian Psychiatrists on using Buprenorphine for the purpose of treatment of opioid dependence. The focused attention paid in this document to the procedural issues make it very relevant for not just the mental health professionals but even the authorities involved in regulation of pharmaceutical products.

I congratulate the members of ADSS and the various stalwarts of addiction Psychiatry who have jointly developed this document. This represents a very important step in addressing the huge treatment gap for substance use disorders in India.

Best wishes,

**Dr. Vinay Kumar**

Hon. General Secretary

Indian Psychiatric Society

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## PREFACE

Evidence based treatment of opioid dependence is an important public health priority in many parts of the country. Opioid agonist medications are regarded as the first line treatment of opioid dependence. Opioid Substitution Treatment (OST) has been instrumental in reducing morbidity and mortality and has proven effective in restoring the lives of millions of opioid dependent patients. However, in view of some concerns related to the potential of diversion and non-medical use of these medications, it is important that all health care providers are equipped with standard guidelines regarding providing treatment using these medications.

In this context, the Department of Health, Government of Punjab entrusted the Indian Psychiatric Society- Addictive Disorders Specialty Section (IPS-ADSS) with the task of developing guidelines for OPIOID AGONISTS FOR TREATMENT OF OPIOID DEPENDENCE (OATOD). Notably, such guidelines for the state of Punjab were developed initially in the year 2014. This document aims to revise the earlier document taking into account: (a) the updated evidence base, (b) clearer picture regarding epidemic of opioid dependence in Punjab, (c) the changes in the regulatory framework as well as (d) the experience with implementation. While the impetus for this document came from the Government of Punjab, the document has been envisaged to be useful for all parts of the country.

The IPS – ADSS recognizes that there exist detailed National (Indian Psychiatric Society) and International (WHO, American Society of Addiction Medicine, Australian, Canadian, etc.) documents in the form of ‘Clinical Practice Guidelines’ to assist the treatment providers. This document, besides providing guidance for clinical decision making also guides the treatment providers regarding operating procedures and governance of clinical settings. While it is agreed that in a document like this it may not be possible to visualize all clinical contexts, the document aspires to meet the needs of most clinicians for most patients in most circumstances.

The IPS-ADSS remains aware that OST (also variously known as OAT, OPT, MAT and MATOD) is probably one of the most misunderstood treatments in Psychiatry. Given the level of disagreement about the concept of Addiction and its treatment, our endeavor is to present the current state of evidence and clear the cobwebs of confusion to the extent possible.

This document will focus only on some of the clinical issues related to treatment and focus more on the processes and procedures that are recommended to ensure a balance between ensuring clinical autonomy, reducing access and availability barriers for patients while at the same time reducing the risk of diversion and misuse of medications that can bring down the reputation of one of the best evidence based treatments for Opioid Use Disorders.

We sincerely acknowledge all the authors and organizations whose earlier work this document has been built upon. First and foremost, we express our sincere thanks to Dr. A. Avasthi and Dr. D. Basu, from Post Graduate Institute of Medical Education and Research (PGIMER) Chandigarh, authors of the previous guidelines document for Punjab. Much of the content has been adapted from the original document and suitably modified wherever required.

In addition, we have consulted practice guidelines and SOPs developed by National Drug Dependence Treatment Centre (NDDTC), All India Institute of Medical Sciences (AIIMS), Delhi

and National AIDS Control Organization besides quite a few international guidelines. Finally, we appreciate the experts from all parts of country who have provided inputs, and suggestions and who have reviewed this document.

The clinical indications, patient selection, and other clinical issues for starting OATOD have been elaborated in the clinical practice guidelines and other documents referenced at the end of this document. They may be perused to obtain more specific and detailed guidance for the clinical practice.

**Atul Ambekar**  
**Ashwin Mohan**



### **Disclaimer**

This document is a general guide to appropriate practice, to be followed subject to the clinician's judgement and patient's preference in each individual case. The document attempts to provide information to assist decision-making and is based on the best available evidence at the time of development of this publication. Although every attempt has been made to make the document user-friendly and comprehensive, the authors cannot be held liable for any mistakes arising from the clinical decision making by the readers.



## BACKGROUND

Opioids belong to the family of substances which act on opioid receptors in the body. Opioids are psychoactive and can be addictive, with some of the users becoming dependent on them psychologically and physically. Opioids are also among the best-known analgesics and have immense therapeutic utility.

Common examples of opioids include crude opium (*afeem*), poppy husk (*bhukki*), poppy seeds (*khuskhus*), heroin known locally as “*smack*”, and relatively pure white powder often used by injecting, locally known in some parts of India as “*chitta*”, “white” or simply “heroin”, and a list of pharmaceutical or prescription opioids<sup>1</sup> (often locally called “medical *nasha*”) including morphine, pentazocine (Fortwin), pethidine, inj. buprenorphine, codeine (in cough syrups such as Corex, earlier Phensedyl and Rexcoff), tramadol and dextropropoxyphene / tramadol (Proxyvon, Spasmoproxyvon or “Neela”, Dexovon) lomotil, etc.

Opioid Dependence is a chronic relapsing brain disorder. The International Classification of Diseases, 10th edition (ICD-10) defines opioid dependence as “a cluster of physiological, behavioral, and cognitive phenomena in which the use of opioids takes on a much higher priority for a given individual than other behaviors that once had greater value”. A central characteristic of the dependence syndrome is the desire (often strong, sometimes overpowering) to take opioids, which may or may not have been medically prescribed. Once a person is opioid dependent, returning to substance use after a period of abstinence leads to a more rapid reappearance of other features of the syndrome than occurs with non-dependent individuals.

### **Opioid dependence causes severe harm to the Individual Family, Society, and the State/nation.**

Many states of India have a serious problem of opioid dependence. Overall at the national level, about 0.7% of Indians aged 10-75 years are estimated to be affected by opioid use disorders<sup>2</sup>. This prevalence is much higher in certain states in the north-eastern and north-western region, including the state of Punjab, which has been grappling with the problem of drug addiction for quite some time now. Various Surveys have shown that the number of opioid dependent individuals in Punjab are quite substantial and it is a huge Public Health issue. The numbers of people with Opioid Dependence in Punjab estimated by various recent surveys are 2.32 lakhs<sup>3</sup>, 2.75 lakhs<sup>4</sup>, and about 7.2 lakh problem opioid users<sup>1</sup>. Indeed, the latest national survey from

<sup>1</sup> Use of brand names do not imply an indictment or endorsement. Brand names have been provided for medical educational purpose only

<sup>2</sup> Ambekar A, Agrawal A, Rao R, Mishra AK, Khandelwal SK, Chadda RK on behalf of the group of investigators for the National Survey on Extent and Pattern of Substance Use in India (2019). [Magnitude of Substance Use in India](#). New Delhi: Ministry of Social Justice and Empowerment, Government of India

<sup>3</sup> Ambekar A, Rao R, Agrawal A, Mishra A, Kumar R, Kumar M (2016) [Punjab Opioid Dependence Survey](#). New Delhi: SPYM and NDDTC, AIIMS

<sup>4</sup> Avasthi A, Basu D, Subodh BN, Gupta PK, Goyal BL, Sidhu BS, Gargi PD, Sharma A, Ghosh A. Epidemiology of dependence on illicit substances, with a special focus on opioid dependence, in the State of Punjab, India: Results

Government of India has recommended that a) Scientific evidence-based treatment needs to be made available for people with Substance use disorders – at an adequate scale and b) A conducive legal and policy environment is needed to help control drug problems.

Opioid agonist maintenance treatment (or Opioid Substitution Treatment – OST)<sup>5</sup> is a recognized, effective, evidence-based, and generally safer option for treating opioid dependence worldwide. OST is understood as the administration of thoroughly evaluated opioid agonists, by accredited professionals, in the framework of recognized medical practice, to people with opioid dependence, for achieving defined treatment aims for preventing relapse of use of illicit opioids and for helping the patients to re-build their lives while on treatment. Methadone and buprenorphine are the most commonly used medications for this purpose, the world over. Both methadone and buprenorphine are sufficiently long acting. Additionally, when taken daily, as prescribed, they do not produce the cycles of intoxication and withdrawal seen with shorter acting opioids, such as heroin. Both methadone and buprenorphine can also be used in reducing doses to assist in withdrawal from opioids (opioid detoxification). Methadone and buprenorphine have a strong evidence base for their use, and have been placed on the WHO model list of essential medicines.

## ABOUT THIS DOCUMENT

There can be no absolute ‘right’ or ‘wrong’ about any Guidelines. However, a treatment provider is expected to possess a reasonable basis for a clinical practice decision which appears to be deviating from the recommendations of a document like this. It must however be noted that, the recommendations in this document are not legally binding rules.

This document is expected to be useful for any state or jurisdiction. Various stakeholders who would find this document useful include:

- The Government authorities (particularly the state Government Drug Controllers, State Health services, State Medical education departments as well as those agencies concerned with regulating Narcotic Drugs and Psychotropic Substance
- The manufacturers and suppliers of sublingual buprenorphine (BN) and sublingual buprenorphine-naloxone combination (BNX)
- The doctors working in both government and private sectors who prescribe / stock / dispense medications for the treatment of opioid dependence

### **Recommendation used in these Guidelines**

Based on the extensive scientific literature, existing guidelines and position papers of national and international bodies, policies in other countries where OST is practiced, experience of using

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from two different yet complementary survey methods. Asian J Psychiatr. 2019 Jan;39:70-79

<sup>5</sup> This treatment modality is known by a variety of names: Opioid agonist maintenance treatment; Opioid Substitution Treatment; Medication Assisted Treatment; Opioid Agonist Treatment of Opioid Dependence etc. Throughout the document the same treatment may have been referred to with these synonyms.

OST in our country and relevant publications, these guidelines are formulated to provide recommendations.

## OBJECTIVES

1. To help the treatment providers and regulators in addressing the existing treatment gap and ensuring availability of evidence-based treatment to thousands of patients suffering from opioid dependence
2. To help the treatment providers follow clinical practices and procedures which involve proper and rational use of OATOD
3. To discourage and minimize improper and irrational use of opioid agonists.

## BASIC FACTS ABOUT OPIOID SUBSTITUTION TREATMENT (OST)

The basic premises of using an opioid agonist agent for treating opioid dependence are:

- Using a legally permissible, evidence based and approved opioid medication which would *alleviate the withdrawal and reduce the craving* for illicit opioids.
- The same medication would also additionally, *block the intoxicating and rewarding effects* of illicit opioids.
- The same medication, being *long-acting* and *relatively safe*, would reduce the harms associated with use of illicit opioids.

Thus, the patient who decides to opt for OATOD would reduce time and resources to procure or use of illicit opioids, including indulging in crimes, drug smuggling, harming others, etc. The patient can now focus on leading a stable life, and avoid harms associated with a lifestyle comprised of using illegal opioids. As mentioned earlier, OST has reduced the illicit opioid related morbidity, and mortality and enough scientific evidence exists for that.

As of now, the only opioid agonists approved for the treatment of opioid dependence in India are:

- Buprenorphine via sublingual route, [either alone (BN) or in a fixed-dose combination with naloxone (BNX), (categorized as a Psychotropic in India)]
- Methadone (classified as an Essential Narcotic Drug). Methadone is not yet extensively used in our country currently.

**The focus of this document is mainly on Buprenorphine.**

Of the two sublingual formulations of buprenorphine available in India, BNX is relatively safer from the viewpoint of diversion and misuse than plain BN. This is because BN may potentially be diverted and used by injections but BNX is expected to cause unpleasant effects if injected. Thus, Plain BN is usually advised to be administered as a Directly Observed Treatment (DOT). However, there may be exceptions.

It is important to emphasize that OATOD is used for two very different indications:

- Short-term Treatment of acute opioid withdrawal during detoxification phase

The short-term treatment is for acute opioid withdrawal during detoxification phase. This usually lasts for 7-14 days (in some cases up to four weeks). Use of opioid agonists is the current standard of treatment for opioid withdrawal during detoxification phase.

- Long-term treatment of opioid dependence during maintenance phase

The long-term treatment is for opioid dependence during maintenance phase, also known as opioid substitution treatment (OST). Sometimes this phase of treatment may be directly continued from the initial (detoxification) phase. Duration of treatment is flexible and is expected to continue till the patient is enabled to lead a life, with minimal craving and preoccupation with using illicit opioids, free of crime, maintaining a job, stable relationships, and in general is reintegrated into mainstream society.

It is this phase of treatment that is generally misunderstood and hence is vulnerable to generate unnecessary controversies. The misconceptions regarding this treatment are not only limited to the policy-makers, but often to the doctors as well as the patients, care-givers and the media. It must be understood that OST is not substituting one addiction with another. It is about achieving treatment goals defined earlier, generally assisting the patient to organize and lead a stable and functional life, which is true for treatment goals for most chronic disorders. Thus, it is to be highlighted and emphasized that it is a scientific evidence-based treatment.

## **PRE-REQUISITES FOR STARTING OST**

1. The first pre-requisite of starting any OST/OATOD (whether for short-term or long-term use) is ESTABLISHING OPIOID DEPENDENCE. This is the first important step. It may be noted here that by their training and qualifications, all psychiatrists possess the required skills to diagnose Opioid Dependence. Medical professionals other than psychiatrists however, may require additional capacity building and training to possess the required skills.
2. The second pre-requisite is ESTABLISHING THE NEED OF OST. Before initiating OST as a treatment, a clinician is expected to arrive at a conclusion that given the clinical characteristics of the case, OST is indeed the best treatment option for a particular patient.
3. The third pre-requisite is CONSIDERING CAUTIONS AND CONTRAINDICATIONS FOR OATOD, along with WILLINGNESS and CONSENT of patient. This includes exploring concomitant use of other substances (especially other CNS depressants), and medical conditions that require caution before starting OATOD. It is essential that a patient for whom OST is being



started, provides a written informed consent expressing that s/he understands the implications of being on this treatment and provides his/her consent.

4. The fourth pre-requisite is to ideally have an OPERATIONAL SET UP where OST can be optimally provided to the patient. This includes following considerations:
  - A. Availability of PSYCHOSOCIAL MANAGEMENT MODALITY. Outcome of OST is generally better when psychosocial management is also available. This may be provided by (a) a multidisciplinary team [psychiatric social worker, psychologist, vocational instructor and psychiatric nurse]; (b) a trained Counsellor, or (c) by the treating psychiatrist himself/herself (if the availability of required time can be ensured).
  - B. Availability of a PSYCHIATRIST. Ideally, only psychiatrists should lead the process of providing OST. However, with training, non-psychiatrists can also be capacitated to provide this treatment. For example, Medical officers with three months training in a Govt. Deaddiction Centre, under the supervision of a Psychiatrist, are authorized to run the Punjab Govt.'s Outpatient Opioid Assisted clinics, till they are in government service. Other medical professionals, apart from psychiatrists, who do not have expertise/training in OST are not authorised to use OST.
  - C. Availability of a VALID AND ACCOUNTABLE SET-UP within which OATOD can be carried out. This includes:
    - essential infrastructure: The essential infrastructure will include doctors' rooms, provisions for registration/data entry, dispensing, counseling, record keeping; adequate space for a waiting area, storage and toilet(s); adequate staff such as nursing/dispensing staff, medical officer if needed, and ancillary staff.
    - management of supply chain and
    - a documented and verifiable system of dispensing of the opioid agonist medication to the patients.

**Guidance: It is important to take a detailed history of drug use to document opioid dependence. OST requires a set up that can fulfil the clinical and regulatory requirements.**



## BUPRENORPHINE FOR OPIOID WITHDRAWAL AND OPIOID MAINTENANCE: CLINICAL GUIDELINES

### Opioid Withdrawal management (Detoxification):

Buprenorphine (BN)/ buprenorphine-naloxone combination (BNX) may be used for managing acute opioid withdrawal symptoms in both inpatient and outpatient settings.

Outpatient treatment may be preferred for most patients. Usually the FDC of Buprenorphine and Naloxone is preferred for outpatient withdrawal management. However, in certain circumstances or selected cases with documentation, plain Buprenorphine may be used. These include issues like hypersensitivity to naloxone or in cases where the combination is not being tolerated by the patient. Even in such cases, it is important to involve family members in treatment who can take the responsibility of handling the medications and giving it to the patient, as per prescription. Such selected cases need to be documented clearly.

The duration of treatment for purely withdrawal management usually lasts for 3-4 weeks, although in cases of protracted withdrawal states, it may be extended beyond four weeks, and this needs to be documented. In general, if withdrawal management phase lasts for more than four weeks, it calls for a revision of treatment plan. This indicates that the patients are probably more suitable for OST (rather than detoxification). It is advisable to use clinical rating scales (OOWS, SOWS, COWS, etc.) to evaluate the severity of withdrawal to assist the clinician to titrate the doses.

Towards the end of detoxification (once the acute withdrawal symptoms have abated), various options for long-term management should be discussed with the patient and family. These include: only psychosocial management (no medicines), long-term management with oral naltrexone (or depot naltrexone whenever and wherever available), and long-term management with sublingual BN/BNX or oral methadone if available. The final choice depends upon various factors including psychiatric and medical condition, social and occupational stability, financial aspects, patient preference and family preference. Proper education about the menu of options are important to help treatment decisions at different stages.

It is not necessary to prescribe OST to each and every patient. It is a collaborative decision between the patient and the treating doctor. It also depends on treatment goals consensually agreed upon by the doctor and the patient.

**Guidance: Buprenorphine can be started for opioid dependence in outpatient or inpatient settings. While it is not necessary to start on BN/BNX for every opioid dependent patient, the current evidence suggests that agonists may be offered as first line treatment to reduce toxicity, morbidity and mortality while taking clinical condition, informed consent and patient preferences into account.**

## **Opioid Maintenance (Opioid Substitution Therapy, OST):**

Before starting OST, the earlier pre-requisites as mentioned above need to be fulfilled. OST may be started in the outpatient or inpatient setting but is always continued in the outpatient setting only as it is a long-term treatment.

OST must not be started without confirming and documenting opioid dependence; for any other substance dependence, and for those with known hypersensitivity to buprenorphine or naloxone. The procedure for induction, doses and duration during different phases of treatment may be perused using the clinical guidelines referenced at the end of this document.

**Guidance: Offering withdrawal management alone (i.e., detoxification without immediate transition to long-term addiction treatment) should be avoided to the extent possible, since this approach has been associated with increased rates of relapse, morbidity, and mortality (due to risk of overdose). During opioid-assisted withdrawal management (detoxification), patients should be transitioned to long-term addiction treatment to help prevent relapse and associated health risks.**

## **REGULATORY ISSUES RELATED TO BN AND BNX**

Both BN and BNX are duly approved medications in India. Buprenorphine is categorized as a Psychotropic under the Narcotic Drugs and Psychotropic Substances Act and as a Scheduled H1 medication under the Drugs and Cosmetic Act. However, regarding their regulations, certain specific conditions have been imposed on these medications (given the concerns about their diversion and misuse).

The Drugs Controller General (India), Government of India, had earlier issued instructions (year 2010) regarding FDC (Fixed-drug combination) of Buprenorphine + Naloxone, that “The preparation shall be supplied only to the designated Deaddiction Centers set up by the Government of India funded by the Ministry of Health and Ministry of Social Justice and Empowerment and Hospitals with Deaddiction facilities and a list of these centers to whom the supply is made should be made to the office Drugs Controller General India periodically indicating the quantity supplied to each center.”

However, recently (on 28.03.2019), in Supersession of those instructions, the Drugs Controller General (India) has issued newer instructions regarding the supply of Buprenorphine 2mg/0.4mg sublingual tablet and FDC of Buprenorphine + Naloxone (2mg +0.4 mg and 0.4 mg + 0.1 mg) Sublingual tablets. As per the newer instructions, these medications can be supplied to “Psychiatric clinics, Hospitals, Nursing Homes, Hospitals with deaddiction facilities in addition to Deaddiction centers”.

Thus, all Psychiatric clinics, Hospitals, Nursing Homes, Hospitals with Deaddiction facilities, and deaddiction centers are now authorized to procure and use the aforementioned medications.

These new instructions are in accordance with the Provisions of The Schedule H1, read with the Rule 65 (9) of the Drugs and Cosmetics Rules, 1945. Buprenorphine and its salts and preparations are covered under the Schedule H1 (vide Notification GSR 588(E) dated 30.08.2013). Rule 65 (9) (b) of the Drugs and Cosmetics Rules, 1945 mentions that the supply of Drugs specified in (Schedule H and Schedule H1) and Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries, and Nursing Homes shall be made only against the signed order in writing which shall be preserved for a period of two years.

## CLINICAL AND OPERATIONAL CONSIDERATIONS

BNX combination can be dispensed to as a “Take-Home” dose, with the following **caveats**:

1. The patient to whom the treatment is being provided should be first duly **registered** in a Clinical facility (clinic, hospital, de-addiction center, etc.). It would be ideal to have a system of some unique identification number by which the registered patients can be linked with a computerized database.
2. It is necessary to **establish the daily dose** requirement for a given patient. The initial few days of treatment are typically the phase of dose titration, where the patient and the doctor, with mutual consultation determine the optimum dose of treatment (i.e. dose on which there are no withdrawal symptoms, no craving, no side effects and which is affordable to the patient). In addition, it is also necessary to **ensure adequate compliance** of the patient. Thus, during the first few days, if feasible, BNX may be dispensed as “daily observed treatment”. This duration of daily observed treatment may last a few days to about two weeks. However, considering the operational difficulties the various options to deal with this situation are:
  - a. Asking the patient to visit the clinical facility everyday as an outpatient to receive their daily treatment
  - b. Initiating and stabilizing the dose in an inpatient setting (if the facility is available) and continue take home treatment in outpatient setting following discharge
  - c. Initiating take home dose for patients who have been stabilized on DOTS during the initial phases at some other facility
  - d. If the above is not feasible, BNX may be given for a period not exceeding five days to seven days on the first visit.
3. The exact total number of BNX tablets dispensed must be documented in (a) patient’s treatment card, (b) patient’s case file), and (c) dispensing records maintained at the clinical facility.

4. The BNX tablets should be dispensed **only by the authorized personnel**. These may include doctor, pharmacist or nursing staff, compounder, etc. in the same premises where the prescription is made, ideally in the same or adjacent room, or close to it as possible.
5. The usual take-home dose can be for about one week (7 days) - two weeks (14 days). However, During the initial phases, it is advisable that take home doses be given for seven to ten days till stabilization. It is also advisable that the number of tablets does not exceed 100 (hundred) tablets usually (see below).
6. In case the patient asks for a take-home dose longer than 14 days or the doses dispensed exceeds 100 (hundred) tablets, the doctor must be convinced about the genuineness and unavailability of the situation. The first option in such cases should be to explore the possibility of patient getting his medications dispensed from some other facility (for instance if the patients is traveling to another city). In case, the dispensing for longer duration is unavoidable, the reasons for the same need to be documented in the patient's case file, with corroborating facts. In any case, the maximum period of dispensing must not extend for more than one month (30 days). Only in very exceptional cases can it be extended beyond 30 days with clear documentation and evidence of that. It is to be emphasized that the decision of take-home doses is the privilege of the treating psychiatrist and to his satisfaction while taking into consideration various factors.

## PSYCHOSOCIAL MANAGEMENT

Psychosocial management is an important part of treatment and may ideally be offered to all patients during the entire duration of OST. Depending upon the resources available, this will include (a) relapse prevention counselling, (b) motivation building, (c) coping skills improvement, (d) assertiveness training, (e) vocational guidance, counselling and liaison, (f) facilitating alternative interests and hobbies, family involvement, lifestyle modification, etc. The intervention may be provided in an individual, group or even family setting.

It is also possible to provide these services through referral to another clinical facility. However, to the extent possible the personnel / team providing psychosocial management services should be linked with the personnel / team providing medical component of OST services. It is suggested that all the new patients be referred for psychosocial management and the frequency of this may vary according to the clinical condition of the patient and phase of treatment. Thus, during the induction and stabilization phases, psychosocial follow up and/or counselling may be done weekly or fortnightly while during the maintenance phases, it may be done monthly.

## DURATION OF OST AND DISCONTINUATION

The typical duration of OST is **not a clearly settled issue**. The decision regarding duration of treatment and treatment-completion should only be arrived at in consultation with the patient and involves evidences that patient is stabilized, is leading a life that is free of illicit opioids and



is socially and occupationally rehabilitated. Till such criteria are evident, the OST should continue, if required, for very long duration (running into years), but only with willingness and cooperation of the patient. Thus, it is better to keep a “goalpost” in view, which may be flexible.

Research evidence indicates that treatment programs with rigid time frames and absolute requirements for abstinence are less effective than those with more flexible arrangements. On the other hand, the longer a patient is retained in treatment, the outcome is likely to be better while on treatment as well as after ceasing the substitution treatment.

It is also important that optimal doses of methadone or buprenorphine are prescribed as suboptimal dosing/inadequate is associated with increased risks of dropout from treatment and restarting of uncontrolled illicit drug use with all the attendant harms.

The final decision to discontinue opioid substitution treatment is the responsibility of the doctor in consultation with the patient. Dose reduction too should be made in consultation with the patient. Thus, it is a shared decision-making process. In general, the slower the rate of reduction, the less severe are the effects of withdrawal.

Deciding criteria for discontinuation should be “**Attainment of treatment goals**”. Tapering off Buprenorphine-Naloxone may be done in either in outpatient or inpatient settings and should be very gradual. Before starting a reduction in medication dose, the clinician should assess the patient and determine their motivation, psychosocial stability, current alcohol and drug use, expectations, and source of support, concerns and aftercare plans.

**Guidance: There is no recommended time limit for treatment with buprenorphine. Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended. Most patients take one to two years of treatment to stabilize, but some people can achieve stability more quickly while others will not achieve this optimal state. Thus a flexible approach is recommended. The most commonly used treatment approach for discontinuation of buprenorphine is to undertake an outpatient gradual taper of the medication over several weeks to months, enabling time for patients to adjust to the necessary physiological, behavioral and social changes that arise during this process. If conducted in inpatient setting, duration of taper can be shortened.**

## MISUSE OF BUPRENORPHINE-NALOXONE (BNX)

The treatment providers must be vigilant for any suspicious activity alerting to the possibility of diversion of BNX, such as:

- Repeated requests for increased quantity of BNX in the absence of withdrawal.



- "Losing" outpatient cards and asking for refill prescriptions.
- Proxy family members turning up instead of the patient for refills.
- Asking for prescriptions for long periods without convincing circumstances or corroboration.
- Appearing drowsy or under influence of opioids at follow-up visits, etc.
- Asking for a much higher dose of buprenorphine than actually needed or for a much longer period – often for 30-day refills - and thus siphoning off extra medication;
- Asking for longer duration of prescription even in the initial periods of treatment.

**Guidance: Buprenorphine misuse and diversion is a complex issue. Research indicates that though diversion of buprenorphine does take place at times, the possibility of harms is substantially reduced with the BNX formulation. It must also be noted that wider and easier availability of treatment would reduce the risk of diversion. Research also indicates that much of the diverted use of medications takes place for therapeutic purposes (easing withdrawal and controlling craving). However, treatment providers need to be vigilant regarding misuse and diversion, ascertain reasons for the same and take steps to minimize it.**

## MISSED DOSES

Retention in treatment and adherence to medication are one of the most challenging situations in all chronic disorders and especially so in Substance Use Disorders. Repeated missed doses (patients not taking their regular dose of methadone or buprenorphine) can be associated with reduced opioid tolerance, opioid withdrawal and/or use of other substances, which in turn impact on treatment safety and effectiveness. There are particular safety concerns for patients recommencing buprenorphine after missing doses on four or more days because of precipitated withdrawal if the patient is under the influence of purer opioid agonists (e.g., heroin, morphine, methadone). On the other hand, if the patient has missed doses for a significant duration and has been abstinent from all opioids, the patient may have reduced the tolerance and upon restarting the BNX in the same dose, may experience side effects.

The treating clinician should review the patient prior to dosing, including:

- The circumstances around the missed doses or missed appointments, including reasons for non-attendance;
- Recent substance use and clinical presentation at dosing (including evidence of intoxication or withdrawal);

- Any relevant medical, psychiatric or social issues.

The patient must be reviewed by the treating doctor prior to restarting treatment. Usual dosing can be resumed if there are no concerns regarding intoxication, significant withdrawal or other clinical issues. Intoxicated patients should not be dosed with methadone or buprenorphine. The clinician must also review the patient if the patient presents in severe opioid withdrawal or other significant medical or psychiatric conditions.

A proportion of patients have poor compliance for dosing. This may be due to ambivalence about treatment, access (e.g. transport, work commitments, limited dosing hours) or medical issues (mobility problems, cognitive impairment), psychiatric problems (depression, personality issues), or financial or legal issues. These patients should be reviewed by their doctor to find out why, and whether the reasons for missing doses can be addressed. Options for improving treatment adherence may include changes in dosing facilities or take home doses options. Some patients who repeatedly miss doses may report that their doses of methadone or buprenorphine are inadequate. It is recommended that regular compliance be encouraged prior to any dose changes.

**Guidance: Missed doses are a major challenge in treatment of Opioid dependence. Steps for retention in treatment and adherence of medications needs to be addressed continuously and such reasons ascertained and addressed. Repeated missed doses can lead to harmful consequences for the patient, the therapeutic relationship and the treatment *per se*.**

## SAFETY CONCERNS

The Clinicians must be vigilant to the following safety concerns:

- Patient taking treatment while intoxicated on same or other licit or illicit drugs leading to - *Intoxication, sedation, and overdose*.
- Patient consuming a dose after period of several missed doses leading to or poor medication adherence leading to - *Intoxication or overdose* (if tolerance has reduced) on restarting; and *Precipitated withdrawal* if restarting BPN/BNX after recent opioid agonist use (e.g. heroin).
- Use by non-prescribed routes (injected, intranasal) leading to – *Intoxication, overdose, and other physical harms*.
- Intentional or accidental use of opioid medication by other persons leading to - *Intoxication and overdose*, Opioid related harms, including adverse drug effects, economic, legal and psychosocial consequences.
- Regular use of opioid medication by person for whom not prescribed leading to - *Development of dependence* to medication

- Illegal activities associated with selling, peddling, or possession of medications not prescribed to patient leading to – *Regulatory and legal consequences.*
- Poor reputation of opioid treatment from misuse of unsupervised medication leading to - *Stigma against patients and treatment services, reduces attractiveness of treatment to target population, health providers and community.*

## ROLE OF URINE DRUG SCREENING

Drug testing uses a biological sample (urine, saliva, hair, blood, etc.) etc. to detect the presence or absence of a specific drug (or drugs) as well as drug metabolites within a specific window of time. Though it can be a useful clinical aid, it may be noted that the diagnosis of drug dependence is based upon clinical criteria (i.e. history and examination). Thus, clinical drug testing can be a useful addition for identification, diagnosis, treatment, medication monitoring, or recovery in the drug dependence treatment settings. However, it need not be regarded as an essential feature of services. Drug testing should be used in combination with patient's self-reported information about substance use. It is suggested that, if the facility is available, all new patients be screened for opioids and other substances by urine screening.

During the initial phase of treatment, drug testing may be done frequently or when there is a high index of suspicion regarding drug use. When a patient is stable in treatment, drug testing may be done less frequently. Individual consideration may be given for less frequent testing if a patient is in stable recovery. When possible, testing should be randomly done. For patients in treatment, the drug test panel should include the therapeutic drug (buprenorphine or methadone) and/or its metabolites, if feasible.

### Clinical Value of Drug Testing

Drug tests are tools that provide information about an individual's substance use. A positive drug test by itself is not sufficient evidence for a diagnosis of a substance use disorder. It also does not explain whether a patient's symptoms are caused just by the presence of a substance. In most cases, a drug test does not measure impairment or the patterns of use over time. A negative result too does not mean that a patient has not used substances; it merely means that the patient has not used the substance(s) targeted by the test within the window of detection or used an amount less than the test is capable of detecting.

Drug testing provides another source of information to complement self-report, other reports, and physician's assessment. In contrast to a patient's self-report, Laboratory test results are considered "objective" in that they are not subject to limitations caused by willful lying, memory, social acceptability, or missing information.

Drug testing can be used as an assessment tool (initial assessment, detection of multiple substances, objective verification, clinical condition, phase of treatment), as a therapeutic tool (Explore dose adequacy, building therapeutic relationships, building motivation), and for

ongoing monitoring of treatment (monitoring recent substance use, detection of other substances, adherence, delineating discrepancies).

**Guidance:** Urine drug screening can be used to identify use of different substances in recent past, depending on the type of drug used, the dose and duration of use and individual metabolism. Urine drug screens enhance the validity of patients' self-report, identify substances not reported by the patient that may assist diagnosis and management, assist in determining adherence and monitoring. As such the frequency of urine drug screening is primarily based on the judgement of the prescribing doctor. An intermittent random schedule of testing is adequate. Illicit opioid positive results should not be used punitively but as a mechanism for improving adherence and monitoring. Similarly, if the therapeutic agent (Buprenorphine) or its metabolite are absent in the urine of patient on OST, this raises a red flag about patient's compliance to treatment and possibility of diversion. Thus, these are complementary rather than definite.

## OPERATIONAL ISSUES TO AID MONITORING AND REGULATION

In order to ensure balance between the increased access, availability and use and to minimize its potential diversion, certain compliance with some standard practices and the monitoring of such compliance by the regulatory authorities are needed.

### ***Registration***

Any new patient reporting to the clinical facility providing OATOD (de-addiction center, Hospital with Deaddiction facilities, Nursing Homes and psychiatric clinics, or other health facilities) needs to be registered and a Unique Identification Number (UID Number) must be assigned to him/her. A mechanism may be developed to generate the UID in order to prevent duplication and reduce the instances of abuse and diversion.

- The treatment facilities need to maintain records of opioid medications procured and dispensed or sold. Following types of records need to be maintained:
- Entry of each procurement of the opioid drugs in the Stock Record;
- Disbursement or dispensing of stock to the OST Clinic Drug Record; and
- Supply/sale of these medicines (with exact quantity dispensed at each visit) to individual patients in the Patient Record maintained at the OST Clinic. All such records should also have signatures of the patients who have received the dose dispensed to them.



They can also maintain a registry of OST patients, with their identifying numbers. A mechanism to ensure that these numbers can be matched with those of other facilities, may to be developed in order to ensure that the same patient does not get medication from multiple sources.

### **Submission of Reports**

Depending upon the mechanism adopted by the Government, each clinical facility can be obliged to submit Monthly/ Quarterly report to the designated authority (such as Civil Surgeon / CMO of the district etc.). The report may show the following indicators:

- Number of new registrations in the reporting month
- Number of follow up visits in the reporting month
- Number of indoor patients discharged in the reporting month
- Stock details of Medicines in the reporting month (i.e. Stock added, dispensed, and the balance)

The above data may be submitted online monthly to the central registry.

**Guidance: All attempts need to be made to ensure meticulous and diligent record keeping. At the same time, it needs to be remembered that inadvertent or unintentional mistakes may happen. Record maintenance includes the details of procurement (bills, invoices, consignment notes, and credit memos), the stocks (stock-in and stock-out) and the details of dispensing (registration, patient details, duration, doses and number of tablets). Apart from being good practices, these are regulatory requirements too. Such records need to be submitted for inspection or monitoring, if needed.**

### **Harmonious environment**

Given the stigmatizing attitudes in the society about Substance Use and patients affected by Substance Use Disorders, there are frequent misgivings between the treatment providers, the patients and their care givers, and the regulatory and administrative authorities. It is essential that these medications be seen as therapeutic drugs used for treatment rather than drugs of “abuse”. In many situations this treatment has been documented to be lifesaving. Thus, every attempt should be made to improve cooperation, coordination, collaboration and communication, and cohesion between all the stakeholders. These could be done by increasing awareness amongst, frequent sensitization, education, imparting evidence-based information, enhancing quality of treatment, maintaining ethical values (respect, beneficence, non-maleficence, and justice), keeping updated about the regulatory requirements and by reducing the stigma and discrimination. There could be inadvertent errors during the process of treatment that may be unintentional. Such errors may be dealt with by following the principles of natural justice. An opportunity to rectify or amend the flaws and defects should be given. A transparent system of redressal may be developed.



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## INDIAN PSYCHIATRIC SOCIETY



The circle in our emblem depicts the mandala - wholeness.  
The wheel - the eternal cycle or eternity. The urn is the urn of knowledge which also denotes the yin-yang principle and the mirror image express the unity behind all apparent duality.  
The staff and the entwined snakes are universal medical symbols.  
Our motto is 'Proshanti' which means peace or calmness.

Plot 43, Sector 55  
Gurgaon, Haryana, India  
Pin: 122003  
Tel.: 0124-4006150, 0124-4006750  
E-mail: [ipssecretaryoffice@gmail.com](mailto:ipssecretaryoffice@gmail.com)