

Standard Operating Procedure for
Oral Substitution Therapy with
Buprenorphine



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Foreword

Under the National AIDS Control Programme, Phase III, Oral Substitution Therapy (OST) has been included in the comprehensive package of services to the Injecting Drug Users. After obtaining necessary approval, National AIDS Control Organisation plans to scale up this component. In this connection, a practice guideline for implementation of buprenorphine substitution has already been prepared.

For obtaining funds from NACO, the agencies desirous of implementing OST have to undergo accreditation. At its first meeting, the National Accreditation Committee set up by NACO felt that a document outlining the standards to be followed by an OST centre is necessary. The present document is prepared by the IDU division at NACO, with feedback from various programme and technical experts, who have been involved in the implementation of OST in India. The document sets standards against which a centre will be assessed for accreditation. Both minimum and ideal standards are outlined. The document also contains the assessment tool and application form for accreditation.

It is hoped that this document would additionally be of great help to the programme managers involved in the implementation of OST.

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Standard Operating **Procedure**

Introduction:

Injecting drug use (IDU) is recognised as a major mode of transmission of HIV in India and elsewhere. As per the sentinel surveillance report 2006, Injecting Drug Users (IDUs) have the highest rate of HIV among the High Risk Groups. The National AIDS Control Organisation (NACO) has adopted harm reduction as a strategy to prevent HIV among IDUs. Under the National AIDS Control Programme – Phase III (NACP III), interventions designed for IDUs have been expanded and strengthened to address the rising HIV prevalence among this group.

Oral/Opioid Substitution Therapy (OST) has been included in NACP III as a new intervention component. OST involves substitution of injecting opioid drugs with oral medication that effectively minimizes craving and withdrawals, and thereby enables IDUs to stop injecting drugs. OST has proved to be successful in reducing drug related harms including HIV transmission.

NACO plans to scale up OST services through Non Governmental Organisations (NGOs) working in the drug treatment sector as well as through Government hospitals. Organizations and institutions intending to take up OST programs funded by NACO are required to seek accreditation by NACO or by an agency deputed by NACO. A National Accreditation Committee has been constituted in this regard. In its first meeting chaired by the Additional Secretary and Director General, NACO, the Committee expressed the need for Standard Operating Procedures (SOP) for running an OST Centre.

There are some minimum prescribed standards that must be met by OST centres desiring accreditation. Centres meeting standards that are seen as ‘ideal’ or ‘more than the minimum’ will have an added advantage over other centres, and these factors will be taken into consideration while awarding scores. Centres meeting the minimum standards may strive to achieve the ideal standards for implementing OST programme.

In preparing the SOP, the existing healthcare systems as well as the functioning of the NGO sector in India have been kept in view. A draft version was circulated to key stakeholders as well as technical experts associated with this field and their valuable feedbacks have been incorporated.

This SOP document complements the existing NACO document ‘**Substitution Therapy with Buprenorphine for Opioid Injecting Drug Users – Practice Guidelines**’; and both these documents should be used in conjunction.

SECTIONS

1. **Space and Infrastructure**
2. **Staffing and Training Related Issues**
3. **Starting OST Related Services**
4. **Delivering OST Services**
5. **Other Services**
6. **Supply chain and Diversion Prevention Mechanisms**
7. **Other Issues**

1. SPACE AND INFRASTRUCTURE

a. Location:

- An OST centre **should** be ideally located near a **hotspot** (places where sizeable number of IDUs congregate or reside). The location should be within 5 – 10 km radius of the hotspot.
- If an OST centre is not located near a hotspot, it **should** be located at a central area of the town, or should be easily accessible to IDUs via public transport.
- An OST centre may also be located in a Drop-in-centre (DIC) of an intervention providing services to IDUs.

b. Space:

An OST centre **should** have rooms for

- **Doctor**
This room is for the doctor to elicit history, examine clients and initiate treatment as well as for follow up. The room should have adequate space for a doctor, a client and his/her companion to sit and discuss various issues, and an area for performing physical examination. The room should provide a sense of privacy to the client to enable him to speak freely about his personal problems.
- **A dispensing room**
This room is for a nurse / pharmacist to dispense medication daily to the clients. The room should have a table with space to store medicines to be dispensed on a single day. There should be enough space for a nurse to sit along with 2 – 3 clients (a client needs to be seated for 3 – 5 minutes till the medicine dissolves under direct observation by the nurse while she administers medicine to another client) and an office support staff.
- **A room for counselling the clients**
This shall contain a room with enough space for a counsellor, client and his/ her family members to be seated. The room should ensure privacy for the clients (closed room to discuss their problems with the counsellor freely. In some centres where the doctor is part-time, the room can be shared by the doctor and counsellor.

- A waiting area
This area is for the clients to be seated while they wait for their turn. This can also be a place for the clients to rest after having received their doses; and may be appropriately furnished. The waiting area could also serve as a room for group discussions, support group meeting as well as for family meetings. Reading materials, television and games may also be provided in this area for keeping the clients engaged.
- A storage space
This is for storing medicines and other commodities in the centre. Utmost precautions should be taken for storing the medicines safely. The medicine should be stored in a securely locked cupboard. . The space should be cool, away from direct sunlight, and properly ventilated. The storage space should not be easily accessible to the clients and visitors.
- Facilities for record keeping in the centre.
There should be adequate space at the centre for maintaining client records and other relevant documents; and proper filing systems should be in place.

c. Amenities

- The centre **should** be able to provide the clients with a sense of comfort, security and privacy, and attractive enough for the clients to access the services.
- All the rooms **should** be properly painted and have adequate lighting and ventilation.
- The centre **should** also have provision of drinking water with restroom facility.

d. Clinic Timings

The OST centre **should** be open 7 days a week. The OST centre **shall** function for at least 7 – 8 hours per day. During public holidays/ Sundays, the clinic may be open for a limited duration of time. Prior information on the timings for Holidays / Sundays should be provided to the clients. The dispensing hours can be decided by the OST centre as per the clients' needs. However, the dispensing of medicines **should** be done for at least 50 – 60% of the centre's timings. A notice board **should** display these timings with contact details of the doctors in case of emergency. Information on the sites where IDUs can access detoxification and Needle Syringe Exchange services **should** also be displayed prominently.

e. Equipments:

- Basic furniture for the staff and clients
- Equipment for basic medical examination: e.g. stethoscope, torch, disposable gloves, BP apparatus, thermometer, etc.
- For dispensing medicines: tablet crusher, dispensing cups, etc.

- In case of centres providing other health care services: equipments for abscess management, waste disposal system, etc.
- Condoms: displayed such that it should be easily accessible to the clients
- Needles and syringes may also be provided at the centre
- Sharp bins for safe disposal of used needles and syringes, and other infectious materials

2. STAFFING AND TRAINING RELATED ISSUES

a. *Staff*

The following categories of staff are essential in an OST centre:

1. Programme manager
2. Doctor
3. Nurse
4. Counsellor
5. Outreach Workers (ORW)
6. Peer Educators (PEs)
7. Office Support Staff: Guard, Office boys, etc.

While the doctor can be part-time employed, the other category of staff should be employed full time in the OST centre. Ideally, the doctor should also be employed full time by the centre. Staff from drug using background would be preferable, and have been found to be more effective in dealing with clients. Also, preference should be given to those who have prior experience of working with drug users.

Mechanism should be in place to provide back-up coverage during a staff member's absence / leave. The staff should ensure that the confidentiality of the client is maintained at all costs. The staff should demonstrate a non-discriminatory attitude, and be sensitive and caring towards IDUs and PLHIV.

1. **Programme/ project manager**

The programme/ project manager plays a pivotal role in the overall running of the programme and centre. There shall be at least *one* project manager in every OST centre.

Qualifications:

The project manager should preferably be a graduate. If he has completed higher secondary education, he should have worked with drug users for at least 5 years.

Roles and responsibilities: The project manager shall be the key person heading the OST team and will be responsible for coordinating and communicating with all stakeholders i.e., clients, their families, staff, SACS, NACO, other service providers, local administration, law enforcement, media and the general public. Key areas of work:

- Taking lead in implementing the project activities
- Preparing action plan for the project
- Coordinating different activities of the project

- Writing/Preparing monthly reports
- Establishing and documenting referrals linkages with other service centres
- Observing and supervising all activities of project staff
- Planning and conducting advocacy activities
- Coordinating and/or conducting in-house staff training
- Conducting staff meetings regularly
- Managing uninterrupted supply of buprenorphine
- Ensuring regular functioning of DIC
- Tasks or responsibilities assigned by SACS/ NACO from time to time.

2. Doctor

Ideally, a doctor should be engaged full-time at the centre. He can also be a part time staff of the centre. He should be available at the centre for at least 3 days a week for at least 3 hours per visit.

Qualification

The doctor should have a minimum qualification of MBBS. A psychiatrist would be preferable.

Roles and responsibilities The doctor plays a lead role in the medical aspects of OST programme. The doctor is expected to provide the best possible medical care for OST as per the standard clinical practice guidelines developed by NACO.

- Assess patients for suitability of initiation into substitution therapy
- Prescribe suitable doses of buprenorphine to appropriate patients, and conduct regular follow ups
- Provide routine health check and basic health care including appropriate clinical management/referrals for wound/abscess, overdoses and STIs, as per the facilities available at the clinic.
- Documentation as per the NACO guidelines/ protocols.
- Provide basic information to the clients and family members about the treatment process
- Referrals to ICTC for HIV diagnosis and other institutions for advanced care treatment
- Follow the NACO technical guidelines/protocols in all clinical practice
- Continuing professional development and sharing information between other substitution providers
- Help the centre in carrying out advocacy activities

3. Nurse

The nurse plays a crucial role in dispensing medicines as well as maintaining stocks records of buprenorphine on a regular basis. There shall be at least one nurse for every 100 clients

Qualification:

The nurse should have a minimum qualification of ANM. Those with diploma nursing / Bachelor of Science (Nursing) would be preferred.

Roles and responsibilities:

- Maintaining minimum standard guidelines (as provided) for the clinic
- Dispensing buprenorphine as per NACO's treatment guidelines/ protocols
- Assisting doctor in treating abscess, providing medication etc
- Maintaining registers (daily stock and dispensing registers) as prescribed in NACO's practice guidelines for buprenorphine
- Regular communication with project manager and treating doctor
- Providing emergency first-aid services in the absence of doctors

4. Counsellor

There shall be at least one counsellor for an OST centre.

Qualification:

The counsellor should have a Bachelor's degree in psychology / social science / humanities. If the counsellor is from drug using background, he / she should have completed higher secondary education with training in counselling. Those who have received training in counselling and prior experience of working with drug users are preferred.

Roles and responsibilities: The counsellor is primarily and directly responsible for individual clients' treatment and progress in the therapy.

- Counsel IDU clients primarily at the DIC, and if required in the community or at home as well
- Provide different forms of counselling including motivational counselling, family counselling, group counselling
- Participate in the weekly staff meetings at DIC
- Provide counselling to PLHIV
- Referrals for STIs, ICTC and other relevant services
- Maintain documentation as outlined in the practice guidelines for OST.

5. Outreach worker:

There shall be at least one outreach worker for every 100 clients.

Qualification:

The outreach worker shall be a person with a working knowledge of the local terrain as well as the community (both IDU and general). He/ she should be literate.

Roles and Responsibilities:

- Identify and motivate IDUs about the OST programme
- Assist the nurse in registration and consent
- Assist nurse in dispensing buprenorphine
- Supervise peer educators and providing on-site support;
- Follow up non-attendance / drop outs and document reasons; in case of drop-outs, home visits to be conducted
- Help establish peer support groups for both female and male IDUs
- Conduct Behavioural Change Communication (BCC) sessions on safer practices, condom demonstration, referrals and follow up with the clients;
- Liaison with IDUs and PLHIV in the field
- Monitor regular condom & IEC materials availability at the DIC;

- Assist the nurse in maintaining the stock and patients registers
- Assist the clients in receiving various other referral services, including accompanied referrals as and when required

6. Peer Educators

The peer educators are the foot-soldiers of the OST programme, and often also serve as role models in the programme. There shall be at least one peer educator for every 40 clients

Qualification

The peer educators should necessarily be from current/recovering IDU background. He/ She should have good communications skills and should be acceptable to the IDU community in general.

Roles and responsibilities

- Conduct Behavioural Change Communication (BCC) sessions in the field and in the DIC (one-to-one and one-to-group);
- Identify new clients, provide motivation and follow up through outreach service to access OST clinic
- Assist IDUs with STI, abscess and other related issues to seek help at the clinic;
- Assist in organising support group/SHG meeting and group discussion.
- Assist ORWs in home visits, and other follow up activities

b. Training

The OST staff should have received training specifically on Substitution Therapy. Ideally they should have been trained by NACO / agencies specified by NACO. In case of training received from a non-NACO agency, the staff should have undergone training organised by any of the agencies which are regarded as technically experienced in OST implementation (such as Emmanuel Hospital Association, United Nations Office on Drugs and Crime, SHARAN, National Drug Dependence Treatment Centre, TTRCRF). Ideally, all the staff members should have received central training. However, at the minimum, the programme manager, doctor, nurse and the counsellor should have received central training; and the outreach staff should have been trained by the programme staff of the OST centre.

3. ACCREDITATION

Agencies desirous of implementing OST through NACO funding should be accredited by NACO/ agency approved by NACO. The accreditation will involve two steps. In the *first step*, agencies will have to submit their application in a prescribed application format. These formats will then be screened by a committee and score the agencies. In *Step Two*, shortlisted agencies shall then be visited, and a team of assessors will verify the agency. They will score the agency on a prescribed assessment tool. Finally, the agencies will be accredited based on the scores obtained. An accreditation certificate will then be given to the agencies. This certificate **should** be displayed in the OST centre at all times, failing which the accreditation can be withdrawn.

The format for applying for accreditation can be found in *Appendix A*, and the assessment tool which will be used during accreditation in *Appendix B and C*.

4. STARTING OST RELATED SERVICES

A. Knowledge of the Community

Prior to starting OST related services, the staff should have a working knowledge on the situation of IDUs in their area. Areas which the staff should be aware of are:

1. Knowing where the IDUs are: awareness of the hotspots in the area,
2. Knowing how 'hot' the spots are: injecting behaviour pattern of the IDUs as well as involvement in risk taking behaviours (both injecting and sexual behaviour)
3. Knowledge of the drug using pattern among the IDUs in the locality: common drugs injected, other drugs used by the IDUs
4. Awareness of the secondary stakeholders: local community leaders, religious leaders, 'influential' people (people who can influence the acceptability of the programme), health care providers, etc.

The above mentioned areas could be covered under a mapping exercise, a Rapid Situation Assessment (RSA), or by conducting a Needs Assessment (NA)

B. Contact with IDUs

The centres/organisations that are in touch with IDUs before starting an OST intervention are more likely to be successful in effectively initiating and rapid scale-up of the OST programme. Thus, it is always preferable that the agency implementing OST should have prior experience either of working with IDUs, or have a good working liaison with other agencies which are providing services for IDUs in the locality.

C. Referral Linkages:

The organisation/ centre should have conducted an assessment on the presence / absence of other services available / likely to be needed by the IDUs. Thus a 'mapping' of the service providers should be conducted prior to starting an OST intervention. The centre can have either a physical mapping of these services, or a directory of these services. Awareness and linkages with the following services should be established beforehand:

1. **Integrated counselling and testing facility (ICTC):** located near the area of intervention, or one that is easily accessible to the clients
2. **DOT centre** for Tuberculosis
3. **ART centre** and **Community Care Centres**
4. **Detoxification and Rehabilitation centre**
5. **STI Clinics**
6. **Clinics/ Hospitals** for providing abscess management and other health services including emergency services for overdose management
7. **Centres** running needle syringe exchange programmes
8. **Laboratory Services:** basic services (e.g. hemogram, LFT, etc.), and for drug screening (if available)

D. Advocacy

The organisation / centre should be actively engaged in carrying out advocacy with various stakeholders both prior to initiating an OST intervention as well as subsequently on an ongoing basis. The stakeholders shall include but not limited to:

1. Law enforcement / local administration: informing the local police stations and narcotics department and soliciting support from them
2. Local community leaders
3. Religious leaders
4. Other groups: e.g. student/ youth organisations, local community based organisations, local medical associations, etc.

5. DELIVERING OST SERVICE

A. Preparatory phase

The client may have been referred to the centre by any of the following: by the ORW/ PE during outreach services, through the drop-in-centre of the TI, referral by other service providers (e.g. ICTC, ART centre, primary health care providers, detox and rehab centres, hospitals, etc.), referral by other drug users or self referral.

Upon arrival at the OST centre, the client can be attended to by the following staff: the counsellor, programme manager or ORW. The concerned staff should briefly interact with the client and address the following issues:

1. Understanding the client's perception towards OST and outcome expectancies
2. To assess the motivational level of the client
3. To dispel myths/ misconceptions of the client towards OST
4. To explain to the client that assessments will be made by the counsellor and doctor prior to initiation on OST to determine whether he (the client) fits the criteria for OST initiation
5. To inform the client the 'do's and don'ts' while he is on OST (e.g. to come daily for OST, to report for any side effects, being honest about his drug use status, etc.)
6. To explain the rules and regulations, clinic timings, procedures to be followed while on OST (e.g. to meet the doctor and counsellor regularly, to participate in group discussions, to involve family members in the programme, etc.)

If during the screening, the client is found suitable for OST, he/she will go through the following steps:

- Registration
- Initiating a client file containing assessment formats, consent form, etc.
- Referral to the doctor for initiating OST

These three steps are primarily the responsibility of the counsellor. However, the project manager could also provide these services as and when required.

B. Induction, Follow Up and Termination Phase

Once the client understands the whole procedure of OST, he / she shall then be assessed by the counsellor and doctor prior to initiating OST. The section on assessment and induction , as well as procedures on starting medication, informed consent, dispensing, and the

frequency of follow up and assessments to be made have been laid down in the practice guidelines. The formats for these have provided in the appendices of the practice guidelines.

6. OTHER SERVICES

Apart from OST, the centre should also be able to provide other services related to IDUs.

This shall include at least

- Primary health care services by the doctor,
- Counselling on harm reduction
- Counselling on safer sex practices,
- Family counselling,

In addition, other services required by the IDUs shall be provided through referrals. These should include (but not limited to):

- ICTC
- DOT for Tuberculosis
- STI services / RCH services for spouse/partner
- ART centre for PLHIV IDUs
- Detoxification and Rehabilitation centre
- Harm reduction services including NSEP, abscess management

Ideally, the centre may provide any/ all of the above mentioned services directly. This would greatly enhance the adherence of the clients to the OST programme. In case the client is being referred to a particular service, the centre should not only provide the addresses of the above referral centres, but also a detailed information about why he/she is being referred, including its benefits and outcomes. Ideally, whenever possible, referral should be accompanied by designated staff; if not possible, a referral slip should be provided to the clients. Additionally, follow up with the referral agency to see whether the client has accessed these services and regular interaction with the referral agencies and sensitising them towards the needs of the IDUs should also be done.

7. SUPPLY CHAIN AND DIVERSION PREVENTION MECHANISMS

This is a very crucial aspect of any OST programme. While an OST centre requires an uninterrupted stock of OST medicines, the staff should also be aware that the medicines are scheduled drugs and regulated under Indian narcotics laws. The laws require that the consumption details be maintained diligently by the centre implementing OST. The onus of maintaining the supply chain shall lie with the programme manager. The responsibility of maintaining the daily stock registers shall lie with the nurse.

A. From Stock to dispensing

The nurse shall maintain a register documenting the daily consumption and dispensing of OST medicines. The Performa for the same is provided in the practice guidelines (*Annexure 10B and 10C*).

- On every dispensing day, before dispensing, the nurse shall collect the average daily requirement of medicines where they have been stored, and duly enter the amount taken out in the Daily Stock Register and sign on the entry.
- The nurse shall then store the stock for the day in the dispensing room
- The nurse shall enter each tablet dispensed to the client in the Dispensing Register. The client should sign on the dispensing register against his/ her name/ ID number daily.
- The procedures to be followed for dispensing the tablets is laid down in the practice guidelines (section 6A and 6B)
- At the end of the day, the nurse should add up the total number of tablets dispensed (for all strengths) and record it in the Dispensing Register. He/she should sign on the final count in the dispensing register.
- The remaining stock of buprenorphine at the end of the day should be taken back to the store in the centre.
- The nurse should then record the day's consumption in the daily stock register against the 'stock dispensed' column, and then calculate the remaining amount of tablets of all the strengths. This, then, should be entered in the 'remaining stock' column. The nurse should then sign on the entry every day.

The Dispensing Register as well as the Stock Register should be kept secured in a well-secured cupboard after entries are made, and the keys (for accessibility) should be kept with the nurse and programme manager only. During days when the nurse is on leave/ absent, this procedure shall be carried out by the counsellor or the programme manager.

B. Stock maintenance in the OST centre

At the OST centre, the medicine stock should be stored in a cupboard which can be securely locked. The cupboard should be such that it is not easily accessible. (A strong iron Almirah can serve this purpose.) Within this cupboard, a drawer should be earmarked for storing the stock, and this drawer should be locked at all times and should be accessible only to the nurse and the programme manager. The stock and dispensing register should also be stored in this safe. The method of transporting the stock out of safe storage daily has been described in the above section.

The bulk of the stock should be kept in the head office of the organisation under secure lock and key, which shall be accessible to the programme manager / organisation's chief functionary only. At the place where actual dispensing takes place, no more than one week's stock should be maintained. The programme manager should ideally check the stock registers and the dispensing registers daily, or at least twice weekly. This verification should be initialled by the programme manager.

In the head office too, a Central Stock Register should be maintained. The Performa for the same is provided in the practice guidelines (Annexure 10D). The organisation chief functionary should check the central stock registers monthly. An analysis of the consumption and stock should be done regularly so that any depletion of stock more than the expected can be brought to notice and appropriate measures can then be taken.

Whenever the stock arrives from the supplier, each strip should be physically verified for missing tablets in the strip. In addition, the batch number of the stocks should be checked

against the bills received, and recorded in the Central Stock Registers. Any change should be promptly brought to the notice of the supervising agency / supplier, and recorded. Also, the expiry dates of the stocks should be checked and recorded in the central stock registers. The chief functionary should sign on every entry made in the Central stock Register.

In case, where there are concerns about the safe keeping mechanism at the OST centre, the stock can also be transported to the OST centre from the head office of the organisation daily. In such a scenario, this should be brought by the programme manager/ counsellor/ nurse only, who shall then be responsible for the transportation.

8. OTHER ISSUES

A. Programme management

The centre should have clear guidelines on the management of the OST programme in the centre. This should include details on who will monitor the staff, how frequently, what activities shall be conducted and by whom. A work-plan should be made by the staff members in consultation with the programme manager. Regular staff meetings should be conducted by the programme manager. The programme manager shall be in-charge of the running of the OST centre daily. The programme manager should also carry out advocacy regularly with the stakeholders. In addition, he/ she shall be responsible for sending out the reports regularly.

B. Record keeping system

The formats for record keeping are provided in the practice guideline; which also clearly delineates the roles of the staff-in-charge of particular records. . The programme manager should conduct periodic reviews of the records and analyse them to improve the functioning of the centre. The records should also be preserved in the record room / space for record keeping for internal/ external monitoring and evaluation. Confidentiality should be maintained at all times.

C. Grievance redressal mechanism

The centre should have a redressal mechanism for the IDU clients and the staff members. There can be a register / drop-box for the IDUs to write their complaints, which should be placed in a room (e.g. waiting room), so that the clients can have an easy access. The register / drop-box should be checked monthly by the programme manager. The issues raised should be brought up in the group discussions and staff meetings. The programme manager / counsellor should also be designated as a Grievance Redressal Officer, so that any client with problems can come and speak to him / her freely. In case of emergency, the issues should be tackled promptly.

SPECIAL CONDITIONS

A. 'Take home' doses for OST medicines

Take home doses for OST medicines should be allowed only in special circumstances. These may include:

1. In case of ***bundh, civil unrest*** in the locality / town, etc.: take home may be permitted as a ‘special case’.
2. The local custom compels ***non-availability of staff on a particular day***: even during those days, there should be a system of rotation among the key (Nurse/ Programme manager/ Counsellor) staff as well as other staff to keep the OST centre open for at least 2 – 3 hours. The key staff member can dispense the medicines on that day.
3. The client has to go ***out of town***: in this case, enquiry should be made and the client’s claim should be verified from his/ her family members. In addition, the past record (adherence to medicines, any documented history of diversion/ attempted diversion/ non-compliance with the rules and regulations, etc.) should be checked. Once these are found to be satisfactory, the client can be given 1 – 2 days of medicines. This also should not be a regular feature and should be done only as ‘special circumstance’.
4. The client is ***sick*** and not able to come to the OST clinic: in such cases, home visits should be made, and this fact ascertained from family members. After confirmation, the programme manager/ counsellor can provide medicines to the client.

B. Attempted diversion/ diversion:

In some cases, the client may attempt to divert medicines from the centre. This could be brought to the notice of the staff members by other clients, or the staff members have themselves caught the client doing so. This should be considered as a serious issue, and reasons for the diversion should be found out. If there are reasons of withdrawal/ craving, then the doses should be adjusted by the doctor. If it is found that the client is trying to sell/ divert the medicines, a warning should be issued during the first offence. The staff members should become more vigilant towards the client. If the same client is found to repeat this, then he should be terminated from treatment by rapidly tapering the dose of OST.

Alternatively, if some staff members may be found to divert the medicines, the organisational head should take a serious view on this, and the staff should be immediately terminated from the job.

CONCLUSION

This document serves to describe the standards that have to be followed and adopted for implementing OST through NACO funding. The agencies will be accredited against the standards set in the document. The centres would be accredited if they have fulfilled the minimum standards outlined in this document. These standards are also liable to change – once the centres and the country acquire considerable experience in OST implementation, higher standards would then be set, which the centres should strive to achieve.

APPENDIX A

Format of Application for
accreditation

APPLICATION FORMAT FOR ACCREDITATION OF OST CENTRE

General Information

- Each OST centre should apply for accreditation using this application format
- Separate application needs to be submitted for different OST centre, even if run by the same NGO
- The filled application form should be sent in a sealed envelope with “**Application Form for Oral Substitution Therapy Accreditation**” mentioned at the top of the envelope
- The application should be addressed to:

National Programme Officer
Targeted Intervention (TI) Division
National AIDS Control Organisation (NACO)
6th Floor, Chandralok Building
36 Janpath
New Delhi – 110 001

- The last date of receipt of application is on **30th September 2008**
- For further queries, the organisation may contact the following officers:
 - ✓ Dr. Ravindra Rao, Programme Officer, IDU, NACO (drvrao@gmail.com)
 - ✓ Mr. Charanjit Sharma, Regional Programme Officer, IDU, NACO North East Office (charan_sc@yahoo.co.in)
 - ✓ Ms. Sophia Khumukcham, Technical Officer, IDU, NACO (Sophia.khumukcham@gmail.com)

CORRESPONDENCE DETAILS

Details of the Organisation

Name of the Organization: _____

Address:

Phone:

Fax:

Email:

Details of the OST site

Title/ Name: _____

Corresponding Address:

Telephone number: _____

Fax number: _____

E mail id (if separate ID): _____

ORGANISATIONAL APPRAISAL

- (i) Is your organization a Registered Society / Trust (whether the organisation is registered under relevant Government acts)? **Yes / No**

Year of registration _____

Registration No _____

Act under which the organization is registered _____

- (ii) Has your organization been blacklisted in the past one year by any of the Government authority?
Yes / No

Documents to be attached (photocopies only)

- 1) *Registration Certificate (Annexure A)*
- 2) *Memorandum of Association (Annexure B)*
- 3) *Audited Receipts and Payments Statements (3 years for NGO, 1 year for CBO) (Annexure C)*
- 4) *Annual Reports (3 years for NGO, 1 year for CBO) (Annexure D)*
- 5) *Written testimonial from the organizational head that the organization is not blacklisted over the past one year (Annexure E)*

(NGO/CBO not furnishing the above documents will not be considered for accreditation process)

- (iii) Is your organization registered with Income Tax authorities and has it obtained Section 12A exemption? **Yes / No**

Particulars: Number _____ Year _____

- (iv) Please state the dates on which returns were filed last year:

Documents to be attached (photocopies only)

- 1) *IT Exemption Certificate (Annexure F)*

WORK EXPERIENCE OF THE ORGANISATION

1. Details of projects / interventions / activities carried out in the last three years

No.	Title of Project	Sectors/ components	Start & end dates	Geographic area of implementation	Beneficiaries / Target group	Activities	Total budget	Donor(s)

2. Pl. indicate whether the organisation is currently involved in implementing any project/s / interventions / activities for IDUs or drug users **Yes / No**

If **Yes**, since when is the intervention / project running?

BACKGROUND INFORMATION ABOUT THE COMMUNITY

A. Injecting Drug Users

Pl. describe (in not more than 1500 words) the organisation's knowledge on the following

1. Estimates of IDUs in the area / town; 2. IDU Hot-spots; 3. Drug use pattern in the community; 4. High-Risk Behaviour among the IDUs

Source on which the above information is based: Experiential / Study / formal assessment conducted
(For the study / formal assessment, pl. mention the period and duration when the study / assessment was carried out, no. of respondents, and methodology)

B. General Community

Pl. describe (in not more than 1500 words) the organisation's understanding on the following

1. Awareness of the HIV related issues in the general community in your area; 2. Attitude of the general community towards drug users / injecting drug users in your area; 3. Information about the stakeholders in the community, including the law enforcement agencies, community leaders, religious leaders, 'influential persons'.

Source on which the above information is based: Experiential / Study / formal assessment conducted
(For the study / formal assessment, pl. mention the period and duration when the study / assessment was carried out, no. of respondents, and methodology)

C. Health Services

Whether the organisation has knowledge of and established linkage with the following service providers:

List mentioning the name, address and contact information of the following service providers in
Annexure G

Services	Awareness of the services	Whether linkage established
ICTC	Yes / No	Yes / No / Not available
STI	Yes / No	Yes / No / Not available
DOT for Tuberculosis	Yes / No	Yes / No / Not available
ART	Yes / No	Yes / No / Not available
General Health	Yes / No	Yes / No / Not available
Laboratory services (for basic tests such as LFT)	Yes / No	Yes / No/ Not available
Tests for Hepatitis B and C	Yes / No	Yes / No/ Not available
Centre offering harm reduction services	Yes / No	Yes / No/ Not available
Drug Detoxification and Rehabilitation centre	Yes / No	Yes / No/ Not available
De-addiction department / centre	Yes / No	Yes / No/ Not available
Occupational therapy centre/ Income generation group	Yes / No	Yes / No/ Not available
Self-help groups such as Narcotics Anonymous, etc.	Yes / No	Yes / No/ Not available

OTHER SERVICES OFFERED BY THE CENTRE / ORGANISATION

- i. Do your centre / organization offer the following services in the project area?
 1. Drug Detoxification Rehabilitation and Treatment Centre
 2. Laboratory (e.g. hemogram, liver function tests, Hep B and Hep C testing, etc.)
 3. Hospital (e.g. with an OPD for general patients with or without inpatient facility, etc.)
 4. Care and support for PLHIVs
 5. Income generation programme

- ii. Is your organisation or a staff of your organisation a member of any network?
Yes / No

If yes, Please give details:

Name of network	Type of membership your NGO / NGO functionaries / Staff has in the network	Are any staffs from your organization officer bearers in the network?

Provide documentary proofs of the same in **Annexure H**

iii. Has your organization been awarded 'Mother NGO' / 'Resource Centre' status for any drug related programme?
Yes / No

If Yes, Give details, including the projects implemented under this award (not more than one page):

DETAILS OF THE OST CENTRE

1. Location:

2. Reasons for choosing the current location:

(Describe in detail how close is it to the hotspots, central area of the town, accessibility by public transport, and whether the location is also a drop-in-centre for IDUs / Drug users)

3. Infrastructure (describe in detail how much space is available for the following, whether privacy is ensured, etc.):

- Room for doctor:
- Dispensing room:
- Counselling room:
- Waiting area:
- Space for storing medicines:
- Record maintenance room/ space:
- Provision for rest room/toilet:
- Provision for other amenities (recreational materials, etc):
- Others:

4. Proposed timings of the functioning of the clinic, including dispensing timings (briefly explain the rationale)

5. Staff details:

Position	Name of staff	Qualification	Experience of working with IDU / drug users	How long has s/he been with organization?	Does s/he have a job description / TOR

Program Manager	For example: John		Managing & monitoring	6 yrs	Yes
Doctor					
Nurse					
Counsellor					
Outreach worker					

6. Staff Training

i. Trainings attended (any training apart from drugs / HIV / Harm reduction / OST)

Position	Name of staff	No. of training attended	Topics/Subjects	Agency/Resource person
Program Manager				
Doctor				
Nurse				
Counsellor				
Outreach worker				

ii. Trainings on Harm reduction (except OST)

Position	Name of staff	No. of training attended	Topics/Subjects	Agency/Resource person
Program Manager				
Doctor				
Nurse				
Counsellor				
Outreach worker				

iii. Trainings on Oral Substitution Therapy

Position	Name of staff	No. of training attended	Topics/Subjects	Name of the agency / resource person
Program Manager				
Doctor				

Nurse				
Counsellor				
Outreach worker				

STOCK KEEPING MECHANISM

- Safe keeping mechanism in the *dispensing room* (please describe where the stock would be placed, is there a lock and key facility available, who would handle the keys, etc.)
- Safe keeping mechanisms in the OST centre (please describe where the stock would be placed; is there a lock and key facility available, is it away from easy accessibility, who would handle the keys, etc.)
- Safe keeping mechanism for the *central stock in the organisation* (please describe where the stock would be placed, is there a lock and key facility available, is it away from easy accessibility, who would handle the keys, etc.)

EXISTING OST CENTRE

1. Pl. describe the timings of the clinic, days of dispensing and duration of dispensing on a given day.
2. Describe in detail the follow-up mechanism followed for an OST client in your centre (including mechanisms undertaken when a client does not follow-up regularly at your centre)
3. Pl. mention details on your 'take-home' policy (including details on under what circumstances a client is allowed 'take-home' medicines)
4. Pl. describe in detail what is the record maintenance system followed in your centre (including description of various records and registers maintained and the staff responsible for the record maintenance)
5. Pl. describe how is the monitoring of OST programme done in your centre
6. Pl. describe what is the back-up mechanism followed in your centre (during holidays, absence of a particular staff, etc.)
7. Please describe the supply chain mechanism followed in your centre (including who is in charge of stocks, who monitors the stock, who is responsible for various stock registers, etc.)

COMMUNITY PARTICIPATION / INVOLVEMENT

- Does your organisation involve drugs users in your program? **Yes / No**

(If yes, please provide details on how the drug users are engaged)

- Is the general community involved in your programme? **Yes / No**
(If yes, please provide details on nature of engagement)
- Are the other stakeholders involved in your programme? **Yes / No**
(If yes, please provide details on nature of engagement)

LIST OF ANNEXURE

Annexure A: Societies Registration Certificate

Annexure B: Memorandum of Association

Annexure C: Audited Receipts and Payments Statements (3 years for NGO, 1 year for CBO)

Annexure D: Annual Reports (3 years for NGO, 1 year for CBO)

Annexure E: Written testimonial from the organizational head that the organization is not blacklisted

Annexure F: Income Tax Exemption Certificate

Annexure G: List of service providers in the project area (with names, address and contact information)

Annexure H: Documentary proof of membership of the organisation / staff with the network

APPENDIX B

Scoring of Accreditation **Application Form**

Desk Review
Scoring of Accreditation Application Form

No.	Item	Documentation	Remarks
1	In case of NGO / CBO, is the following furnished		
A	Societies Registration Certificate (Annexure A)	Yes / No	
B	Memorandum of Association (Annexure B)	Yes / No	
D	Audited Receipts and Payments Statements (3 years for NGO, 1 year for CBO) (Annexure C)	Yes / No	
E	Annual Reports (3 years for NGO, 1 year for CBO) (Annexure D)	Yes / No	
F	Written testimonial from the organizational head that the organization is not blacklisted by any Government authority (Annexure E)	Yes / No	
<i>If the NGO/CBO has not furnished the above documents it will not be considered for accreditation process</i>			
2	Has the organisation carried out a baseline information of		
A	Injecting drug users	Yes / No	
	If 'Yes', Quality of the information		Score out of maximum 5
B	General Community	Yes / No	Score out of maximum 3
3	Has the organisation mapped the following Health services and established linkage with them?		
a	Integrated counselling and testing facility (ICTC):		Score 1 for each yes
b	DOT centre for Tuberculosis		
c	ART centre		
d	Community Care Centres		
e	Detoxification, Rehabilitation and Drug Treatment Centre		
f	STI Clinics		
g	Clinics / Hospitals for providing abscess management and other health services including emergency services for overdose management		
h	Centres running needle syringe exchange programmes		
i	Laboratory Services: basic services (e.g. hemogram, LFT, etc.),		
j	Laboratory Services for drug screening (if available)		
4	Work Experience of the Organisation		
A	Is the organisation <i>currently</i> implementing OST projects?	Yes / No	Score 5 for yes
<i>If YES, go to the next section</i>			
	Is the organisation <i>currently</i> implementing TI projects on IDUs	Yes / No	Score 3 for yes

	<i>If YES, go to the next section</i>		
	Is the organisation <i>currently</i> implementing any projects for drug users?	Yes / No	Score 2 for yes
	<i>If YES, go to the next section</i>		
	Has the organisation <i>ever</i> implemented any interventions for drug users / IDUs?	Yes / No	Score 1 for yes
5	Other services by the same centre / organisation		
A	Does the centre / organisation offer the following services in the project area		Score 1 point for each 'YES'
	Detoxification / Rehabilitation / Drug treatment	Yes / No	
	Laboratory (e.g. hemogram, liver function tests, Hep B and Hep C testing, etc.)	Yes / No	
	Hospital (OPD for general patients with or without inpatient facility, etc.)	Yes / No	
	Care and support for PLHIVs	Yes / No	
	Income generation programme	Yes / No	
B	Is your organisation a member of any network		Score 1 point for each 'YES'
	Harm reduction network (state / region / national / international)	Yes / No	
	NGO network (state / region / national / international)	Yes / No	
	Positive network	Yes / No	
C	Has your organisation been awarded 'Mother NGO' / 'Resource Centre' status for any drug related programme / project		Yes / No
6	Proposed OST centre		
A	Choice of location		Score out of maximum 3
B	Is there enough space for the following:		Score 1 for each yes
	Doctor	Yes / No	
	Dispensing	Yes / No	
	Counselling	Yes / No	
	Waiting area	Yes / No	
	storing medicine	Yes / No	
	Record maintenance	Yes / No	
	Rest room / toilet	Yes / No	
	Other amenities (such as recreational materials, etc.)	Yes / No	
	Any other area / space / room	Yes / No	
Staff details			
C	Is the following staff in place as per the prescribed qualification		Score 1 point for each 'YES'
	Programme Manager	Yes / No	
	Doctor	Yes / No	
	Nurse	Yes / No	
	Counsellor	Yes / No	
	Outreach Worker	Yes / No	
D	Training		
	Is the following staff trained	Score 3 for training in OST, score 2 for	

		Harm reduction but without OST, score 1 for training on HIV/drug only	
	Programme Manager		
	Doctor		
	Nurse		
	Counsellor		
	Outreach Worker		
E	Stock keeping		
	Is there a safe keeping mechanism in		Score out of maximum 2 for each of the following
	Dispensing room	Yes / No	
	OST centre	Yes / No	
	Main office	Yes / No	
7	For pre-existing OST centre		
			Score out of maximum 3 for each of the following
A	Clinic timings		
B	Follow-up mechanism		
C	Take-home policy and mechanism		
D	Record maintenance		
E	Programme monitoring		
F	Supply chain mechanism		
G	Back-up mechanism		
8	Community involvement		
A	Drug users		Score out of maximum 3
B	General community		Score out of maximum 3
C	Other 'Stakeholders'		Score out of maximum 3

APPENDIX C

Field Assessment Tool for **Accreditation**

FIELD ASSESSMENT TOOL FOR ACCREDITING OST CENTRES

Date of Assessment

Name of the Lead Assessor:

Name of the assessors:

Organisation details

Name of the Parent Organisation

Address:

Telephone Number

Fax No.

Email:

Details of the OST centre

Name of the OST Centre

Location / address

Telephone Number

Fax No.

Email:

Assessment Tool

No.	Item/ Requirement	Means of verification	Documentation	Remarks
A	Organisation related			
	Is the centre run by a Government Hospital / Government Health Clinic / NGO / CBO?	Inspection and related records		
B	Space and Infrastructure			
1	Is the centre readily accessible? (e.g. located at/ near a hotspot / in central area/ at an area with easy access by public transport)	Inspection of the centre	Yes: 1; No: 0	
2	Are there separate rooms / space for:			
	Doctor <i>(The room should have adequate space for a doctor, a client and his/ her companion to sit and an area for performing physical examination. The room should provide a sense of privacy to the client for enabling him/ her to speak freely about his/ her problems)</i>	Inspection of the centre	Yes: 1; No: 0	
	Dispensing <i>(The room should have a table with spaces to store medicines dispensed during the given day. Space should be enough for a nurse to sit along with 2 – 3 clients and an office support staff)</i>	Inspection of the centre	Yes: 1; No: 0	
	Counselling <i>(Sufficient space for a counsellor, client and his / her family members to be seated; room should be such that privacy for the client is ensured (closed room). In some cases, the room may be shared by a counsellor and doctor, where the doctor is a part-time staff)</i>	Inspection of the centre	Yes: 1; No: 0	
	Waiting area <i>(This is for the clients to sit and wait for their turn. This can also be a place for the clients to rest after having received their doses. The place may also provide some reading materials, television and games for the clients to be engaged during their waiting)</i>	Inspection of the centre	Yes: 1; No: 0	
	Space for record keeping	Inspection of the centre	Yes: 1; No: 0	
3	Safe keeping mechanism for medicines			
	Does the dispensing room have a safe keeping mechanism for storage of OST medicines to be dispensed during the day (e.g. a table with a drawer with lock and key)?	Inspection of the centre	Yes: 1; No: 0	
	Does the OST centre have a safe keeping mechanism for storing OST medicines for minimum one-week period (e.g. Almirah with lock and key)?	Inspection of the centre	Yes: 1; No: 0	

	Is the Almirah in a safe place? (e.g., access to the almirah area restricted to the clients and visitors)	Inspection of the centre	Yes: 1; No: 0	
	Is there an adequate mechanism in place for safe custody of large stocks of medicines?	Inspection of the centre / place where monthly stocks of medicines will be kept	Yes: 1; No: 0	
Total Score obtained in the section				/ 10
C	Staff			
	Are the following staff members available (with the prescribed qualification)			
1	Programme manager (<i>The project/programme manager should be a graduate/ or passed higher secondary education with at least 5 years of experience of working with drug users.</i>)	Contract letter with TOR specifying roles and responsibilities	Yes: 1; No: 0	
2	Doctor (<i>The doctor should have a minimum qualification of MBBS</i>)	- Do -	Yes: 1; No: 0	
3	Nurse (<i>The nurse should have a minimum qualification of ANM</i>)	- Do -	Yes: 1; No: 0	
4	Counsellor (<i>The counsellor should have received a Bachelor's degree in psychology/ social science/ humanities If the counsellor is from drug using background, he / she should have completed higher secondary education with certificate training in counselling.</i>)	- Do -	Yes: 1; No: 0	
5	Outreach worker (<i>The outreach worker shall be a person with a working knowledge of the local terrain as well as the community (both IDU and general). He/ she should be literate.</i>)	- Do -	Yes: 1; No: 0	
Total Score obtained in the section				/ 5
G	Linkages with other services/service providers			
	Has the centre established linkages with the following services:			
1	ICTC	List directory with Random check of two services by assessor either physically or telephonically	Yes: 1 No: 0	
2	DOT for Tuberculosis		Yes: 1 No: 0	
3	STI		Yes: 1 No: 0	
4	ART Centre		Yes: 1 No: 0	
5	Community Care centre		Yes: 1 No: 0	
6	Detoxification and Rehabilitation		Yes: 1 No: 0	
7	Centres providing harm reduction services (especially Needle Syringe Exchange)		Yes: 1 No: 0	
8	General health services (especially for abscess management)		Yes: 1 No: 0	

9	Income generation programmes		Yes: 1 No: 0	
10	Laboratory services (e.g. hemogram, LFT, etc.)		Yes: 1 No: 0	
Total Score obtained in the section				/ 10
H	Other service provision in the centre			
Does the centre provide the following services in the same premise / nearby?				
1	Detoxification, Rehabilitation and drug treatment services	Physical verification	Yes: 1 No: 0	
2	Laboratory services (e.g. hemogram, Liver Function Test, etc.)		Yes: 1 No: 0	
3	Hospital services (e.g. with an OPD for general patients, inpatient facility, etc.)		Yes: 1 No: 0	
Total score in the section				/ 3
I	Advocacy			
	Has the organisation carried out advocacy with the stakeholders on OST: law enforcement, general community, local community leaders, religious leaders, and general community based organisations?	Meeting minutes / photographs / letter of endorsement	Yes: 1 No: 0	
Total Score obtained in the section				/ 1
J	OST related services (only for centres already running OST interventions)			
1	Does the centre maintain dispensing registers?	Examination of the records of the previous 3 months	Yes: 1 No: 0	
2	Does the centre maintain stock registers?	Examination of the records of the previous 3 months	Yes: 1 No: 0	
3	Is the staff (programme manager, doctor, nurse and counsellor at the minimum) trained in OST?	Training certificate/ other documentary proofs	Yes: 1 No: 0	
4	Does the centre maintain the receipts required under NDPS act (Form 6)?	Examination of receipt	Yes: 1 No: 0	
5	Is the medicine initiated by a doctor?	Client file / relevant record	Yes: 1 No/ No document: 0	
6	Is the dose change done only by a doctor?	Client file / relevant record	Yes: 1 No/ No document: 0	
7	Whether any guideline/ protocol followed in treatment?	Guideline document	Yes: 1 No: 0	
8	Is a consent form being signed by the client before initiating OST?	Signed Consent forms in client file	Yes: 1 No/ No document: 0	
9	Is the medicine daily dispensed by a nurse?	Dispensing register	Yes: 1, No: 0	
10	Is follow-up done regularly by the doctor and counsellor?	Follow up record	Yes: 1 No/ No	

			document: 0	
11	Do clients receive counselling (individual and/or group) services in addition to OST medication?	Counselling records	Yes: 1 No/ No document: 0	
	<i>For centres where documents are not available, the assessor may ascertain this from other sources</i>			
	Total Score obtained in the section			/ 11
K	Other areas			
1	Is your staff from IDU background (at least 50%)?	Testimonial from the organisation head	Yes: 1 No: 0	
2	Is your doctor a psychiatrist?	Certificate	Yes: 2 No: 0	
3	Is the doctor full-time employed in the centre	TOR	Yes: 1 No: 0	
3	Does the centre have basic facilities? (e.g., provision for safe drinking water and access to rest room)	Inspection	Yes: 1 No: 0	
4	Has the centre formed a support group of drug users (support group: a group of drug users who are accessing the services or have recovered to help each other during treatment)	Minutes of the support group meeting / ascertained by other means	Yes: 1 No: 0	
5	Has the centre involved the drug users / recovering drug users in the programme by forming committees (e.g. DIC committee, advocacy group, etc.)?	Minutes / reports of the committee meetings / ascertained by other means	Yes: 1 No: 0	
6	Are there equipments for			
	Examination of clients (<i>Stethoscope, torch, sphygmomanometer, etc.</i>)	Physical verification	Yes: 1; No: 0	
	Dispensing of medicines (<i>Crusher, dispensing cups, etc.</i>)	Physical verification	Yes: 1; No: 0	
7	Are condoms dispensed at the centre?	Physical verification	Yes: 1; No: 0	
	Total Score obtained in the section			/ 10
	Final Score obtained			/ 50