

# Substitution Therapy with Buprenorphine for Opioid Injecting Drug Users

## Practice Guidelines



**National AIDS Control Organisation**  
Ministry of Health and Family Welfare  
9<sup>th</sup> Floor, Chandralok Building, 36, Janpath  
New Delhi – 110001

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**Publication authored by**

Dr. Ravindra Rao, Programme Officer (IDU), Targeted Intervention Division  
National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of  
India

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Copies of the document can also be requested from:

National AIDS Control Organisation, Chandralok Building, 36-Janpath, New Delhi – 110001,  
India

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## **The following materials were referred to during the preparation of this document:**

1. Targeted Interventions under NACP III – Operational Guidelines, Volume I (IDU Guideline), NACO
2. Intervention Tool – Kit, Module – 4, Buprenorphine Substitution, Prevention of Transmission of HIV among Drug Users in SAARC Countries. Author: Suresh Kumar M, developed by UNODC ROSA under the project TD/RAS/03/H13.
3. Ray Rajat, Dhawan Anju. Protocol on Oral Buprenorphine Substitution Therapy. Developed under UNODC ROSA project AD/ RAS/F90.
4. Reporting formats developed by EHA, SHARAN and UNODC for NGOs implementing OST project under DFID PMO funding.





**K. Sujatha Rao**

*Additional Secretary & Director General*



National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India

## FOREWORD

National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India

In the recent years, Injecting drug users have emerged as a high risk group with one of the highest prevalence of HIV. Under the second phase of National AIDS Control Programme (NACP), harm reduction package including needle and syringe exchange were provided to this group. However, there was a felt need to include Opioid Substitution Therapy (OST), in this harm reduction package.

In the third phase of the NACP, OST has been included in the comprehensive range of services to be made available to this group. National AIDS Control Organisation is planning to scale up this component of the package. As this is the first time initiative from NACO, it was felt that a practice guideline is essential.

This practice guideline has been prepared by the IDU team in NACO, with feedback from various programme and technical experts, who have been involved in the implementation of OST in India. It is hoped that this guideline would be of great help to the doctors, nurses as well as programme managers involved in the implementation of OST.

**K. Sujatha Rao, IAS**

Additional Secretary and Director General  
National AIDS Control Organisation  
Ministry of Health and Family Welfare  
Government of India

6th Floor, Chandralok Building, 36 Janpath, New Delhi - 110001 Phone : 011-23325331 Fax : 011-23731746  
E-mail : asdg@nacoindia.org

अपनी एचआईवी अवस्था जानें; निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ।

**Know your HIV status; go to the nearest Government Hospital for free Voluntary Counselling and Testing.**



# PREFACE

This practice guideline is meant mainly for the treating physician as well as Nurse, who are in charge of initiating and dispensing the medicine. In addition, other staff members such as the project coordinators/ programme managers can also benefit from this document.

This document gives an outline on the basic pharmacology of buprenorphine, followed by guidelines on various aspects of initiation, continuation and termination of therapy. Also explained are the necessary documentation and records that should be maintained while implementing opioid substitution therapy, along with performas of the required records. This performas can be readily used by the programme managers/ project coordinators to improve record keeping in their clinic.

The guideline is prepared in accordance with the NACO guidelines for high risk groups, including injecting drug users.



# TABLE OF CONTENTS

Acknowledgements	iii
Foreword	v
Preface	vii
1. Introduction	1
2. About Buprenorphine	3
3. Requirements to implement Buprenorphine	5
4. Assessment and Diagnosis	7
5. Initiation and continuation of buprenorphine	9
6. Administration of Buprenorphine	12
7. Follow Up	14
8. Other issues in treatment	16
9. Record Maintenance	19
10. Summary & Conclusion	23
<b>Appendices</b>	
1. Opioid Intoxication and Withdrawal symptoms	25
2. Client Intake Form	29
3. Diagnostic Criteria for Substance Dependence	35
4. Consent Form for Initiation of Buprenorphine Treatment	39
5. Prescription Slip Format	43
6. Side Effects Checklist for Buprenorphine	47
7. Follow Up Format for the Physician	51
8. Referral Format	55
9. Registers Performa	59
10. Medication Related Records	65





# 1. Introduction

Injecting Drug Users (IDUs) have emerged as an important high risk group with potential of contracting and transmitting HIV. The current seroprevalence of HIV among IDUs is 6.96%, as per the NACO 2006 sentinel surveillance data. HIV prevalence in IDUs has crossed the threshold for a 'concentrated epidemic' i.e. 5% in many places where surveillance was carried out. IDUs are at increased risk of HIV because of both unsafe injecting and sexual practice. The unsafe injecting practices include sharing of needles, syringes and other paraphernalia. The strategy adopted in NACP III to prevent transmission of HIV among IDUs is 'harm reduction'. The harm reduction strategy includes Needle Syringe Exchange programme (NSEP), Behaviour Change Communication (BCC), Outreach, Condom Promotion and Substitution therapy.

Substitution therapy with opioids (Opioid Substitution Therapy, OST) is a well accepted treatment strategy for harm minimisation in IDUs. OST has been shown in several studies from around the world to reduce the prevalence of HIV and HIV risk behaviours among IDUs. OST is available in various parts of the world. The two most commonly used opioid medications for OST are Buprenorphine and Methadone, both of which have been found to be effective in HIV prevention. Buprenorphine scores over methadone in that buprenorphine, being a partial agonist, decreases the risk of respiratory depression with overdose. Buprenorphine substitution has also been shown to improve retention in treatment.

Buprenorphine is a scheduled drug listed as a 'psychotropic substance' under the Narcotic Drugs and Psychotropic Substances (NDPS) Act and hence its manufacturing, distribution, sale and consumption, like other opioids, are controlled. The NDPS act also has provision to establish treatment or de-addiction centres by the Government and the use of psychotropic substances such as Buprenorphine for medical and scientific purpose to treat 'addicts'.

## Rationale for Opioid Substitution Therapy

Opioid substitution therapy involves replacing the client's primary drug of use (opioid) with a medically safe drug or the same opioid in a safer mode of administration under medical supervision. In OST, an opioid (such as heroin), which is unsafe, requiring repeated administration through unsafe/ hazardous route is substituted with a medication (such as Buprenorphine) which is long acting, and safer, and administered through oral / sublingual route. The medication used in OST helps the client not to experience either withdrawal or euphoria ('high').

As OST helps in achieving a comfortable level, the client stops injecting drug, thus preventing the potential harm of contracting HIV and other diseases transmitted through injecting route (e.g. Hepatitis B, Hepatitis

C). While on OST, clients do not require to spend all their time looking for their next 'fix' or injection. Thus, they can be engaged in other activities including counselling and group discussions, which help also in delivering Behaviour Change Communication. In addition, there is also an improvement in the psychosocial status of the clients, leading to an overall improvement in quality of life.

## 2. About Buprenorphine

Buprenorphine is a semi-synthetic opioid derivative of thebaine, which is a derivative of opium. It is 25 – 50 times more potent than morphine. Buprenorphine can suppress withdrawal symptoms precipitated by sudden discontinuation of opioid use in persons dependent on them. However, at very high levels of dependence on an opioid, it may itself precipitate withdrawal. Buprenorphine also has a potent antagonistic action at  $\kappa$  receptor.

### 2A) Pharmacology

Buprenorphine is a partial  $\mu$  receptor agonist. Thus, while buprenorphine has an intrinsic agonist action, it can act as an antagonist in the presence of a full agonist. About 0.4 milligram of buprenorphine is equi-analgesic to 10 mg of intramuscular morphine.

Buprenorphine is well absorbed sublingually. Blood concentration peaks within 1 – 2 hours after sublingual administration. The half life of buprenorphine in plasma is upto 3 hours. However, because of its avid binding, the duration of action of buprenorphine is much longer (> 24 hours). About 96% of the circulating drug is bound to proteins.

### 2B) Physical dependence potential

When buprenorphine is discontinued, a withdrawal syndrome is developed which has an onset from 2 days – 2 weeks and persisting for 1 – 2 weeks. The withdrawal features are similar to morphine; however, the features are not very severe. For symptoms of opioid withdrawal, refer to **Appendix 1**.

### 2C) Overdose and toxicity

Deaths related to overdose have been reported with intravenous use or using very high doses of combination of Buprenorphine and benzodiazepines or alcohol.

### 2D) Side effects

#### Side effects

- |                |                   |
|----------------|-------------------|
| ■ Constipation | ■ Disturbed sleep |
| ■ Drowsiness   | ■ Headaches       |
| ■ Sweating     | ■ Nausea          |

It is to be noted that these side effects are mild and not discomforting enough to warrant stopping the medication.

## 2E) Contraindications

- **Severe medical illness:** Bronchial asthma, severe respiratory impairment, hepatic impairment, pheochromocytoma, inflammatory bowel disease, and hypothyroidism
- **Drug reactions:** Established history of side effects (hypersensitivity) to buprenorphine
- **Concomitant use of high doses of other drugs:** Concurrent use of high dose of hypnotic, sedative or alcohol leads to aggravation of respiratory depression.
- **Young or very young subjects:** Age less than 18 years
- **Pregnancy:** Though pregnancy is not an absolute contraindication, the evidence at this point, is not conclusive enough to advocate use of buprenorphine during pregnancy

**Caution** should be exercised in those with high-risk of polydrug use, concomitant medical/psychiatric conditions or in those with chronic pain.

### Contraindications

- Pregnancy
- Known hypersensitivity
- Primary dependence on non-opioid drugs
- Young patients
- Certain medical/ psychiatric illnesses

## 2F) Availability

In India, Buprenorphine is available in strengths of 0.2mg, 0.4mg and 2mg as sublingual tablets. As guided in the NDPS act, buprenorphine can be dispensed only by those agencies which have been approved by Government for treating 'opioid addicts', and that the drug can be used for scientific and medical purpose. As sublingual tablets, 0.4 and 2 mg is not available in the local pharmaceutical shop.

## 3. Requirements to implement Buprenorphine

### 3A) Accreditation

Agencies must be **accredited** by NACO for implementing OST through NACO/ SACS. The procedure for accreditation is outlined in 'Operational Guidelines for Targeted Interventions Under NACP III', Vol I.

### 3B) Infrastructure/ requirements for establishing an OST service

- OST clinic must be easily accessed from points where drug users congregate, as the drugs need to be administered daily
- Separate Space for clinical interview by staff, drug dispensing, and counselling where privacy for the IDU client is assured
- Adequate space for drug storage and record keeping
- Adequate and established mechanisms to ensure safe keeping of OST medicines: mechanism for supply/storage/dispensing of OST medicines
- Provision of condoms in spaces which are easily accessible to IDU clients
- Linkages with centres offering other services to IDU clients, including:
  - ◆ Counselling and testing centres for HIV (ICTC)
  - ◆ ART and HIV related care for HIV infected clients
  - ◆ Detoxification centres
  - ◆ Hospitals/emergency rooms for management of overdose/complicated abscess/other general health conditions including tuberculosis (in cases where the OST staff is unable to provide treatment at the OST clinic)
  - ◆ Rehabilitation centres/ programmes
  - ◆ Self-help groups
- Redressal mechanism for IDU clients
- Involvement and advocacy with local communities/leaders/law enforcement agencies.

### 3C) Staffing

- One medical doctor with a minimum qualification of MBBS (preferably full-time. If part-

time, back- up coverage for other days as well as absence/leave of the doctor should be established.)

- One nurse
- One counsellor
- Outreach Worker (one for 5 peer educators)
- Peer educator (one for 40 clients)

The technical staff (doctor, nurse) should have received specific training on OST from agencies specified/ approved by NACO. Other staff education and training is also necessary.

## 4. Assessment of client

Before initiating OST, the client is assessed, which should be conducted by a doctor as well as counsellor. Assessment not only helps in understanding the client's immediate problem, but also helps in building a rapport with the client. The assessment is not a one time activity, but a continuous process. Often the client is not able to come out with his problems initially, because of lack of confidence and rapport with the treating team. The client may also be intoxicated or in withdrawal during the initial assessment period, making assessment difficult. In such cases, the physician needs to carry out basic assessment initially, and later revisit the assessment once the client is comfortable and not in withdrawals or intoxication.

The initial aspects of assessment i.e. collecting socio-demographic details and basic history of drug use and associated complications may be carried out by counsellor. The physical examination and technical aspects such as diagnosing dependence can then be conducted by the physician. A performa for assessment is provided in **Appendix 2**.

### 4A) Assessment:

- Baseline **socio-demographic** details;
- **History of drug intake:** a chronological sequence of drug intake, along with establishing whether the client was taking it regularly, whether he had developed dependence on the drug of abuse, whether he was using in harmful way. In this section, the client's current status of drug intake (current being defined as intake over the past 30 days) along with dose and frequency should also be assessed.
- **Complications of drug use:** the complications may be
  - ◆ **Financial** – loss of earned money, debts, etc.
  - ◆ **Legal** – involved in illegal activities including peddling, being caught by police, jailed, etc.
  - ◆ **Occupational** – loss of job, irregular in work, etc.
  - ◆ **Familial/ marital** (fights in family, verbal or physical abuse, divorce/separation, disowned by family, etc.
  - ◆ **Physical:** this should be assessed thoroughly by a physician, as this has bearing on initiation of OST. The physical problems may be
    - **Local:** abscesses, ulcers, thrombophlebitis, venous thrombosis, etc.

- **Respiratory:** tuberculosis, bronchitis and obstructive lung disease, etc.
- **Abdominal/ hepatic:** hepatitis, abscesses, ascites, etc.
- **Cardiovascular:** emboli
- **Neurological:** stroke, palsies, etc.
- ◆ **Psychological:** this aspect should also be looked into by the physician, as co-morbid psychological problems often exist along with drug use problems.
- **High risk behaviour** for HIV/ AIDS or other blood borne viruses such as hepatitis B and C. The high risk behaviours include both injecting and sexual behaviour. High risk injecting behaviour includes sharing of the needles and syringes, as well as other paraphernalia such as cooking vessels, cottons, water, etc. High risk sexual behaviour includes having multiple sexual partners, sexual intercourse without barrier methods such as condoms. Assessment of these aspects would also help the counsellor in motivating the client to undergo a voluntary counselling and testing for these blood borne viruses.
- **Other details:** the client's current living arrangement, presence of other stressors and personality may also be assessed
- **Physical examination:** Apart from measuring vital signs, the general condition examination should focus into the nutritional status, jaundice and look for other signs of liver damage. In addition, vein marks along with abscesses, thrombophlebitis, and thrombosis should be examined. Signs of withdrawal of opioid as well as other substances must be examined.

A detailed systemic examination of the abdominal, respiratory, neurological and cardiovascular system is very important to assess the client's physical well being and eligibility to initiate opioid substitution therapy. Finally, an assessment of psychological status and motivation of the client to leave drugs should be made.

#### 4B) Diagnosing substance related problems:

Substance related problems have been broadly classified by the World Health Organisation (International Classification of Disease, ICD – version 10) into dependence and harmful use. The criteria for dependence and harmful use are provided in **Annexure 3**.

## 5 Initiation and continuation with Buprenorphine

Buprenorphine should be initiated in those clients who fulfill the inclusion and exclusion criteria.

### 5A) Inclusion Criteria

- *Diagnosed case of opioid dependence with injecting drug:* This is through history taken from the IDU client as well as by family members, and physical examination to look for signs of withdrawal/ injection use. (*An injecting drug user is one who has used substances for recreation through injecting route in the past 3 months*).
- *Age:* more than 18 years
- *Failed detoxification:* An IDU client should have attempted detoxification before being considered for substitution therapy
- *Informed consent:* Willing to provide informed consent for OST treatment

### 5B) Exclusion Criteria

- *Severe medical illness:* Bronchial asthma, severe respiratory impairment, hepatic impairment, pheochromocytoma, inflammatory bowel disease, and hypothyroidism
- *Drug reactions:* Established history of side effects (hypersensitivity) to buprenorphine
- *Incapable of providing informed consent:* due to conditions which impairs a client's judgement, e.g. acute psychosis, major depressive illness or cognitive impairment.
- *Primary dependence on non Opioid drugs:* Buprenorphine maintenance is not appropriate for people who are primarily dependent on non-opioid drugs such as alcohol, benzodiazepines, amphetamines, or combinations of these.
- *Concomitant use of other drugs:* Concurrent use of high dose of hypnotic, sedative or alcohol leads to aggravation of respiratory depression.
- *Young or very young subjects:* Age less than 18 years
- *Pregnancy*

### 5C) Procedures to initiate buprenorphine

For initiating buprenorphine, the following steps should be followed:

- Prior to initiating buprenorphine, a physician must collect detailed history and conduct general physical examination. The suggested Performa is in **Appendix 2**.

- The physician should be able to establish a current diagnosis of opioid dependence syndrome. (The criteria for diagnosis of opioid dependence is in **Appendix 3**)
- Once the diagnosis is established, the physician should then assess the client for suitability to initiate buprenorphine which includes assessing whether the client fits the inclusion and exclusion criteria.
- The client should then be explained about the concept of oral substitution therapy in detail along with information about the drug. A consent form should be signed by the client before initiating buprenorphine. (See **Appendix 4**)
- The physician himself/ herself should initiate buprenorphine and a prescription to that effect must be recorded in the client file (see **Appendix 5** for a performa for prescription slip).

#### 5D) Dose of buprenorphine

##### Initial dose

- There should be a gap of at least 6 – 8 hours after the last dose of heroin/ primary drug of use, before the first dose of buprenorphine is given to the client.
- Though there are no strict guidelines on the initial dose of buprenorphine, a useful procedure would be to start a client on about 2 – 4 mg.
- Following the initial dose, the client should be observed for a period of about 2 – 4 hours. During this 2 – 4 hours, the client should be observed for
  - ◆ Withdrawal symptoms
  - ◆ Symptoms of Intoxication: sedation, difficulty in coordination, slurring of speech, loss of judgement, etc.
- If withdrawal symptoms persist, an additional 0.4 – 2 mg dose can be given depending on the severity of withdrawals.
- The dose of buprenorphine has to be decreased if intoxication symptoms are present.
- In case of unknown tolerance, the initial dose should be about 2 – 4 mg of buprenorphine.
- Generally, not more than 6 – 8 mg of buprenorphine should be given on the first day.
- The initial dose should be continued for the next 2 – 3 days, during which the blood level of buprenorphine would stabilise.

## Stabilisation dose

- For further increase in dose, on day 3 or 4 of Buprenorphine treatment, after the initial stabilisation, enquiry must be made and the client observed. The following issues should be checked:
  - 1) Whether the client reports withdrawals/ discomfort inspite of receiving his usual dose
  - 2) Whether the client continues to consume opioid (inject/ chase) inspite of his usual dose
  - 3) Whether the client reports any features of intoxication or sedation with his usual dose
- In case of (1) and (2) above, the dose of the client needs to be increased, while in case of (3), the dose needs to be decreased. The client should be stabilised at a dose at which the client neither experiences craving and withdrawal nor has intoxication with buprenorphine. Injecting, though, may continue for some time before a client finally stops drug use.
- For a majority of the clients in India, the usual dose required during stabilisation phase is about **4 – 8 mg of buprenorphine per day**
- If a client is found to need doses >16 mg per day, he/she must be referred to a higher centre.

### Initiation and continuation of Buprenorphine

- Initiate Buprenorphine in those fulfilling the inclusion and exclusion criteria
- Establish current diagnosis of opioid dependence syndrome
- Explain the client about OST and get the consent form signed
- Initial dose to be around 2 – 4 mg, maximum of 6 – 8 mg as initial dose
- Stabilise by day 4 – 7; stabilisation dose to be around 4 – 8 mg
- Maximum dose of 16 mg per day

## 6. Administration of Buprenorphine

Buprenorphine must be initiated by a physician who will prescribe the medicine on a prescription slip. The slip must then be shown by the client to the dispensing staff, who must record the dose in the client's dose sheet and the dispensing register.

### 6A) Prior to administering the medication, the dispensing staff must

- Establish the identity of the patient (either through an ID card, or through the clinical staff)
- Confirm that the patient is not intoxicated
- Check for current prescription
- Check that the current day is the dosing day on the patient's regime
- Confirm the dose for the current day if it is an alternate-day or three-times-a-week regime
- Record the dose in the recording system

### 6B) Administering buprenorphine through Directly Observed Treatment (DOT)

Buprenorphine is preferably given by way of Directly Observed Treatment (DOT). This means that the drug is given by the designated staff member, and the client observed to allow dissolution of the drug in the mouth. This will ensure that the drug is not taken away, crushed and injected by the clients.

After the necessary documentation and identification methods are completed (as discussed above), the following procedures should be observed by the nurse

- Count and check the buprenorphine tablets into a dry dosing cup. Double check the number and strength.
- Place the tablet under the tongue of the client. To avoid diversion by the client, the tablets should be crushed into powder, and the powder placed under the tongue of the client.
- The following instructions should be given to the client:
  - ◆ Avoid tea/coffee 15 minutes before and after Buprenorphine
  - ◆ Do not swallow saliva until powdered tablets have dissolved (7 – 10 minutes on average)
  - ◆ Do not swallow the powdered tables

- ◆ Once the tablets crushed in the form of a powder are given to you, they are your responsibility and will not be replaced.
- Observe the client until you are satisfied the tablets are fully dissolved (usually 10 minutes). Check the client's mouth once before he leaves the dispensing room.
- Ask to see “how the powdered tablets are dissolving” enough times for this to become an acceptable part of the patient's delivery routine.
- Offer water to rinse taste out of mouth.
- The client should sign/affix thumb impression that they have received their dose.
- The doctor should be notified if the dosing administrator has concerns that the client may be attempting to divert their medication.

## 7. Follow Up

The client should be followed up regularly by the physician as well as other staff.

### 7A) Physician

Initially, the physician should see the client regularly till the dose of buprenorphine is stabilised. Once the dose is stabilised, the physician should see the client once a week for the initial one month; once in two weeks for the next two months and later once a month. During each visit, the physician should enquire

- Whether the dose of buprenorphine is adequate for the client (whether the client reports withdrawals/ intoxication/ discomfort)
- Whether the client reports any side effects of the medication (a Side Effect checklist is enclosed as **Appendix 6**)
- Whether the client is continuing injecting drugs
- Whether the client has switched to/ continued using other drugs (e.g. alcohol, cannabis, etc)
- Client's psychosocial status
- Clients involvement in other high risk behaviours

A follow up format is enclosed as **Appendix 7**

If a client misses his dose of buprenorphine, the physician/ nurse should enquire about the reason for missing doses. In case a client misses his dose for more than seven days at a stretch, the client should be considered as a new case, and the treatment started all over again.

### 7B) Counsellor

The client, in addition to drug use per se, would also have problems in other areas of functioning. These may include

- **Familial/ Marital:** discord in the family with frequent fights and quarrels; distrust among the family members
- **Occupational:** loss of job; unemployment
- **Legal:** involvement in illegal activity (pick pocketing, thefts); incarceration

**Counsellor:** The counsellor should follow up for at least once a fortnight initially and later once a month. The counsellor will have a one to one interaction with each client. During the initial sessions, the counsellor must focus on assessing the high risk behaviour of the client, including both injecting and sexual high risk. Also, the psychosocial status of client, including his employment, legal, marital, psychological problems must be assessed. The counsellor should set goals, with active participation from the client. The client must also be encouraged to undergo voluntary counselling and testing for HIV.

During the follow up, the counsellor must try to address the areas that were seen as problematic during the assessment. The goals that have been set should be revisited during each follow up, and the client should be encouraged to achieve them.

In addition, the counsellor should actively encourage the client to engage the family members in the treatment decision. Also, the family members should be interviewed to make them understand the treatment process and solicit their help in the client recovery. The sexual partners of the client should also be contacted and advised to go for VCTC. They should also be counselled for high risk behaviours and safer practices.

**Group discussions:** In addition to the above, the outreach workers and peer educators will carry out group discussions, wherein issues such as 'basics of drugs' 'basics of HIV and AIDS' 'concept of harm reduction' 'benefits of oral substitution' etc. may be taken up. This will help the client into developing an understanding about the issues directly related to his health status.

## Addressing psychosocial problems of the client

- Psychosocial problems should be addressed by two levels of staff:
  - ◆ Counsellor: One – One counselling
  - ◆ Outreach workers/ Peer Educators: One – Group discussion
- Focus:
  - ◆ Initial – A assessment of high risk behaviour (both injection and sexual)
  - ◆ Later – Psychosocial problems (familial, legal, occupational, and marital)
- Clear goals should be set and reviewed periodically
- Active engagement of family members in treatment is essential for successful outcome
- Sexual partners of IDU clients should be addressed

## 8. Other issues in treatment

### 8A) Adjunctive medications

In addition to buprenorphine, additionally, medicines may be given for sleep problems encountered by the client. Thus, one may recommend the following for sleep at night time:

- Tablet Diazepam in doses upto 10 – 20 mg per day
- Tablet Zolpidem in doses upto 10 – 20 mg per day
- Tablet Amitriptyline in doses upto 50 – 75 mg per day (avoided in those with psychiatric problem, seizures, cardiac problems, urinary retention, asthma, etc)

However, care must be taken to ensure that the medicines used for sleep, especially diazepam and zolpidem, must not be given for a long period of time as these are potentially 'addictive' medicines. In addition, sleep hygiene should be taught to the clients. This will ensure that there is lesser need of the sedative/ hypnotics for management of sleep problems.

### 8B) Discontinuation of treatment

There are some grounds on which treatment may be discontinued. These are:

- Violence, threatened violence, or verbal abuse towards other patients or staff,
- Repeated failure to attend medical or counselling appointments,
- Frequently missing doses,
- Unlawful entry into the premises,
- Diversion of buprenorphine doses,
- Engaging in unlawful activity such as drug dealing around the clinic or pharmacy

These issues are important and should be tackled promptly, as a client engaged in these activities may disrupt the smooth functioning of the clinic, and jeopardise the well being and functioning of the other clients as well as the staff working in the clinic. However, it should also be noted that discontinuation of treatment may be seen as being rejected by the client. Hence, there should be clear set rules of 'do's' and 'don'ts' at the outset. These rules should be clearly and consistently applied to all the clients. The clients may be given warning at first instance, before taking the extreme step of discontinuation.

Finally, such episodes may also reflect on the functioning of the OST centre and the attitude of the staff in dealing with clients. This should be duly noted and taken up at staff meetings for a review of the centre's functioning.

### 8C) Duration of buprenorphine treatment

Generally, most of the clients would benefit from one year of treatment with buprenorphine. Few clients would require more than one year of treatment with buprenorphine.

### 8D) Tapering buprenorphine

Buprenorphine should be tapered gradually. Sudden tapering will lead to withdrawals in the client. For some clients, the dose can be tapered over a period of 10 days – two weeks. Alternatively, in some cases, the dose can be tapered gradually over a longer period (one to two months). This can be achieved in outpatient setting. In case the client finds it difficult in outpatient setting, the client can be referred to a detoxification facility for tapering buprenorphine.

Thus, the dose can be decreased by 0.4 mg per day if the client is comfortable. If the client is uncomfortable, then this dose may be decreased every alternate day.

### 8E) Relapse

There is always a chance that a client might relapse while on buprenorphine. Some of the early pointers towards relapse are:

- The client starts missing his doses,
- The client starts becoming defensive/ hostile to the staff suddenly
- The client drops out of OST before completion of the treatment duration.

In such situations, as well as in cases where the client has gone back to his drug use, efforts must be made to contact the client and the reasons for relapse should be enquired into. The client should be provided hope that he/ she can try once again to quit drug use. Relapse should not be seen as a failure on the part of the client to quit using drugs. The client should be further encouraged to restart substitution with buprenorphine. In case the client declines, he should be encouraged to use other harm reduction measures (e.g. needle syringe exchange) till he is ready for considering OST.

### 8F) Co-morbid medical problems:

**1. Concomitant alcohol/ sedative/hypnotic use:** In case of concomitant alcohol or other sedative/ hypnotic use by the client, the following precautions need to be taken:

- The dose of buprenorphine needs to be decreased, as there is a risk of respiratory depression with concomitant use of buprenorphine and sedative/ hypnotic or alcohol.
- The client should be monitored for abnormal liver pathology in case of alcohol use (through Liver Function Test). In case of deranged LFT, buprenorphine may have to be withdrawn.

**2. Co-morbid psychiatric illness:** IDU clients have on occasions, co-morbid psychiatric illness, especially depression. In such cases, the client should be assessed, and a psychiatrist must be consulted.

**3. Concurrent administration of ART drugs:** OST with Buprenorphine improves the adherence of HIV positive clients on ART drugs. There is no significant drug – drug interactions between Buprenorphine and ART medications. The following table is produced from the ‘*Antiretroviral therapy guidelines for HIV-infected adults and adolescents including post-exposure prophylaxes*’ published by NACO, May 2007.

**Table: Interaction between Buprenorphine and ART Drugs**

Antretrovirals	Effect on Bruprenorphine	Effect on ARV	Comments
<b>NRTIs (Nucleoside Reverse Transcriptase Inhibitors)</b>			
E.g. Zidovudine, abacavir, didanosine, stavudine, etc.	No significant interactions reported		
<b>NNRTIs (Non-Nucleoside Reverse Transcriptase Inhibitors)</b>			
<b>EFV (Efavirenz)</b>	Buprenorphine concentrations decreased but not significantly	None reported	No dose adjustment of EFV required
<b>PIs (Protease Inhibitors)</b>			
<b>RTV (Ritonavir)</b>	Inhibition of buprenorphine metabolism, resulting in a clinically significant increase in buprenorphine levels	None reported	Buprenorphine dose may need to be reduced
<b>ATV (Atazanavir)</b>			

## 9. Record maintenance:

Emphasis should be placed on maintaining records of the clients. Every client on OST should be given an identification (I.D.) number. This number should be used when recording details of the client by any of the staff member. This will ensure client confidentiality. A separate '**Client File**' should be maintained for every client. In addition, files for the activities undertaken should be maintained. Table 1 provides a list of records to be maintained as well as the responsible and supervising person. The following records should be maintained:

- A. Client file:** A separate file should be maintained for every client. The name and the I.D. number of the client should be mentioned at the top of the file. Any activity undertaken for the client should be recorded in the client file. The client file should contain:
- Client intake form (Appendix 2)
  - Consent form for initiating buprenorphine (Appendix 4)
  - Prescription slip (Appendix 5)
  - Follow up form (Appendix 7)
  - Side effects checklist (Appendix 6)
  - Referral form (Appendix 8)
  - Group discussions carried out (by the PEs and ORWs) (mentioning the date, and the topic covered)
  - Counselling held for the client (by the counsellor) (mentioning the date, and the topic covered)
  - Meetings with the family members (by the counsellor/ ORW/ PE) and the discussions held

The client file should be reviewed periodically by the programme manager/ project coordinator. This review would bring into light, issues that have not been addressed by the team for a particular client.

- B. Registers:** The following registers should be maintained by the staff. These registers should be periodically reviewed by the programme manager/ project coordinator.
- **Client register:** A register which mentions the socio-demographic details of the client along with his address and I.D. Number. This should be maintained by the counsellor or outreach worker (**Appendix 9A**).
  - **Referral register:** This register shall contain the referrals made by the staff on a

day to day basis. Thus, on a given day, the record should show how many clients have been referred to various services. At the end of the month, a tally of the referrals made across various service heads, should be made so as to provide the total number of referrals made during the month. (See **Appendix 9C** for a format of the referral register).

- **Counselling register:** This should be maintained by the counsellor. Herein, a day to day record of the counselling carried out by the counsellor is made, and the same should be recorded in the client file. (See **Appendix 9B** for a format of the Counselling register).
  - **Group discussion register:** this is to be maintained by the outreach worker. Herein, record should be made of the topic which has been discussed, the number of participants, duration of discussion, the clarifications and questions raised in the discussion, and the result of the discussion. The same should be recorded in the clients file who have attended the group discussion. (See **Appendix 9D** for a format of the Group Discussion register).
- C. Medication related records:** these records should be maintained diligently. The programme manager/ project coordinator should review these records weekly. These records would give the programme manager about the consumption pattern of the medicines, available stock for dispensing, and whether there is any diversion of medicines.
- **Client's dose sheet:** Every client should have a sheet which keeps a record of his daily dose of medicine that he receives. At the end of the month, the sheet should then be transferred to the client's file. This sheet should be filled by the nurse. (See **Appendix 10A** for a format of the Client dose sheet).
  - **Dispensing Register:** this should be maintained by the nurse. A performa of the same is provided in the appendix (**Appendix 10B**).
  - **Daily Stock register:** this should be maintained by the nurse. (See **Appendix 10C** for a format of the Daily Stock Register). The nurse should tally this number with the total number mentioned in the Dispensing register.
  - **Central Stock Register:** A similar stock register should be maintained by the programme manager, which should be recorded on a weekly basis. This register would specify the stock received by the pharmaceutical company and given to nurse (**Appendix 10D**).

The programme manager/project director should take care in storing buprenorphine tablets. Usually not more than one week stock should be kept in the dispensing clinic.

S. No.	Name of the record	Description	Responsibility	Overall Supervision
1.	Client register	Register containing names, age/sex and address of clients along with client ID No. (Appendix 9A)	Counsellor / outreach worker	Programme Manager
2.	Client file	A file for each client containing:		Programme Manager
		■ Names, age/sex and address of clients along with client ID No.	Counsellor	
		■ Client intake form (Appendix 2)	Counsellor and Physician	
		■ Consent form for initiating buprenorphine (Appendix 4)	Physician	
		■ Follow up form (Appendix 7)		
		■ Side effects checklist (Appendix 6)		
		■ Referral form (Appendix 8)	Counsellor / Physician	
		■ Record of Group Discussions attended by the client (mentioning the date, and the topic covered)	Outreach worker (ORW)	
■ Record of Counselling sessions attended by the client (mentioning the date, and the topic covered)	Counsellor			
■ Record of meetings with the family members with date and topics covered during discussions	Counsellor / ORW			
3.	Referral register	Register containing client ID No., date and places where they are referred to (Appendix 9C)	Counsellor / Physician	Programme Manager
4.	Counselling register	Register containing client ID No., date and brief mention of topics covered in counselling (Appendix 9B)	Counsellor	Programme Manager

S. No.	Name of the record	Description	Responsibility	Overall Supervision
5.	Group discussion register	Register containing dates, topics covered, number of participants, along with client IDs, and remarks (Appendix 9D)	ORW	Counsellor / Programme Manager
6.	Prescription-slip	A slip containing, ID No. and date along with the prescription (i.e. medications with doses) (Appendix 5)	Physician to fill & nurse/pharmacist to retain	Programme Manager
7.	Clients dose sheet	One sheet for each client containing: ID no., date, dose of medication received, TO BE RENEWED EACH CALENDER MONTH (Appendix 10A)	nurse/pharmacist	Physician / Programme Manager
8.	Dispensing register	A register with each sheet filled and renewed every day with ID No., dose received, signature of client (Appendix 10B)	nurse / pharmacist	Programme Manager
9.	Daily stock register	A register in which the daily situation of buprenorphine stock will be entered (Appendix 10C)	nurse / pharmacist and Project Manager	Programme Manager
10	Central stock register	A register in which the stock of buprenorphine received from the pharmaceutical company/ SACS/ parent agency as well as the stock dispensed periodically to the clinic will be entered (Appendix 10D).	Programme manager/ Project director	Project Director

## 10. Summary and conclusion

Oral substitution with buprenorphine is recognised world wide as an effective harm reduction strategy for preventing HIV among IDUs. Buprenorphine is a safe compound, with minimal side effects and minimal chances of overdoses, if used knowledgeably. The procedure to implement OST is simple, and does not require extensive clinical setup. The outcome with OST is best, when combined with psychosocial interventions.

OST is a medical intervention which requires a physician to initiate treatment with regular follow up. The nurse is involved in the daily dispensing of medicines and maintenance of stock related to buprenorphine. The nurse is also responsible for overseeing the client's physical welfare on daily basis, as she is available and accessible to the clients daily. The counsellor has an important role to play in providing psychosocial support, and also act as a bridge for other types of services provided by the agency. Finally, the project coordinator is in overall charge of the centre, as well as provides a supervisory role in the daily running of the centre, including taking care of the stocks, records, staff and maintaining a link with the other community members.

Broad guidelines exist on procedures to initiate, maintain and taper buprenorphine. Along with the proper implementation of medicine and appropriate psychosocial intervention, the records should be maintained regularly by all the categories of staff. The medication related records should be maintained properly with regular evaluation by the senior staff, as these records are liable for external, including legal scrutiny.



# APPENDIX 1

## Opiate intoxication and withdrawal symptoms



## A) Symptoms of opioid withdrawal

Signs and symptoms of opioid withdrawal include any or all of the following, which may develop at a time appropriate for the ingested opioid (i.e., within 6–12 hours after the last dose of a short acting opioid, such as heroin or 36-48 hours after the last dose of a long acting opioid, such as methadone):

- Craving for opioids
- Restlessness or irritability
- Nausea or abdominal cramps
- Increased sensitivity to pain
- Muscle aches
- Dysphoric mood
- Insomnia or anxiety
- Pupillary dilation
- Sweating
- Piloerection (i.e., gooseflesh)
- Tachycardia
- Vomiting or diarrhea
- Increased blood pressure
- Yawning
- Lacrimation

Withdrawals can also be **graded** according to their severity and duration of onset:

Grade 1	Grade 2	Grade 3
Yawning	Mydriasis (dilated pupils)	Insomnia
Sweating	Piloerection (goose bumps)	Increased pulse
Lacrimation (tearing)	Muscle twitching	Increased respiratory rate
Rhinorrhea (runny nose)	Anorexia	Elevated blood pressure Abdominal cramps Vomiting Diarrhea Weakness

**B) Symptoms of opiate intoxication:**

- Pupillary constriction (or dilation due to anoxia from overdose)
- Drowsiness or coma
- Slurred speech
- Impairment in attention or memory
- Shallow and slow respiration or apnea

**Note:** *Acute opiate intoxication can present as a medical emergency with unconsciousness, apnea, and pinpoint pupils*

# APPENDIX 2

## Client Intake Form



## Name of centre:

Name of interviewer with Designation:

Registration Number of client:

Date of registration: Date \_\_\_ Month \_\_\_ Year \_\_\_

Source of referral: Self Referred/ Outreach/ Authorities/ Others (Specify):

### Socio demographic profile:

1. SEX

1	Male
2	Female

2. AGE (in years):

3. MARITAL STATUS:

1	Never Married
2	Married
3	Widow/ Widower
4	Divorced
5	Seperated
99	Not known

4. EDUCATION:

1	Illiterate
2	Literate (can read and write)
3	Primary education (upto 5 years of schooling)
4	Middle education (upto 8 years of schooling)
5	Matriculation/ Higher secondary (upto 10–12 years of schooling)
6	Graduate & above
99	Not Known

5. EMPLOYMENT STATUS:

1	Never Employed
2	Currently unemployed
3	Full time employed
4	Part time employed
5	Student/ housewife
6	Any other
99	Not known

6. DRUGS OF USE:

Drugs	Age at onset (in years)	No. of years of use	Injecting route (yes/no)	Dependence? (yes/no)	Current use (last one month? yes/no)
Heroin					
Buprenorphine					
Cap. Spasmoproxyvon					
Other opioids (Opium, Pentazocine, Codeine)					
Alcohol					
Cannabis (Ganja/ Charas/ Hashish/ Bhang)					
Sedative/ Hypnotics [Diazepam, Nitrazepam, Chlordiazepoxide, Chlorpheniramine (Avil), Phenargan, etc.]					
Cocaine					
Amphetamines and other ATS					
Inhalants					

■ **Complications with drug use (yes / no)**

1. Physical
  - a. Abscesses/ Ulcers
  - b. Respiratory Problems (chronic airway disease/ Tuberculosis)
  - c. Hepatitis/ other abdominal complaints
  - d. Cardiovascular (emboli)
  - e. HIV/AIDS
2. Legal (involved in stealing/ pick-pocketing/ other illegal activities/ caught by police, etc)
3. Marital (discord)
4. Familial (discord)
5. Occupational (loss of job/ demotion/ not able to work properly)
6. Financial (loss of money/ property/ debts)

■ **High Risk Behaviour**

1. Injection related
  - a. Sharing of needles and syringes (ever): yes/ no  
If yes: whether shared on last occasion of injecting
  - b. Sharing of other paraphernalia(ever): yes/ no  
If yes: whether shared on last occasion of injecting
2. Sex related
  - a. No. of sexual partners (last 30 days)
  - b. Last sexual encounter, whether:
    - i. Unprotected
    - ii. Protected

■ **Previous attempts to achieve abstinence, if any and results:**

Specify time period	Duration of abstinence	Type of help / intervention	Reasons of relapse

- **Motivation – Reasons for wanting to abstain:**
  
- **Current living arrangement**
  
- **General physical examination:**

Pulse rate:	Temperature (whether Febrile/
Blood pressure:	afebrile):
Respiratory rate	Cyanosis:
Weight:	Jaundice:
Pallor:	Oedema:
	Clubbing:
Lymphadenopathy:	
Skin (Needle marks; Abscess; Open wounds): (Describe in detail):	
  
- **Systemic examination:**
  - Chest:
  
  - Abdomen: (especially liver)
  
  - Neurological examination:
  
- **Mental status examination:**
  
- **Diagnosis: (including substance dependence and co-morbid medical problems)**
  
- **Advise (including prescription by physician for tablet buprenorphine):**

# APPENDIX 3

## Diagnostic Criteria for Substance Dependence and Harmful Use (WHO, ICD 10)



## I. Dependence syndrome

**Three or more** of the following manifestations should have occurred together **for at least one month**, or if persisting for less than one month, should have occurred together repeatedly **within a 12- month period**.

1. A physiological **withdrawal** state when substance use has ceased or reduced, as evidenced by the characteristic withdrawal syndrome for substance use, or use of same (or closely related) substance with the intention to relieve or avoid withdrawal symptoms.

Every class of substance produces its own characteristic set of withdrawal signs and symptoms. For e.g. opioid withdrawal produces symptoms such as lacrimation, rhinorrhea, body ache, diarrhea, and signs such as dilation of pupils (mydriasis), increased sweating, rhinorrhea, etc. The client continues to consume the substance in order to obtain relief from the withdrawal symptoms.

2. Evidence of **Tolerance** to the effects of the substance, such that there is a need for significantly increased amounts of the substance to achieve intoxication or desired effects, or a marked diminished effect with continued use of the same amount of the substance

For e.g. a person has been taking about 250 mg of heroin to feel high initially. With repeated use of the same dose, he doesn't get the same high as before. Hence, he has to increase the dose to feel the same high as he would experience before.

3. Strong desire or sense of compulsion to take the substance

This is also called as **craving**. Craving is characterised by a strong urge to use the substance.

4. **Difficulties in controlling** substance taking behaviour in terms of onset, termination or levels of use, as evidenced by: the substance being often taken in larger amounts or over a longer period than intended; or by a persistent desire or unsuccessful efforts to reduce or control substance use.

Once the person is dependent on the particular substance, he would find it difficult to avoid using substance at a particular place or time, or restrict himself to the predetermined dose or level of the substance.

5. **Preoccupation** with substance use, as manifested by important alternative pleasures/ interests being given up/ reduced because of substance use; or a great deal of time being spent in activities necessary to obtain, take or recover from the effects of the substance.

As a result of his substance use, a person dependent on the substance starts neglecting his usual activities, and indulges in the substance use. He does not indulge in other activities that he found pleasurable before. The person also spends a considerable amount of time to either procure the substance or recover from its effect. In short, his life now revolves around the substance on which he has become dependent.

6. **Persisting** with substance use **despite** clear evidence of **harmful consequences**, as evidenced by continued use when the individual is actually aware, or may be expected to be aware, of the nature and extent of harm.

## II. Harmful Use:

- A. There must be clear evidence that the substance use was responsible for (or substantially contributed) to physical or psychological harm, including impaired judgement, or dysfunctional behaviour, which may lead to disability or have adverse consequences for interpersonal relationships.
- B. The nature of the harm should be clearly identifiable (and specified).
- C. The pattern of use has persisted for at least one month, or has occurred repeatedly within a 12-month period.
- D. The disorder does not meet the criteria for any other mental or behavioural disorder related to the same drug in the same time period.

# APPENDIX 4

## Consent Form for initiation of Buprenorphine treatment *(To be translated in local language)*



I, \_\_\_\_\_ consent to start tablet buprenorphine for oral substitution therapy.

I have been explained that Buprenorphine is being initiated as a part of the comprehensive treatment for opioid dependence. As an opioid agonist (action similar to heroin), buprenorphine maintenance treatment will substitute an illicit, medically unsafe, short acting opiate such as heroin with a medically safer, long acting drug with similar effect i.e. buprenorphine. The agonist maintenance will eliminate drug hunger and the drug that I was using will not be able to produce the same effect as before, so that I do not experience any withdrawal symptoms and there will be no craving for the drug being abused. When combined with psychosocial interventions it will minimize dysfunction and help me to become productive and will improve my self-esteem and personal dignity. My attendance to group sessions will improve the chances of successful outcome.

I need to be honest regarding follow up visit, revealing of any medication side-effects, craving for opioid use and psycho-social stressors. Even if I discontinue buprenorphine and relapse to opioid use, early treatment seeking within days is advisable.

**In addition, I have been given to understand that**

- The use of other drugs (such as alcohol, tranquillisers, sleeping pills, heroin or other opioids) may be dangerous in combination with buprenorphine, and can lead to overdose, breathing failure and death.
- My dose of buprenorphine may be withheld or reduced in the event that I present intoxicated with alcohol or other drugs.

**I understand that my treatment may be stopped without my consent for reasons such as:**

- Violence, threatened violence, or verbal abuse towards other patients or staff,
- Failure to attend medical or counselling appointments,
- Frequently missing doses,
- Unlawful entry onto the premises,
- Diversion of buprenorphine doses,
- Engaging in unlawful activity such as drug dealing around the clinic or pharmacy

I have fully understood the above-mentioned information. I am willing to start buprenorphine and follow the instructions explained to me.

Patient's signature

Date and time

Signature of family member & relationship to the patient

Date and time

Signature of treating physician

Date and time



# APPENDIX 5

## Prescription Slip Format



**Prescription slip**

Date

Name of the client:

Client ID No.:

Advise:

Signature:

Name of the Physician:



# APPENDIX 6

## Side Effects Checklist for Buprenorphine



### Side Effects Checklist for Buprenorphine

(To be applied by the physician/ nurse during follow up of the client on OST)

**Date**

**Current dose**

Sr. Number	Symptoms / signs	Yes / No
1	Sedation	
2	Diplopia	
3	Giddiness	
4	Headaches	
5	Confusion	
6	Light headedness	
7	Blurred Vision	
8	Hallucination	
9	Drowsiness	
10	Incoordination	
11	Slurred Speech	
12	Itching	
13	Oral Ulceration	
14	Constipation	
15	Weakness	
16	Sexual Problem	
17	Other (specify)	



# APPENDIX 7

## Follow Up Format



Date : .....

Client ID Number : .....

**Current Drug Use (LAST 1 WEEK)**

- I. Frequency and Average amount of drug use in last one week (no. of days)  
Primary drug –  
Other drug –
- II. Last dose-  
Primary drug –  
Any other drug –
- III. If continued drugs, reason for continuation

**Medication related issues:**

No. of days during which the client has missed medication in last one week:

Side effects of medication (as per checklist provided in appendix 4):

**Sexual high risk behaviour:**

**Psychosocial status of the client:**

**General physical and systemic examination:**

**Recommendation / further plan:**



# APPENDIX 8

## Referral Format for a Client



(Please mention whether the referral was an accompanied referral, any remarks made, and any follow up of the referral was made)

Date	VCTC	DOTs	STI	Detoxification	Rehabilitation centres	ART	Counselling centres	Other (please specify)



# APPENDIX 9

## Register Performa











# APPENDIX 10

## Medication Related Records



## A. Client's dose sheet

Client ID No.		Date of OST initiation:			
Month:					
Day	Date	Number of 0.2 mg Buprenorphine consumed	Number of 0.4 mg Buprenorphine consumed	Number of 2 mg Buprenorphine consumed	Total dose consumed
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

**B. Dispensing register:**

The dispensing register should be filled by the nurse daily and the total number of tablets (each strength) dispensed during the day should be calculated at the end of the day and entered into the daily stock register

Month:						
Date:						
No.	Name	ID No.	No. of Buprenorphine Tablet dispensed			Signature
			2 mg	0.4 mg	0.2mg	
<b>Total no. dispensed</b>						

## C. Daily Stock Register (maintained by Nurse)

**N.B.:** The opening stock of the day would be the closing stock of the previous day. The stock dispensed during the day shall be obtained from the daily dispensing register. Dividing the stock dispensed from the opening stock will give the remaining stock.

Date	Stock	No. of Buprenorphine tablets		
		0.2 mg	0.4 mg	2 mg
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			
	Opening Stock			
	Stock Dispensed			
	Remaining Stock			

### D. Central Stock Register (maintained by Project Coordinator/ Programme Manager)

This is to maintained by project coordinator whenever he receives stock from distributing agency, and when he supplies it to the nurse for dispensing

Date:	2 mg	0.4 mg	0.2 mg
1. Stock remaining			
2. Stock obtained from the distributing agency			
3. Total stock available			
4. Stock supplied to the nurse/OST agency			
5. Stock remaining			
<b>Date:</b>			
1. Stock available			
2. Stock dispensed to the nurse/ OST agency			
3. Stock remaining			

