Implementation of Opioid Substitution Therapy in Government Health Care Facilities for Injecting Drug Users

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

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1. Introduction

Injecting drug use (IDU) is recognised as an important mode of transmission of HIV in India and elsewhere. As per the sentinel surveillance report 2007, Injecting Drug Users (IDUs) have one of the highest rates of HIV among the High Risk Groups. The HIV positivity rate among the IDUs is 7.2% compared to 0.36% in general population. The high positivity rate is as a result of sharing of needles/syringes and other injecting paraphernalia among IDUs. HIV also spreads rapidly among IDUs. In addition, HIV spreads from the IDUs to their female sexual partners, leading to spread of HIV to the general population.

To address this issue, National AIDS Control Organisation (NACO) has adopted harm reduction as a strategy to prevent HIV among IDUs. Interventions have been designed such that the IDUs are provided with services including needle syringe exchange, behaviour change communication, condom distribution and referral to a number of health services, right at their 'doorstep'.

Under the National AIDS Control Programme – Phase III (NACP III), interventions for IDUs have been expanded and strengthened to address the rising HIV prevalence among this group. Apart from the interventions specified above, a new intervention component which has been added under NACP III is the Oral / Opioid Substitution Therapy (OST). OST has been recognised worldwide as an effective treatment for opioid dependence and harm reduction strategy. OST is listed as one of the essential comprehensive packages of services to be provided for IDUs.

1.1 Philosophy of Oral Substitution Therapy

OST involves substitution of illicit, unsafe opioid drugs which may be taken through injecting route with a legal medicine which has similar properties as that of the injection opioid but taken with a safer route. The medicine is prescribed by a doctor and administered under the supervision of a trained health-care staff in such doses that the opioid dependent IDUs would not have craving or withdrawals. As the medicine takes care of the drug hunger, IDUs stop or reduce injecting drugs, leading to decreased risk of transmission of HIV and other blood borne viruses.

However, the benefit of OST goes beyond prevention of HIV and other blood borne viruses. OST has been successful in reducing other harms related to drug, especially when combined with psychosocial interventions. The client on OST stops indulging in petty crimes, becomes stabilised psychologically, is able to think coherently and also able to take care of his family and also becomes gainfully employed.

1.2 NACO OST programme

NACO has committed itself to initiate and scale up OST in the NACP III. As a part of scaling up OST services in India, NACO plans to scale up OST services through Non Governmental Organisations (NGOs) working in the drug treatment sector as well as through Government hospitals.

NACO has already initiated OST programme through those NGOs already providing OST. For this purpose, standard operating procedures were prepared. The NGOs were then evaluated and, if found eligible, were accredited to implement OST using buprenorphine. Currently there are about 45 such OST centres catering to about 4500 IDUs throughout the country.

It is felt that NGO sector alone would be insufficient to scale-up OST programme. The country has a large number of Government health care institutions which can be another avenue for initiating and scaling up OST. In addition, there are psychiatry department in Medical colleges and Ministry of Health funded De-addiction Centres (DACs) within these

Medical Colleges as well as District Hospitals. All of these institutions can be potential centres for OST implementation. Hence, it has been decided to initiate OST programme through Government Hospitals in addition to the existing NGO OST facilities.

1.3 Scheme - Overview

There are a number of Government health-care facilities existing in the country ranging from Medical Colleges to Hospitals at District and sub-district levels. The medical care provided by some of these institutions is at par with the best in the country. A number of departments operate in these hospitals, whose services are essential to a person injecting drugs. These include Sexually Transmitted Infections (STI) clinics, Integrated Counselling and Testing Centres (ICTCs), Anti-retroviral Therapy (ART) Centres, Surgery and Medicine departments. Integrating OST in such a multi-skilled setup will strengthen the overall services available to the IDU. Another advantage of partnering with the Government health-care systems would be ensuring sustainability. It is hoped that the Government centres can gradually take over the NGO implemented OST programme for long term sustainability.

One of the drawbacks of the Government health care facilities is that IDUs often find them inaccessible and services offered are not patient friendly. Especially the component of 'outreach' is very important to provide health-care to drug users. In this area, Non Governmental Organisations (NGOs) have been able to reach out to IDUs at places where they reside/congregate. Such NGOs, especially those running Targeted Intervention (TI) projects are in constant contact with such IDU population. The scheme outlined below envisages utilising the strengths of both these institutions to provide optimal OST services to the IDU.

It is proposed that there would be a tie-up between the Government hospitals and the NGO implementing Targeted Interventions for IDUs to provide OST services to the IDU clients. For this purpose, a guideline has been prepared outlining in detail, the various steps to be followed for choosing an OST centre, the mechanisms to be followed for initiating OST in a particular client, and the medicine stock keeping and supply chain mechanisms.

2. Selection of the Government Health care facility

2.1 Selection of centre

A. Determining the districts for initiating OST programme

The district in the particular state shall be the unit for consideration of setting up OST programme. NACO shall come up with such list of the districts from time to time. The selection of districts would be based on:

- IDU estimates in the district
- IDU coverage in the district
- Prevalence of HIV among IDUs in the district
- Presence and number of Targeted interventions in the district
- Number of clients on OST already present in the district
- Number of clients on OST required to be scaled up

The total number of IDUs to be on OST would be about 20% of the IDU estimates/covered, as the current NACO guideline envisages coverage of 20% of the clients on OST.

The number of centres required in the district will be decided on the basis of the calculation made above.

B. Determining the location of the public facility in the district

Once the requirement of OST centre in a particular district is determined, the Government health-care facility of the district will be chosen. The OST centre shall be located in one of the following categories of the Government health-care facilities:

- Medical College Hospital
- District Hospital / Civil Hospital
- Community Health Centres

Considerations while choosing a Government health-care facility:

- Distance of the Government health-care facility from the IDUs. For this the following will be considered:
    - Mapping of the hotspots (place where the IDUs congregate for buying, consuming drugs or resting after drug intake) or place of residence in co-ordination with the NGO operating in the area
    - Location of IDU TI
    - Ease of commuting to/from the Government health-care facility

  A Government health-care facility *which is located* ***within 5 kilometre radius*** *of the hotspots / Drop-in-centre of TI will be preferred.*

- Availability of adequate infrastructure for setting up an OST clinic within the hospital area
- Availability of adequate storage space for OST medicines with adequate safekeeping mechanism
- Willingness to provide support in terms of pharmacy, office support staff, and linkage with other departments
- Willingness to provide general medicines (such as sedative/hypnotics, NSAIDs and antibiotics) to the OST centre through hospital stock
- Commitment to follow NACO guidelines and protocols for OST implementation

- Commitment to regularly furnish information on data related to OST services.

On the basis of the 'distance' factor, the Government health-care facilities shall be shortlisted, and then a physical inspection shall be carried out to look into the other factors.

C. Inspection of the public health facility

Once the Government health-care facility is shortlisted, a team will visit the centre to assess the feasibility of setting up OST clinic. The team would comprise of representatives from NACO, SACS and independent consultants, who would visit the identified sites and assess whether the Government health-care facility is suitable for setting up an OST centre. During the visit, the department most appropriate for carrying out this activity must also be decided.

Departments where OST centres will be located

Ideally, the OST centre should be located in the Government De-addiction Centre of the Hospital. In such a case if the de-addiction centre is already providing OST (through a non-NACO source of funds) would be preferred. However if such centres do not exist, then the psychiatry department in the hospital providing inpatient or outpatient psychiatry care will be preferred. If the district hospital / Medical College do not have either of the above, preference will be given to ART centre within the hospital. Finally, preference will be given to Medicine department within the hospital. Thus the rank-wise preference is:
De-addiction Centre (with already running OST services) →De-addiction Centre (without OST services) →psychiatry department →ART centre →Medicine department

For inspection, the team shall interact with the head of the hospital administration (Medical Superintendant/CMO), and also the head of the department who is chosen as the in-charge of the OST programme. After inspection, the team shall submit a report to NACO for further action.

D. Responsibility

During the physical inspection, the CMO / Medical superintendant should designate a medical officer as the '**Nodal Officer'** for supervising the day-to-day running of the centre. The nodal officer should ideally be the head of the department where the centre will be located (e.g. head of the de-addiction centre, head of the psychiatry, or head of the ART centre/medicine department). This nodal officer shall be responsible for

- Ensuring that the centre functions on all days smoothly
- Ensuring that OST medicines are stocked adequately and stored properly
- Troubleshooting the various problems encountered during the functioning of the OST centre.
- Ensuring appointment of the contractual staff
- Ensuring support from various stakeholders, including different departments in the hospital for running of the OST centre.
- Ensuring that regular reports are furnished to SACS/NACO
- Co-ordination with various departments within the hospital as well as outside the hospital for health care related referrals

- Reviewing the OST functioning once a quarter with the staff of the OST centre
- Maintaining the linkages with the NGO providing TI services

2.2 Infrastructure requirements for running an OST centre

An OST centre should have easy accessibility to the clients requiring OST. It should be maintained with utmost standards of hygiene. The centre **should** have following kinds of separate rooms (*each measuring about 8 × 10 feet*)

- **Doctor's room**
  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.

- **Dispensing room / Pharmacy**
  This room is for a nurse 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) and an office support staff.

- **Counselling Room**
  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.

- **Waiting area/Room**
  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.

- **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. If the pharmacy does not serve as the storage space, the storage space can also be located in the doctor's room.

- **Registration-cum-record room**
  There should be adequate space at the entrance for registration of clients, along with space for maintaining client records and other relevant documents; and proper filing systems should be in place. This space shall also be used for the data entry operator to be seated for maintaining records.

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.
- The centre should have IEC messages on HIV/testing/drugs prominently displayed to serve as an educative material for the clients. Information on the sites where IDUs can access detoxification and Needle Syringe Exchange services **should** also be displayed prominently.

Clinic Timings

Since the medications for OST have to be administered daily under supervision ('direct observation') the OST centre – for the purpose of dispensing – **should** be open 7 days a week, including on gazetted holidays. The OST centre **shall** function for at least 7 – 8 hours per day. Out of this, at least 50 – 60% of the centre's timings **should** be dispensing timings. During public holidays / sundays, the dispensing facility of the clinic **should** be open for a limited duration of time (2 – 3 designated hours) for daily dispensing of OST medicines. Prior information on the timings for Holidays / Sundays **should** be provided to the clients. These timings **should** be prominently displayed on Notice boards.

Equipments:

- Basic **furniture** for the staff and clients – tables, chairs and stools
- Equipment for basic **medical examination**: e.g. stethoscope, torch, disposable gloves, BP apparatus, thermometer, etc.
- Examination table with curtains
- For **dispensing medicines**: tablet crusher, dispensing cups, etc.
- **Condoms**: displayed such that it should be easily accessible to the clients
- **Penis model** for condom demonstration
- Almirah/**strong and secure cupboards** for safe storage of medicines and other commodities
- Shelves for record maintenance
- Computers and audiovisual equipment
    - Computers should be a desktop computer having configuration enough to support any web-based MIS. This may include – Pentium IV, at least 40 GB hard disk, 512 MB DDR RAM, 15 inch colour monitor, keyboard, optical mouse, CD/DVD reader-cum-writer, provision for internet connectivity
    - Audio-visual equipments such as a television may be installed in the waiting area for recreation

2.3 STAFFING

The OST centre should have a staff dedicated to the day-to-day functioning of OST programme. The categories of staff along with the minimum number essential in an OST centre are as follows:

1. Doctor - 1
2. Nurse – 1 per 50 clients
3. Counsellor - 1
4. Data entry operator – 1
5. Office Support Staff: Guard, Class IV workers, sweepers, etc.

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 IDUs living with HIV.

While the doctor, nurses and counsellor will be appointed on contractual basis through funding from NACO/SACS, the other category of staff viz. Pharmacist, office support staff would be contributed from the hospital staff. In case, where De-addiction centres / Psychiatry departments are functional in Medical Colleges/District Hospitals, the doctor can be from the department itself. This doctor – if not he/she the nodal officer – shall be designated by the nodal officer as the doctor-in-charge for the day-to-day running of the OST clinic.

The contractual staff shall be appointed by the Medical superintendant/CMO of the hospital through an interview conducted by a panel comprised of not less than three permanent doctors / senior management of the hospital (such as the nursing superintendent). One of the members of the panel should be the nodal officer of the OST centre. The contract shall be for a period of one year, renewable every year based on performance appraisal.

Once the staff members are appointed, this shall be intimated to the SACS/NACO. After appointment, the staff (doctor, nurse, counsellor and pharmacist) shall undergo training in training centres designated by NACO or trainings organised by NACO. The staff can initiate their work after undergoing such training.

Terms of reference for the staff

1. **Doctor**

   The Doctor plays a pivotal role in the overall running of the OST programme. There shall be at least ***one*** doctor in every OST centre.

   Qualifications:

   The doctor should have a minimum qualification of MBBS with valid registration from the medical council. Those with MD Psychiatry/Diploma in Psychiatry Medicine (DPM) will be preferred.

   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 OST medicine 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 care providers
   - Help the centre in carrying out advocacy activities

2. **Nurse**

The nurse plays a crucial role in dispensing medicines as well as maintaining stocks /records of medications on a regular basis. There shall be at least one nurse for every 50 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:

- Maintain minimum standard guidelines as prescribed by NACO for the clinic
- Dispense medications as per NACO's treatment guidelines/ protocols
- Assist doctor in treating abscess, providing medication etc
- Maintain registers (daily stock and dispensing registers) as prescribed in NACO's practice guidelines for OST
- Regular communication with treating doctor
- Provide emergency first-aid services in the absence of doctors
- In addition, the following responsibilities shall be handled by nurse regarding the stocks of OST medicines
  - Receive the medicine stocks from the supplier
  - Count the medicines and confirm that the stocks supplied are in accordance with the consignment records sent by the supplier
  - Ensure that consignment note and form 6 are maintained properly as required by the NDPS act
  - Ensure that OST medicines are properly stored in the storage room at the hospital
  - Ensure that records of OST medicines are properly maintained as required by NACO/SACS
  - Alert the nodal officer/doctor-in-charge of the OST centre, if there is an impending stock-outs
  - Furnish stock position regularly as required by NACO/SACS

3. **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. Those who have received training in counselling drug users 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 OST centre, and, if required, in the community or at home as well
- Provide different forms of counselling including motivational counselling, family counselling, group counselling
- Provide counselling to PLHIV
- Referrals for STIs, ICTC and other relevant services
- Maintain documentation as outlined in the practice guidelines for OST.

4. **Data Manager**

There shall be one data Manager for an OST centre

Qualification:

The data Manager should be a graduate and should have received a formal training in computer applications.

Roles and responsibilities:

The data entry operator shall be responsible for maintaining the data in OST centre.

- Register patients in the OST centre on all work days
- Take out the client related files during every visit by the client for follow-up
- Ensure that the records are maintained by every staff
- Prepare and send monthly reports
- Analyse the reports and provide feedback on dropouts to the staff, especially Outreach Worker (ORW) for follow up
- Feed the data in the MIS as and when the centre is linked with the MIS

5. Office support staff

There shall be one office support staff at the OST centre. She/he shall assist the data entry operator and nurse to streamline the patients coming for OST.

The other office support staff such as sweeper, guard, etc would be provided by the hospital.

3. Role of the Targeted Intervention

The OST programme should be implemented in close co-ordination with the IDU TI NGO. The selection of the OST centre will be such that the centre will be located in the vicinity of the IDU TI.

For the purpose of partnership with the IDU TI, NACO shall direct the SACS to contract the IDU TI to implement the OST along with the Government Centre.

During the initial mapping, an IDU TI shall be identified by NACO in co-ordination with SACS. The scheme shall be discussed with the project director and programme manager of the IDU TI. For carrying out the activities outlined in the scheme, the TI shall be provided with an outreach worker. In addition, the staff of the IDU TI including the programme manager, doctor, nurse/counsellor will be oriented on the OST programme as well as the scheme. The outreach worker appointed for this purpose will be trained along with other staff of the OST centre intensively for enabling him/her to carry out the activities.

The programme manager and the project director of the NGO implementing IDU TI shall ensure that the OST programme should reach out to the beneficiaries.

- Carry out discussions and meetings with the staff of the OST centre on the OST programme once a month.
- Motivate and facilitate clients in the project area to access OST.
- Ensure that the outreach worker carries out regular follow-up with the clients.
- Carry out regular advocacy programme on OST with various stakeholders including police, general community, local leaders, other centres working on drug addiction, etc. in coordination with OST centre. The services of the doctor-in-charge or the nodal officer and the counsellor will be utilised by the TI to carry out these activities.

3.1 Outreach Worker

The outreach worker is the link between the IDU TI and the OST centre on a day-to-day basis. S/he 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. The outreach worker should be in close contact with the IDU community, so that s/he is able to motivate them to access OST and follow them up.

Roles and Responsibilities:

- Identify and motivate IDUs for the OST programme
- Follow up non-attendance / drop outs and document reasons; in case of drop-outs, home visits should be conducted
- Motivate the family members to come to the OST centre along with the client for counselling.
- Help establish peer support groups for both female and male IDUs
- Liaison with IDUs and PLHIV in the field
- Monitor regular condom & IEC materials availability at the OST centre;
- Assist the clients in receiving various other referral services, including accompanied referrals as and when required

The outreach worker shall report to the counsellor of the OST centre on a day-to-day basis.

4. Providing OST services

OST services shall be provided in accordance with the practice guideline prepared by NACO '*Substitution Therapy with Buprenorphine for Opioid Injecting Drug Users*' for this purpose, which will be provided to the staff of the OST centre. Alternatively, the document can be downloaded from the NACO website.

The various criteria including inclusion criteria of a client/patient for OST, exclusion criteria, dosages, adverse effects, administration of the medicines, follow up and termination of OST are outlined in the practice guidelines.

4.1 Procedures for client enrolment and OST initiation

The client may have been referred to the centre by any of the following routes: 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, detoxification and rehabilitation centres, hospitals, etc.), or self referral.

Upon arrival at the OST centre, the client will be registered at the OST centre. The registration counter will be located in the centre itself, and will be separate from the general registration counter of the hospital. After registration, the client will be attended to by the counsellor. The counsellor should interact with the client and address the following issues:

- Understanding the client's perception towards OST and outcome expectancies
- To assess the motivational level of the client
- To dispel myths/ misconceptions of the client towards OST
- 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
- To inform the client the 'do's and dont's' while he is on OST (e.g. to come daily for OST, to report for any side effects, honest about his drug use status, etc.)
- 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.)

After this screening, if the client is found willing for OST, a separate file will then be initiated containing the assessment and consent forms. The counsellor will then fill the assessment form excluding the medical details, and then send it to the doctor for completion of the medical assessment. The doctor shall conduct detailed assessment and examination of client for suitability of OST. If the client is found suitable, he/she will then be given a separate identification number for enrolment in the OST programme from the registration counter (by the data manager), a consent form must be signed, and then a prescription slip for Buprenorphine should be filled by the doctor. The client will then deposit the prescription slip to the nurse. The nurse shall enrol the client on the dispensing register, and a separate sheet for the daily dispensing of the medicines shall be created for the client.

4.2 Follow up

For the initial 3 – 7 days, the client has to meet the doctor-in-charge daily for the doctor to be satisfied that the dose of Buprenorphine is adequate. Once the dose is stabilised, the client has to visit the doctor weekly for the first one month, fortnightly for the next two months, and then monthly thereafter, in usual cases. The assessments necessary during such follow ups are outlined in the practice guideline document.

The client has to come to the centre daily for receiving and consuming the medicine. Daily registration at the registration counter is not required. The client shall come to the nurse

dispensing the medicine directly, where the nurse shall administer the medicines as described in the practice guidelines.
Regular follow up with the counsellor is also essential. The various issues to be handled by the counsellor during such follow up are outlined in the practice guideline document. The counsellor should strive to stabilise the psychosocial aspects of the client and motivate him to be gainfully employed. In addition, group discussions on a number of issues should be conducted by the counsellor. In addition, the counsellor should attempt to provide vocational rehabilitation and counselling to the client, and link him up with the various vocations available in the region.

4.3 Referral linkages
In addition to receiving OST medicines, the client should also be referred to various other health services. Some of the important and essential ones are:

1. ICTC after due counselling, to test the HIV status of the client.
2. STI: in case, the client complaints of signs and symptoms of STI.
3. ART: in case the client is HIV positive. In such cases, the ORW should ensure that the client is also receiving ART regularly, or should tie up with the field worker in the ART centre.
4. Laboratory investigations: routine investigations, especially liver function tests
5. Surgical department: in case of abscesses

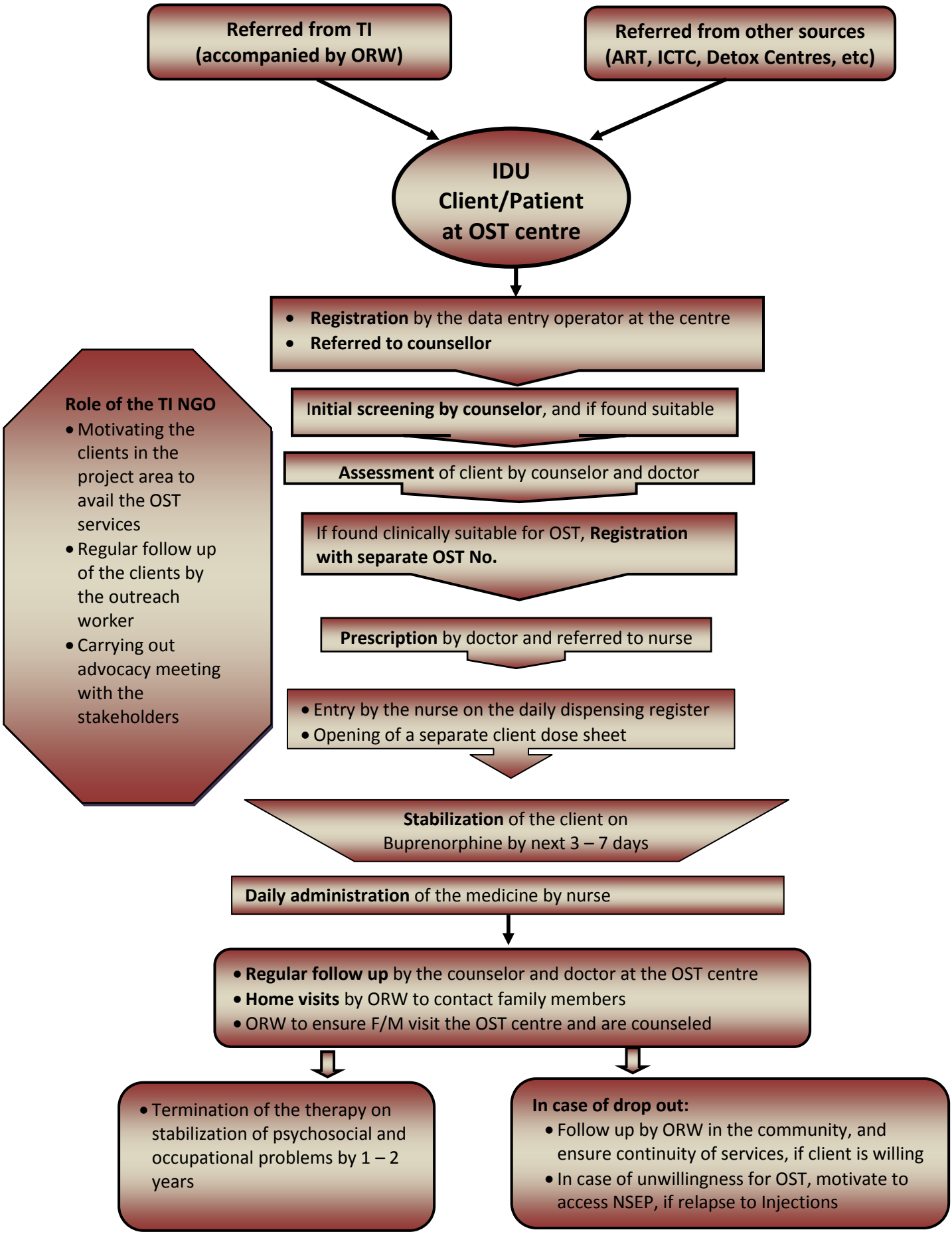
Since the scheme envisages establishing OST centres in the general hospitals where most of the above mentioned services are expected to be available there should be nor problems for the clients to access these services. Nevertheless, wherever possible the ORW of the TI should help / accompany the client while seeking these referral services.

4.4 Family involvement
Involvement of family members is essential for the successful outcome of OST. The family members should be explained about the therapy, the need for daily visits to the centre, and the need to support the client during such periods. In addition, the family members should be made active partners in the follow ups.
The spouse plays a very important role in the support system. In addition, she is also at a high risk of contracting HIV. Hence, every effort should be made by the outreach worker to bring the spouse of the IDU to the OST centre. In this, the counsellor should counsel the spouse on HIV/AIDS, high risk behaviour, and also the OST issues of the IDU client.

4.5 Integration with other services related to drug use:
In case of centres which are also de-addiction centres or psychiatry department, OST should be integrated with other de-addiction services already being offered in these departments. This includes:

1. For the client who is found unsuitable for OST: the client can be offered detoxification and other modalities, as necessary
2. For the client who is ready to terminate OST treatment: the client can be offered detoxification on indoor basis, if he is having difficulty in tapering OST on outpatient basis.

Patient flow chart



5. Commodities stock and supply chain management

5.1 About OST medicine:

The OST medicine currently approved by NACO for use in its sponsored programme is Buprenorphine. Buprenorphine is a semi-synthetic opioid derivative of thebaine (a derivative of poppy plant). It is 25 – 50 times more potent than morphine, the prototype opioid. It is a partial agonist of μ opioid receptors, and an antagonist of κ receptors. Because of its partial agonist property, it has a ceiling effect, and hence chances of overdoses with this opioid is minimal. Buprenorphine is a psychotropic substance and is regulated under the Narcotic Drugs and Psychotropic Substances (NDPS) Act. Because of this, the stock and supply chain mechanism should be rigorously followed.

5.2 Stock keeping in the OST centre

The main stock may be placed in the pharmacy / store of the hospital. The stock should be kept in an almirah with proper lock and key. Only the nurse should have access to the keys of the almirah. The stock received from the SACS/NACO designated supplier should be kept here. A central stock register should be kept along with the stocks received. Entries should be made and signed duly whenever stocks are added or taken away from the central stock. The nodal officer should carry out regular inspections of the stocks and duly sign the register.

Store room in the OST centre: this should be located in the dispensing room of the OST centre. Not more than one week of stock should be stored in the OST centre. The store in the OST centre should also be kept in an Almirah with lock and key. The almirah should be kept in a place with minimal access to clients and general public. A stock register should be kept along with the stocks of medicine. The Nurse will be in-charge of the stocks of OST centres. Every week, the medicines should be taken from the central store room of OST centre and stored in the OST centre store room. This transaction should be signed by the doctor-in-charge as well as the nurse. From this stock, the nurse in-charge should draw the daily stock during initiation of dispensing and enter into the stock register. The medicines remaining after the dispensing should then be deposited back in the OST centre store room at the end of the day.

The performa of stock registers is at **Annexure A**.

The nurse is the personnel in charge of the daily maintenance of the stock registers and records. At the end of the month, the nurse should provide a summary of the stock position to the data manager, who shall then send the same along with other records to SACS/NACO.

The doctor-in-charge should inspect the stock registers on a weekly basis and countersign on the registers with remarks. Finally the nodal officer should also inspect the registers and stocks once in a fortnight along with conducting surprise checks every once in a while. The nodal officer should also sign and add his remarks during such inspection in the stock register itself.

5.3 Adjunctive medicines

In addition to OST medicines, clients generally require other medicines used by the hospital. This includes:

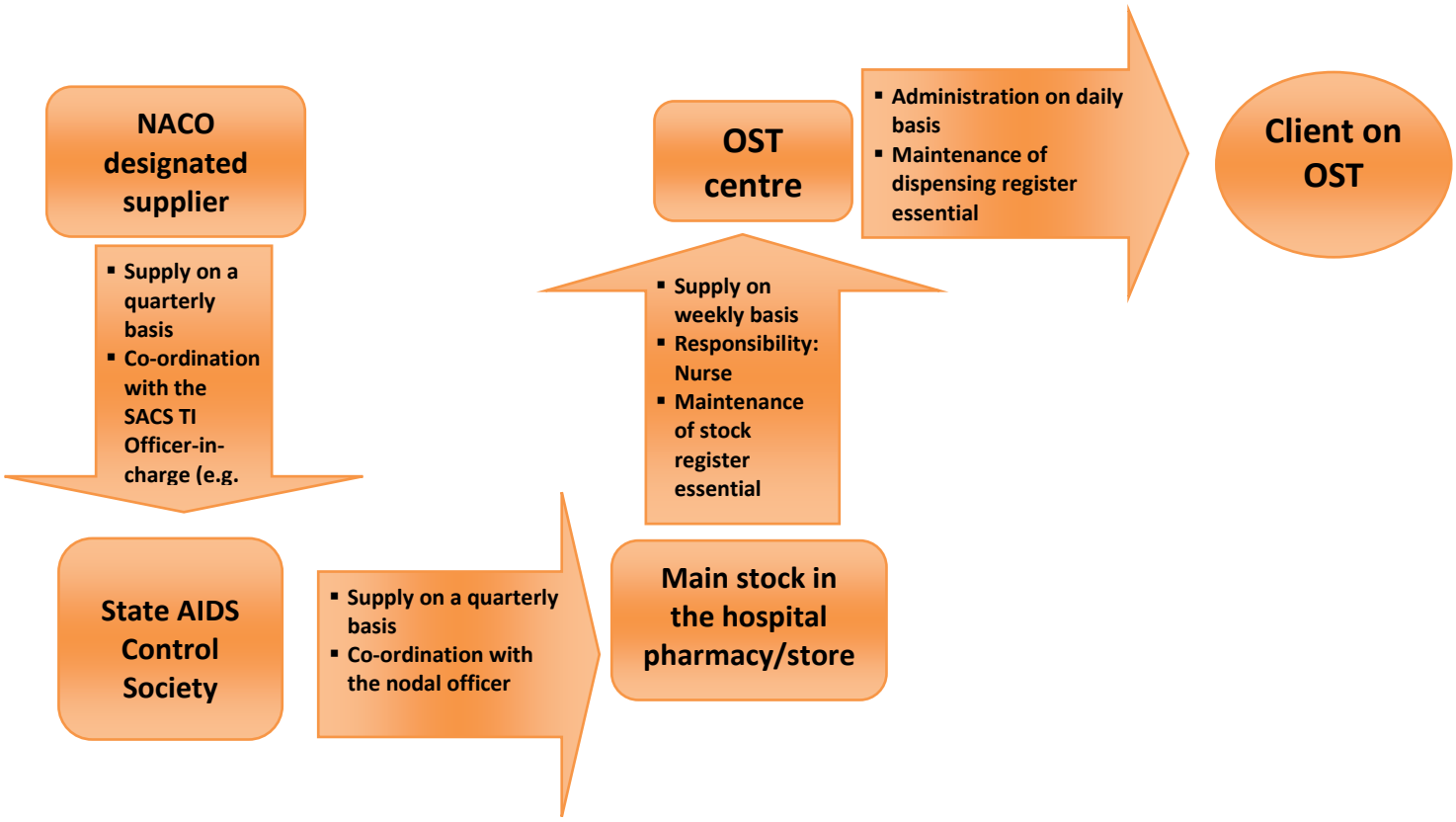
1. Sedative/hypnotics: as adjunctive medicines for sleep problems
2. Analgesics: such as Ibuprofen for bodyaches and pains
3. Antibiotics: for associated infections

   Other medicines (such as salbutamol and other bronchodilators, etc.) are also required by the IDUs; however, the above 3 medicines are very commonly required. Hence these medicines should be indented by the Nurse-in-charge of the OST centre from the hospital pharmacy, and stored with her along with OST medicines.

5.4 Condom stocks

The condoms shall be distributed by the SACS on a periodic basis to the OST centre. In case, there is an impending stock out of the condoms, the nodal officer shall inform the SACS TI officer in charge, who shall immediately arrange for the same.

Flow-chart of Supply chain mechanism of Buprenorphine



6. Record Maintenance

The various records to be maintained at the OST centre is mentioned in detail in the Practice guidelines on Buprenorphine. The performa of each record to be maintained is provided as annexure in the practice guideline document. In summary, the various records to be maintained are:

Client register	Register containing names, age/sex and address of clients along with client i.d. no.	Data manager
Client intake format	Detailed history and examination of the client	Counsellor & doctor
Consent form	A sheet containing the basic information on OST	Counsellor
Follow up form	Format for filling the information obtained during follow up	Physician
Side-effects checklist	Format for monitoring side effects	Physician
Referral form	Format for filling up data on referral	Physician/Counsellor
Group discussion record	Format for filling up records in group discussion	Outreach worker
Counselling register	Format for recording the counselling details	Counsellor
Client's dose sheet	One sheet for each client containing the date and dose of medication received	Nurse
Dispensing register	Details of dispensing carried out by the nurse every day	Nurse
Daily stock register	Details of stock in and stock out every day	Nurse
Central stock register	Details of stock in and stock out once a week	Nurse

The records should be verified periodically and decisions on patient management should be taken on the basis of the review of the records.

- The physician and counsellor must review the client's records regularly and assess the progress made by the client.
- On the basis of the records, the nurse must inform the outreach worker on clients who are not following up at the clinic. The outreach worker must then plan home visits on the basis of this information
- At the end of the month, the data manager must analyse the records, especially in terms of total number of clients on OST, regular coverage, and drop outs
- The stock records must be verified as described in the section on Medicine stock keeping and supply chain management.

7. Monitoring and supervision

7.1 Internal monitoring mechanism

- The nodal officer is the person who is overall in-charge of the OST programme. He shall carry out supervisory visits to the OST centre and ensure that the OST centre is functioning smoothly
- The doctor-in-charge of the OST centre is responsible for day-to-day functioning of the OST centre. He shall carry out review meetings once in two weeks with all the staff members and monitor the programme. In addition, he shall supervise the work of the other staff members of the OST centre.
- A monthly meeting of the OST centre staff and the TI attached to the OST centre shall be conducted under the supervision of the nodal officer
- The data manager shall send monthly reports to the SACS and NACO, as per the reporting format provided in **Annexure B**. The format should be filled after analysing the data at the end of the month, and submitted by the 5th of the next month electronically.

7.2 External monitoring mechanism

- The reports sent by the data manager on the 5th of every month should be analysed by the SACS TI officer/TSU (who will be designated by NACO)
- An analysis of the report shall be submitted by the officer at SACS/TSU by the 10th of every month electronically.
- SACS TI officer/TSU officer shall personally inspect the OST centre once in a quarter and assess the programme by reviewing the records, interacting with the clients and the OST staff members
- NACO TI officers will also carry out periodic inspections from time to time.

8. Financial management and procurement

8.1 Costing guidelines

The costing guidelines to be used may be found at **Annexure C**. The indicated figures are the maximum amount that can be used under the particular head.

The appointment of the doctor depends on the setting – if the setting is that of psychiatry department in the medical college, or that of a de-addiction centre, then the nodal officer may designate one of his subordinates as the doctor-in-charge who is expected to provide clinical services in the OST centre. In other settings, a doctor can be hired by the centre to manage the day to day clinical duties.

8.2 Grant to the OST centre

NACO shall transfer funds for OST centre to the respective SACS at the beginning of the financial year. The SACS, in turn, shall transfer funds to the OST centre once in 6 months.

8.3 Financial guidelines for the OST centre

- A separate bank account needs to be opened in the name of 'OST centre – (name of the institution)'.
- This account would be operated by the nodal officer.
- All payments, including salaries, shall be made by cheques, except for amounts less than Rs. 2000/-.
- Accounts shall be managed by the data manager on a day-to-day basis

- The OST centre shall submit detailed statement of accounts and utilisation certificates at the end of every six months, after which the next lot of funds shall be released to the OST centre
- The accounts of the OST centre shall be audited by auditors empanelled by the SACS annually.

8.4 Procurement procedures

The OST centre shall follow proper procurement procedures while procuring any goods for the centre. In all cases of procurement, three quotations must be obtained, and goods procured from the least quoted agency. Proper records for the same should be maintained for this purpose.

Annexure A: Performa of the stock registers to be maintained at SACS and central pharmacy of the public facility

A1: Performa for stock register in SACS office

Sl. No.	Date	Stock received			Stock distributed			Balance Stock			Issued by (name and signature)	Issued to (Name of agency/centre)	Received by (name, organisation and signature)
		2 mg	0.4mg	0.2 mg	2 mg	0.4mg	0.2 mg	2 mg	0.4mg	0.2 mg			

A2: Performa of central stock register to be maintained in the *main Pharmacy* of the hospital

Sl. No.	Date	Stock received			Stock distributed to the OST Centre			Balance Stock			Issued by (name and signature)	Received by (name, designation and signature)
		2 mg	0.4mg	0.2 mg	2 mg	0.4mg	0.2 mg	2 mg	0.4mg	0.2 mg		

A3: Performa of stock register maintained in the *OST centre*

Sl. No.	Date	Opening Stock			Stock transacted			Closing Stock			Issued by (name and signature)	Received by (name, designation and signature)
		2 mg	0.4mg	0.2 mg	2 mg	0.4mg	0.2 mg	2 mg	0.4mg	0.2 mg		

Annexure B: Monthly reporting format to be sent from the OST centre to NACO/SACS

(To be filled by the 30th of every month)

Name of the Hospital where the OST centre is located:

Name of the reporting Officer:
Reporting for the month:

1. Staff details

Staff allotted (as per the contract)	Trained Yes: Y No: N	Name of the training organisation
Doctor		
Nurse 1		
Nurse 2		
Counsellor		
Data manager		
ORW		

2. Client details

Sl. No.	Indicators	Numbers Achieved	Remarks
2a.	Total number of slots allocated for the centre		
2 b.	Total no. of clients registered for OST till this month		
2 c.	Total number of clients regularly accessing OST in the month ('Regular' defined as >24/30 days or >25/31 days)		
2d.	Total no. of clients dropped out (drop out defined as clients not receiving the medicines for 7 days continuously)		
2e.	No. of dropped-out who were followed up		
2f.	No. of clients whose family were contracted and counselled		
2g.	Total no. of clients completed the treatment		

3. Medication record details

Stock details	No. of 2 mg tablets	No. of 0.4 mg tablets	No. of 0.2 mg tablets
Stock received from SACS at the beginning of the month			
Stock dispensed in the month			
Stock remaining at the end of the month			

4. Service uptake by the OST clients

No. of condoms distributed	
No. of clients accessing the STI services	

5. Referral & linkages made for the OST clients

Services	**No. of referrals made**	**No. of clients accessed the referred services**	**Follow- up plan/ Remarks**
ICTC			
ART			
Detoxification			
Rehabilitation			
Others (like welfare services, legal aid, etc)			

(Signature of the reporting officer)

Annexure C: Costing guideline for OST centre

sl. No.	item	per unit cost	no. of units	Annual cost (in Rupees)	comments
1	**Infrastructure (to be paid to the OST centre through SACS)**				
1.1	**Refurbishment of the centre**			100000	One time cost; to be utilised for making necessary changes in the existing infrastructure for OST centre available in the hospital e.g. partitioning, painting
1.2	**furniture**			20000	one time cost; for purchasing furniture such as tables, chairs, computer table, almirahs, electrical equipments such as fans, lights
1.3	**computers and peripherals, audiovisual equipments, etc.**			60000	one time cost; for purchasing desktop computer, printer, UPS, etc., as well as audio-visual equipments such as TV, DVD, which can be used for educational purpose
1.4	**AMC**			6000	annual cost; applicable from 2nd year onwards; to be used for maintenance of computers, audio-visual equipments, etc.
1.5	**office expenses**	2000		24000	Payment related to use of stationary, internet expenses, photocopying, documentation etc.
1.6	**recruitment cost**			3000	used for conducting interviews for recruitment of contractual staff
1.7	**travel cost for administrative purpose**	500	1	6000	to be used by the data manager for administrative purpose
	Subtotal			**219000**	
2	**Salaries (to be paid to the OST centre through SACS)**				
2.1	**Doctor (MBBS)**	25000	1	300000	qualification, roles and responsibilities outlined in the operational guideline
2.2	**Nurse**	7000	2	168000	
2.3	**counsellor**	7000	1	84000	
2.4	**Data Manager**	6500	1	78000	
2.5	**Office support staff**	2000	1	24000	
	Subtotal			**654000**	
3	**NGO cost (to be paid to NGO through SACS)**				
3.1	**ORW salary**	5500	1	66000	qualification, roles and responsibilities outlined in the operational guideline
3.2	**travel cost to ORW for programme purpose**	500	1	6000	travel of ORW to the field, home visits and follow up the drop outs
3.3	**advocacy for OST**			3000	For the NGO to conduct advocacy related to the OST programme. Costing based on actual expenditure
	Subtotal			**75000**	
	GRAND TOTAL				
	1st year cost per centre			**948000**	
	2nd year onwards per centre			**765000**	