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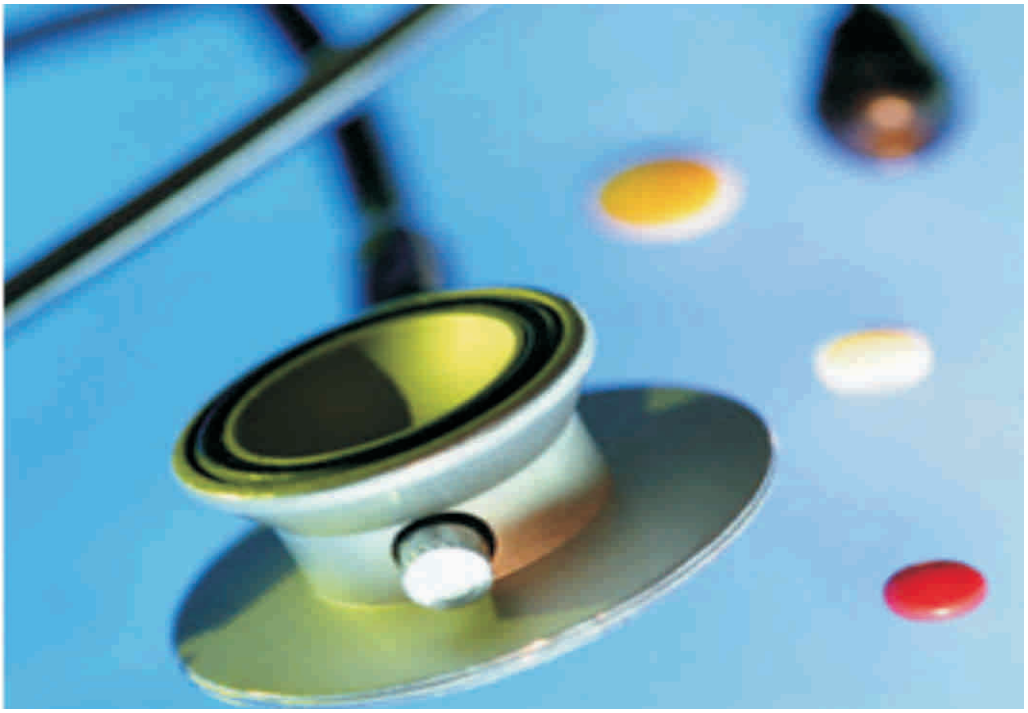
Quality Assurance of Opioid Substitution Treatment in India

-A Reference Guide for Mentors



Project HIFAZAT: Strengthen the capacity, reach and quality of IDU harm reduction services

QUALITY ASSURANCE OF OPIOID SUBSTITUTION TREATMENT IN INDIA

-A REFERENCE GUIDE FOR MENTORS

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PREFACE

TheNational Drug Dependence Treatment Centre (NDDTC), All India Institute of Medical Sciences (AIIMS), New Delhi, has been mandated to produce resource materials, build the capacity of service providers at other centres and, in general, take a leadership role in enhancing the quality of drug treatment services in India. In partnership with the National AIDS Control Organisation (NACO), NDDTC has been providing valuable inputs towards scaling-up of the opioid substitution treatment (OST) programme in the country. The present publication is one of the series of resource materials developed by the NDDTC on OST.

Injecting drug users (IDUs) are a population group vulnerable to high risk of transmission of human immunodeficiency virus (HIV). Indeed, this group currently has the highest prevalence of HIV in India, among other groups, displaying high-risk behaviour. Various harmreduction interventions for preventing HIV among IDUs are being provided under the National AIDS Control Programme, and among them, OST is arguably the most technically intensive. It is heartening to note that NACO is currently undertaking a rapid scale-up of OST services in the country. With a rapid expansion in the number of OST centres in the country, ensuring the quality of OST services becomes a formidable challenge. Even after receiving classroom-type induction training, the service providers do encounter a lot of challenging situations when they begin implementing the services in the field. Additionally, a host of programme management issues surface only when a centre starts functioning. Further, even after a centre begins providing services, it becomes important to monitor the functioning through periodic visits by OST experts and provide on-site guidance and mentoring.

To address these challenges, this reference guide has been developed by the NDDTC and would serve as a resource material for mentors, entrusted with the task of carrying out periodic 'quality assurance (QA) visits' to OST centres. This guide provides a detailed, step-by-step description for mentors on how to plan, conduct and report these visits. The draft versions have undergone multiple rounds of field testing and revisions. The most recent draft of this guide has been developed with feedback received from mentors from various parts of the country in a national training programme held in August 2013. The final version of this guide is in your hands.

It is expected that the guide would be received as a handy, useful resource for all the mentors who would be involved in the QA process. The authors wish to express sincere thanks to NACO, the project management unit (PLU) of project 'Hifazat' and all the experts who have provided their valuable feedback.

Prof. Rajat Ray
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New Delhi

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ABBREVIATIONS

- AD: Assistant director
- AIIMS: All India Institute of Medical Sciences
- ANM: Auxiliary nurse midwifery
- ART: Anti-retroviral treatment
- ATT: Anti-tubercular treatment
- DD: Deputy director
- GFATM: Global Fund To Fight AIDS, Tuberculosis And Malaria
- HIV: Human immunodeficiency virus
- IDU: Injecting drug user
- JD: Joint director
- LFU: Lost to follow-up
- NACO: National AIDS Control Organisation
- NACP: National AIDS Control Programme
- NDDTC: National Drug Dependence Treatment Centre
- NERO: NACO Northeast Regional Office
- NGO: Non-governmental organisation
- NSEP: Needle Syringe Exchange Programme
- NTTC: National Technical Training Centre
- ORW: Outreach worker
- OST: Opioid substitution treatment
- PM: Project/Programme manager
- PMU: Project Management Unit
- PO: Project/Programme officer
- QA: Quality assurance
- RTTC: Regional Technical Training Centre
- SACS: State AIDS Control Society
- SOPs: Standard Operating Procedures
- TI: Targeted intervention
- TL: Team leader
- TSU: Technical support unit

A. Introduction

Injecting drug users (IDUs) have emerged as an important group vulnerable to contracting and transmitting human immunodeficiency virus (HIV) infection in India. As per HIV sentinel surveillance 2010, HIV prevalence among IDUs is 7.1%, which is one of the highest among any population group. IDUs are vulnerable to HIV due to sharing of contaminated needles/syringes and other injecting equipment, as well as unsafe sexual practices. In response to high HIV among IDUs, the National AIDS Control Organisation (NACO) has scaled up HIV prevention programme for IDUs. There has been a significant increase in the number of such interventions implemented by NGOs (targeted interventions or TIs) throughout the country, and a near saturation of coverage of IDUs with HIV prevention services has been achieved.

Another important strategy for prevention of HIV transmission among IDUs is provision of opioid substitution therapy (OST). OST has been introduced in the National AIDS Control Programme (NACP) during phase III (2007–2012), and all OST centres (which were then run by non-governmental organisations [NGOs] only) were accredited to implement OST throughout the country. To ensure sustainability and quality of services, OST was additionally introduced through government hospitals in collaboration with NGO-run TI centres. In the NACO-supported OST programme, all OST centres provide buprenorphine-based substitution treatment to IDUs. Recently, methadone has also been introduced in the country as a pilot project in five centres. As on September 2013, OST is being provided in more than 100 centres in both governmentaland NGO settings. NACO plans to introduce OST in all districts with significant IDU population, with an aim to achieve 20% coverage with OST.

A series of training programmes are being conducted for building the capacity of staff working in the OST centres funded by NACO. These include an initial induction training of 5 days' duration, followed by refresher psychosocial training and training on comorbid conditions. These training programmes help the staff to acquire the knowledge, attitude and skills required to provide OST to IDU clients. However, it is felt that the service providers will also require periodic mentoring and on-site handholding. Additionally, it was deemed important to periodically monitor the implementation, to take stock of the situation and to recommend coursecorrection measures, if any.

In this regard, NACO has planned to organise periodic field visits to OST centresby technical experts on OST to assess their functioning as well as to provide technical inputs to the staff working in OST centres in order to improve and assure the quality of the OST programme. These quality assurance (QA) visits shall complement and supplement the existing capacity building, monitoring and supervisory mechanisms of the NACP. The purpose of this reference guide is to provide a standard framework to technical experts (called as 'mentors'in the document) undertaking such field visits.

B. About the Reference Guide

Quality assurance (QA)is a broad concept and has been defined as 'the systematic monitoring and evaluation of the various aspects of a project, service or facility to maximise the probability that minimum standards of quality are being attained …'.Although there may be various ways in which QA of OST services may be operationalised, one of the important mechanisms envisaged for ensuring the quality of OST services delivered under the National AIDS Programme is periodic visits by mentors on OST for mentoring and supportive supervision of the staff of these centres.

Consequently, this guide has been developed as a set of guidelines and procedures for those individuals and organisations entrusted with the task of assuring the quality of OST services. The broad objectives of this reference guide are:

1. To provide a framework for consistent assessment of the quality of OST services and steps to be taken to continuously improve the quality
2. To confirm whether the OST centres in question meet the basic requirements of quality through assessment of key indicators of QA
3. To help determine the aspects of the services that need to be strengthened
4. To provide on-site guidance as well as detailed, programme-level feedback for strengthening of OST services
5. To develop capacity of state-level monitoring and supervisory structures (the State AIDS Control Society [SACS] and thetechnical support unit [TSU]) on OST implementation

A number of documents have acted as the basis and premises for this reference guide. These are:

- Operational Guidelines for Implementation of OST for IDU in Government Health Care Facilities (i.e. the Government OST 'scheme' document)
- Implementing OST – A Training Manual for Service Providers (i.e. the 'OST training manual')
- 'A Manual for Quality Assurance of OST Centres'(draft) – developed for NACO, with the assistance from the DFID – TAST (Department for International Development – Technical Assistance Support Team), by faculty from theNational Drug Dependence Treatment Centre (NDDTC), All India Institute of Medical Sciences (AIIMS), New Delhi(i.e. the previous version of this document)
- NACO Standard Operating Procedures (SOPs) for OST with Buprenorphine for Government and NGO settings (under development)
- Clinical Practice Guidelines for Implementing OST with Buprenorphine (NACO, under revision)

C. Conducting a quality assurance visit

This reference guide provides step-by-step instructions on assessment of QAindicators. It is important formentors using this reference guide to be thoroughly familiar with the content of the above-mentioned documents, too.

C1. Aims and objectives

The overall aim of a QA visit is to ensure that standards of care are being metin OST service being provided at the OST centre being visited. The specific objectives of the QA visit are:

1. To assess the quality of services provided at the OST centre
2. To interact with the staff of the OST centre and understand specific challenges faced by them in the implementation of OST
3. To guide the staff in ensuring the availability of OST-related optimum care and support to IDU clients

C2. The 'mentor'

The mentor who would visit the OST centres should have certain qualifications and experience of conducting QA visits. Apart from this, the supervisor should also have certain qualities for conducting QA visits. It is desirable that the supervisor should undergo training organised through NACO on conducting QA visits and using the tools for QA. The supervisor should also have the ability to assume the role of a teacher/guide to provide demonstrations as and when required.

Qualifications/Experience of a Mentor

- Qualification: Minimum MBBS, preferably postgraduate degree/diploma in Psychiatry
- Experience of working in the field of substance use disorders
- Experience in clinical management of opioid dependence using long-term opioid agonists
- Experience of having worked in a senior supervisory role at a centre involved in implementing OST
- Undergone training on conducting QA visits as well as on the use of QA tools

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Attributes of a Mentor

- Non-judgemental and non-confrontational attitude
- Ability to listen, observe, analyse and provide feedback
- Ability to guide/mentor the staff implementing OST
- Willing to travel to OST centres

The mentor should carry out the QA visit in the following steps:

A. Following initial instructions, initiate a **general discussion** with the staff of the centre, enquiring about the following points:

- When did the centre start functioning?
- How long have each staff member been working in the centre?
- Have the staff members undergone training?
- What is the timing of the centre – general timings and dispensing timings?
- What is the target allotted to the OST centre?
- How many clients have been recruited into OST till now?
- How is a client recruited in the OST programme(i.e. processes being followed)?
- What is the general impression of OST among IDU clients and their families?
- What is the general impression of OST among OST and IDU-TI staff?
- What are the challenges in OST implementation?

B. Following the general discussion, **conduct a tour of the centre**, observing for the following:

- What kind of infrastructure is available for the OST centre?Is the space adequate for implementation of OST?
- Is the doctor's room adequate for assessment and diagnosis of the client?
- Is there audio-visual privacy in the counsellor's room?
- Is the nursing/dispensing station secure enough? What are the mechanisms for dispensing of OST medicines in the dispensing room?
- Where are stocks of OST medicines kept? Are they secured enough?
- Is the waiting area for clients adequate?
- Where are records maintained in the OST centre? Are they as per the prescribed format? Are they accurate and being updated as required?

C. Following the observation, **interact with individual staff** and assess the following issues for each staff:

- Training details: total number of trainings attended till date; last training attended
- Role clarity
- Confidence in discharging roles/responsibilities
- Expectation of the staff about the OST programme
- Attitude of the staff towards the clients and the OST programme
- Specific details of those aspects of OST implementation as relevant to the staff
- Challenges faced in discharging the responsibilities assigned to the staff

D. Next, conduct a **review of the records** maintained at the centre. For this purpose, ask for client files of about 8–10 clients (chosen randomly) and go through the files, making observations necessary for collecting information mentioned under sections4 and 5 of the 'Tool for OST Quality Assurance Visit' (Section E). Check the various registers maintained by the OST centre and note for accuracy, correctness and any improvement required.

E. Finally, conduct a **meeting with OST clients** and their family members (if present at the OST centre) to understand their views on the OST programme. For this purpose, request the OST centre at the beginning of the QA visit to ask those clients who have come to the centre to receive their daily dose:

- A group discussion can be held with 8–10 such clients.
- Initiate the discussion by introducing yourself, the purpose of your visit and asking the clients to introduce themselves and mentioning how long they have been on OST
- Ask the clients their experience with OST –accessibilityof the centre, ease of entry into treatment, attitude of the staff, changes in their life while on OST, any side effects observed, attitude of other clients regarding the OST programme, any myths/misconceptions regarding OST, effect on the families/society due to OST, etc.
- Finally, ask the clients for suggestions to improve the functioning of the OST centre.

In addition, clinical advice may also be given for certain 'difficult' cases. Cases which have peculiar clinical issues, on which the medical staff of OST centres may need additional consultation or advice, may be reviewed and discussed and appropriate consultation may be provided. For this purpose, the nodal officer/medical officer may inform such patients in advance and make them available for consultation.

F. Although not ordinarily required in all cases, it may become necessary to visit the linked IDU-TI in the case of some government hospital-runOST centres (in the case of NGO-OST centres, the IDU-TI and OST services are co-located and, hence, interaction with the TI staff can be held at the same facility). The situations in which amentorcan consider visit to the linked IDU-TI may include:

- Very few clients referred from the TI to the OST centre despite the OST centre being functional for more 6 months (for instance, active client load of less than 30 in 6 months from the IDU-TI)
- Reports of inadequate coordination between OST and IDU-TI staff
- Reports of myths regarding OST among IDU clients of the area
- Information provided by the IDU-TI staff regarding outreach for OST clients is considered unsatisfactory
- Non-availability of IDU-TI staff (PM, auxiliary nurse midwifery [ANM] / counsellor and at least one ORW) at the OST centre during the visit
- On specific request of the IDU-TI staff
- Any other indications as considered appropriate by the mentor

During the visit to the linked TI, the mentor may conduct the following activities:

- Interact with the IDU-TI team, including ORWs and peer educators

- Conduct a group discussion with clients (those who are on OST or have come to the TI for other services, including the Needle Syringe Exchange Programme [NSEP]) regarding OST services
- Review outreach records of the TI to understand injecting patterns of IDUs and the nature of services being provided by the TI

- Visit a hotspot to interact with clients if not available at the drop-in centre

A tool for conducting QA and capturing the information has been discussed in Section E. The mentor should use the tool as a guide for conducting activities for QA at the OST centre. He/She may fill it simultaneously during the interview itself or later after the visit is over. However, care should be taken to ensure that all the areas listed in the tool are adequately captured for a comprehensive report. The QA tool contains the following sections:

1. Background information
2. Details of the OST centre
3. Staff-related details
4. Implementation of OST
5. Record keeping-related details
6. Feedback from OST clients and their families
7. Stock maintenance and programme management
8. Gaps identified and addressed during the visit
9. Impression on the quality of the OST centre

C4. Impression of the mentor on the quality of the OST centre

A rating tool consisting of items pertaining to the quality of OST service at the OST centre has been included in the checklist for QA visits. The tool consists of items pertaining to (a) uptake of services at the OST centre, (b) processes followed for service delivery at the centre, (c) understanding of the prescribed guidelines and SOPs and their usage in clinical practice, (d) maintenance of records, (e) satisfaction of clients and family members with the services rendered and (f) outcomes of OST at the centre in terms of retention and adherence.

The rating tool consists of a mix of objective and subjective indicators designed to assess the overall quality of OST services at an OST centre. The rating tool is not designed to serve as a measure of the performance of an OST centre. Rather, the rating should be seen as a global impression of the service quality at an OST centre. The rating would helpgenerate impressions about the service quality of a given centre at different points in time and, thus,help track the changes in service quality with systematic inputs such asQA visits.

A brief description of various items included in the rating tool is provided below.

Item 1: OST uptake

This item assesses the uptake of OST services by IDU clients of the area and reflects the effectiveness of demand generation activities by the IDU-TI and the attractiveness of services delivered by the OST centre. It should be rated by comparing the number of IDUs initiated on OST by the centre with the number of IDUs ever registered with the linked IDU-TI or TI implementing the OST centre (calculated as a percentage). It is expected that for any OST centre functioning for more than 6 months, the proportion of clients who have ever registered for OST should be 20% or above to be considered 'acceptable' and above 40% for a rating of 'good'. However, mentors can relax the criteria for OST centres located in areas with highly scattered populations or difficult terrain. If during the visit, it is felt that the target of the proportion of clients to be covered by OST is higher, the same may be noted with reasons in the 'Remarks' column and included in recommendations of the field visit.

Item 2: Recruitment and training of staff

The OST centre should be adequately staffed as per the approved operational and costing guidelines of the NACO. All the staff of the OST centre and the key staff of the IDU-TI (PM, ANM/counsellor and ORWs) should be trained on the NACO-approved module for OST induction training. The training should be conducted by an agency/institution approved by NACO for this purpose and by OST trainers who have received 'Training of Trainers' on the said module. The 5-day induction training of all staff is essential prior to the rolling out of services in new OST centres. In the case of staff turnover, the same should be organised within 2 months of joining of the new staff. At any centre, it is essential that the doctor managing the clinic should receive induction training as it is critical to the quality of OST services. Therefore, if the doctor at a given centre is untrained, the score on this item would be poor even if all the other staff members are trained.

Item 3: Knowledge and confidence of staff on OST-related issues

During the visit, the mentor is required to assess the knowledge and skills of OST centreand IDU-TI staff regardingvarious aspects of OST implementation. A list of such topics has been included in the QA tool (section 3). Based on the interaction with the staff and the review of records, the mentor should make an overall impression about the knowledge and competency of the staff in OST implementation. While making thisjudgement, the mentor should contextualise the knowledge and skills with the role a given staff is supposed to play in the OST centre. For example,for a nurse not to not be fully aware or confident about the inclusion and exclusion criteria for OST may not be considered a critical gap in knowledge and skills, but for a doctor/counsellor,it is essential that he/she knows it well and isable to use in routine practice.

Item 4: Role clarity

After the interaction with OST centreand IDU-TI staff, the mentor should rate this item based on whether the staff are aware and clear of their own roles and responsibilities in OST implementation. The staff should be clear about what is expected of them in terms of service

delivery components to be looked after by them and records to be maintained for the same. They should also be aware that which of their work responsibilities requires working in coordination with other staff members and be able to seek support/assistance for the same. The item should be scored based on the overall judgement of the mentor on role clarity among staff of OST centre and IDU TI.

Item 5:Initial assessment of clients before OST initiation

It is essential that a thorough assessment of all clients is performed prior to initiation of treatment. The assessment of clients should be done by both the counsellor and the doctor and the records for the assessment should be maintained in the prescribed formats (counsellor's and doctor's intake proforma). Under no circumstances should a client be initiated on OST without clinical assessment by a trained doctor. The visiting mentor should make an opinion after reviewing some of the client files and interacting with the OST centre staff and OST clients, and rate the item as per the practices followed in the centre.

Item 6: Stabilisation dose of buprenorphine

The dose of buprenorphine is one of the most critical determinants of the success of OST services in terms of retention and adherence. It is important that dosage requirements of clients are assessed carefully during initial assessment and follow-ups, and clients are stabilised at optimal doses as per individual requirements. The experience of OST implementation in India reveals that the stabilisation dosefor most clients should be between 8 and 12mg per day. Hence, the mentor should ascertain the average dosage, most common dose, lowest dose and highest dose being prescribed at the centre to rate this item. This information would be collected by a review of client files as well as dispensing-related records.

Item 7:Follow-up of OST clients

The doctor and the counsellor of the OST centre should regularly follow-up OST clients during the course of treatment and maintain records for the same on the prescribed formats (clinical and psychosocial follow-up forms). The minimum recommended frequency of follow-up is: weekly in the first month of treatment, fortnightly over the next 2months and monthly thereafter. Follow-up may be done more frequentlyfor clients who are irregular on treatment or not able to stop/substantially reduce injecting themselves while receiving treatment. The visiting mentor should review client files for follow-up forms and follow-up register,and interact with the staff to make an opinion regarding the adequacy of follow-ups conducted and accordingly score the item.

Item 8:Changes in dose of buprenorphine

Under the NACP, OST is considered a medical treatment supplemented by psychosocial interventions. Hence, the responsibility of prescribing OST medicines initially and adjusting the dose during the course of treatment rests with the doctor of the OST centre. No other staff

member should make changes to OST dosages prescribed to clients under any circumstance. The visiting mentor should review client dose sheets/dispensing register of the OST centre and cross-check it with the prescription clips/follow-up forms of the doctor to verify if dosage changes have been made by the doctor or by some other staff member. The item is accordingly graded as either good or poor, as even a single instance of dosage change by any other staff member is not considered acceptable.

Item 9: Duration of maintenance phase of treatment

OST is a long-term medical treatment for opioid dependence and is considered complete when the client has shown substantial improvement/stabilisation in several domains of functioning. To achievedesired stabilisation/improvement in these domains, most opioid-dependent clients would require treatment extending up to 2–3 years or more. Early cessation of treatment has been associated with inadequate recovery and a high risk of relapse to injecting drug use. Hence, the average duration of treatment is considered an important determinant of the quality of OST services. The visiting mentor should review the dispensing register and interact with staff to understand the average duration of maintenance treatment at the centre and score the item accordingly. Not just the actual practice being followed at the centre, but even an incorrect understanding among the staff (for instance, staff opining that 'after 6–9 months of treatment, dose of buprenorphine should be tapered off') is a cause for concern and should be addressed.

Item 10: Follow-up of lost to follow-up(LFU)/irregular clients in the field

In both NGO- and government-setting models of OST, the outreach staff of the IDU-TI should follow-up irregular clients or those discontinuing treatment (lost to follow-up, LFU) on a regular basis. The field teams should motivate clients to return back to treatment or be more regular in taking medicines and should identify factors responsible for dropout/irregularity. The outreach teams should also ensure the availability of other harm reduction services to such clients (needle/syringe distribution, abscess management, etc.) if continue to inject. The mentor should interact with OST centre and IDU-TI staff and some clients and score the item based on the information available. If adequate information on this aspect is not forthcoming during the interaction, the mentor should consider visiting the TI for a detailed discussion and review of TI outreach records, particularly if it appears that quite a few OST clients are irregular or LFU.

Item 11: Dispensing-related protocols

Under the NACP, OST is dispensed only as a directly supervised treatment on a daily basis. The procedure to be followed by the nurse while dispensing the medicines is detailed in section4of the QA tool (Section E). The visiting mentor should interact with the nurse, observe dispensing for some clients, review dispensing-related records and make an impression regarding dispensing procedures being followed at the centre. The item should be scored based on the overall impression regarding adherence to prescribed procedures for OST dispensing.

Item 12:Record maintenance

The mentor should review all the clinical, dispensing-related and stock-related records and check if the records are being maintained as per the prescribed format and are updated as required. Based on the above, a global impression of record maintenance at the centre should be made and the item scored accordingly.

Item 13:Stock management

Stock management at an OST centre includes timely indenting and receipt of fresh stocks from the SACS, safe-keeping of the stock at the central pharmacy or store of the hospital/head office of the NGO (in the case of NGO-run OST centres), periodic supply of stock from the central stock to the OST centre, maintenance of all stock-related records as per prescribed formats and accurate entries, the ability of the nurse to project stock requirements correctly and efficient management of different strengths of buprenorphine tablets by the nurse. The visiting mentor should review the above aspects as outlined in the QA tool and make an opinion about stock management at the centre.

Item 14:Satisfaction of clients and family members

The mentor should interact with some OST clients and their family members during the visit and ascertain their opinion about various aspects of OST services such as accessibility, ease of entering into treatment, operating timings, staff attitudes, dosage, counselling services, linkage with other medical services, etc. Based on the overall impression of satisfaction with OST services, the item should be scored as good, average or poor. It should be remembered here that clients may demand for services which are not mandated to be provided by the OST centre (such as food, clothing, shelter, etc.). The mentor should rate this item only on the basis of those services deemed as mandatory as per NACO guidelines.

Item 15:Client retention

Although there can be many determinants of client retention in OST services, it is also closely related with the quality of OST services being provided at the centre. It is expected that centres with better service quality will have better retention rates. Client retention is the proportion of clients still receiving treatment (received at least one dose during the preceding calendar month) out of the total number of clients started on OST from the centre (cumulative OST uptake). However, while calculating retention rate, clients who have completed treatment and clients who have met other outcomes (death, migration, imprisonment and transfer to other centres) should be deducted from the denominator. The resultant retention rate (in percentage) should then be used to score this item.

Item 16: Treatment adherence and compliance

The OST implementation experience reveals that clients coming 25 days or more in a month to receive their medicines experience maximum benefits out of OST treatment; hence, the

treating team should ensure that most clients who are retained in treatment come 'very regularly'. In this item, the mentor should ascertain the proportion of clients receiving treatment very regularly (25 or more days in the preceding calendar month) out of those clients who are currently on treatment (active client load). The resultant adherence rate (in percentage) should then be used to score this item.

C5. Scoring and grading the rating tool

Each item of the rating tool (except item 8) has three options (good, average and poor) and generates scores of 1, 2 or 3. The rating tool has a total of 16 items, which result in a combined maximum score of 47 and a minimum score of 16. However, items 1, 9, 15 and 16 of the rating tool are only applicable for centres which have been functional for at least 6 months. Hence, in the case of centres functional for less than 6 months, the maximum and the minimum score would be 35 and 12, respectively.

The mentor should score the items as per the description provided above and calculate the total score obtained for the centre by adding the individual item score. Next, a percentage score should be calculated as per the following formula:

$$\text{Percentage score obtained} = \frac{\text{Total score obtained by the centre} * 100}{\text{Maximum score applicable for the centre (47 for old centres and 35 for new centres)}}$$

The percentage score obtained should then be used to ascertain the quality grading of the centre as per the table below:

S. No.	Percentage score range	Quality grading
1	90% or above	A+
2	75–89%	A
3	60–74%	B
4	40–59%	C
5	Less than 40%	D

A Note of Caution in Scoring

It should be noted that most of the items require the mentors to use their overall impression and judgement to score. Only a few items are operationalised based upon the objective, quantitative criteria. Consequently, there is an element of subjectivity while assigning scores to an OST centre. However, these scores should not be seen as directly reflecting the performance of the staff of OST centres, nor should they be used to penalise the centre in any form. The primary purpose of this scoring/grading system is to draw attention to OST centres which need further inputs.

Additionally, as mentioned earlier, the purpose of the QA visit is not just to monitor and evaluate, but also to guide and mentor. Consequently, in any of the areas, upon finding a deficiency, the mentor is expected to take some remedial steps by providing appropriate knowledge and guidance, there and then. The final report in such cases would reflect the areas of deficiency as well as the correctional measures adopted by the mentors.

D.Preparing a quality assurance visit report

At the end of the QA visit, the supervisor is expected to share the findings through submission of the filled-up QA tool (Section E) and report (Section F). The report would be for the consumption of the SACS, TSU and NACO,whichwould use this to take strategic decisions on the nature and type of further support/modifications required to improve the functioning of the OST centre as well as the OST programme in the state/country. Hence, it is important that the report is properly prepared and submitted.

Currently, the activity of QA visits to OST centres is supported through project 'Hifazat'. Till such time as support from project Hifazat is available, the mentor should submit the tool and the report to the concerned RTTC managing the visits for the region for review and feedback. Once the report is finalised, the RTTC shall forward the report to the concerned SACS, TSU and NACO for information and necessary action.

E.Tool for OST quality assurance visit

SECTION 1: BACKGROUND INFORMATION

Date of visit	
OST centre visited, with complete address	
Date (month and year) since the OST centre is functional	

S.No.	Name of the linked IDU-TI/TIsa,b	Date (month and year)since the linked IDU-TI is functional	Active population of the TI	Clients referred to the OST centre till date	Clients started on OST till date	Clients currently receiving OST (at least one dose in the last 1 month)
1.						
2.						
3.						

a. Multiple in the case there are more than one IDU-TIs that are linked with the OST centre.
b. In the case of an NGO-TI-led OST centre, mention the details of the NGO-IDU-TI and the other IDU-TIs within the catchment area of this OST centre

Names (with designation) of the visiting officers/mentors

S.No.	Name of the visiting officers/mentors	Designation

Names (with designation) of the staff present at the time of the visit

S.No.	Designation	Sanctioned	Appointed	Name of staff	Remarks: Duringthe visit
1.	Nodal officer	Yes/No	Yes/No		Present/Absent
2.	Medical officer, OST centre	Yes/No	Yes/No		Present/Absent
3.	Back-up doctor, OST centre	Yes/No	Yes/No		Present/Absent
4.	Nurse, OST centre	Yes/No	Yes/No		Present/Absent
5.	Back-up nurse, OST centre	Yes/No	Yes/No		Present/Absent
6.	Counsellor, OST centre	Yes/No	Yes/No		Present/Absent
7.	Data manager, OST centre	Yes/No	Yes/No		Present/Absent
8.	PM, IDU-TI	Yes/No	Yes/No		Present/Absent
9.	ANM, IDU-TI	Yes/No	Yes/No		Present/Absent
10.	Counsellor, IDU TI	Yes/No	Yes/No		Present/Absent
11.	ORW, IDU-TI	Yes/No	Yes/No		Present/Absent
12.	Any other (please specify)				Present/Absent

SECTION 2: DETAILS OF THE OST CENTRE

(Information collected through inspection of the centre)

S.No.	Item	Response (yes/no)	Remark (if any)
1.	Is the doctor's room adequate for assessment and diagnosis?		
2.	Is the counselling room adequate for counselling/assessment?		
3.	Is the dispensing room adequate and secure enough for the nurse to dispense medications?		
4.	Is the area where stocks are maintained secure enough for storage of stocks of buprenorphine?		
5.	Any other observation (please specify)		

SECTION 3: STAFF-RELATED DETAILS

(Information collected through interaction with staff)

Training-related details

S.No.	Cadre of staff	Trained on OST implementation in a formal and structured training?* (Yes/No)	Month and year of induction training attended	Month and year of induction training attended
1.	Doctor			
2.	Nurse			
3.	Counsellor			
4.	Data entry operator (in the case of government hospital -run OSTcentres)			
5.	PM-IDU TI			
6.	Outreach workers			
7.	Back-up doctor			
8.	Back-up nurse			
9.	Nodal officer			

*For any staff appointed after January 2012, this would mean a 5-day induction training on the National OST Training Module approved byNACO.

Staff rating of training areas

S.No.	Areas of training	Doctor	Nurse	Counsellor	Data manager	Programme manager	Outreach workers
1.	Understanding drug use/injecting drug use						
2.	Understanding harm reduction approaches to drug treatment						

S.No.	Areas of training	Doctor	Nurse	Counsellor	Data manager	Programme manager	Outreach workers
3.	Assessment and diagnosis of clients for suitability of OST						
4.	Understanding OST, including pharmacological issues						
5.	Clinical practice for implementing OST with buprenorphine (such as initiation, stabilisation, dosing, dispensing, etc.)						
6.	OST for special population groups (such as pregnant women, adolescents, comorbidity, etc.)						
7.	Psychosocial/Counselling interventions as part of OST						
8.	Referral and linkages as part of OST						
9.	Managing an OST programme						
10.	Documentation, records and reporting						
11.	Informing and referring clients for OST						
12.	Enhancing compliance among irregular or LFU clients						

Notes: The rating is done in the following manner: 1 = fully trained and confident, 2 =trained before, but need more training to be fully confident, 3 = not trained before. If a particular item is not applicable to a staff member, the corresponding box has been shaded.

Role clarityof staff members (The member primarily responsible for a given activity/issue is in bold.)

S. No	Item	Yes/No
1.	The **PM** and other TI staff ensure that clients are informed and referred to seek OST services.	
2.	The **data manager** ensures that each client is registered and each clientfile is maintained (in the case of an NGO -OST centre, the role would be taken up by the ANM/counsellor).	
3.	The **counsellor** takes the lead role in first assessment and preparation of the client for OST (psycho-education, motivation/enhancement and informed consent).	
4.	The **nurse** ensures that medicines are dispensed only if doctor's prescription is available and only for the duration of the prescription.	
5.	Medicines dispensed only by a trained **nurse**.	
6.	The **nurse** dispenses medicines to all clients sublingually under supervision, except when take-home is specifically permitted by the doctor/counsellor for a limited duration.	
7.	The **nurse** has to ensure availability of sufficient quantities of medicines (at least 7 days' stock) in the clinic by indenting it on a periodic basis.	
8.	Both the **doctor** and the **nurse** are responsible for identifying side effects.	
9.	The **nurse** is responsible for detecting intoxication and withholding medication in an intoxicated case.	
10.	The **doctor** and the **counsellor** refer patients for other health problems.	
11.	Accompanied referrals are facilitated by the **IDU-TI staff.**	
12.	For the clients who have been lost to follow-up, efforts are made to trace them and bring them back into treatment by the **IDU-TI staff**	
13.	For clients on OST, efforts are made by the **counsellor** of the OST centre and the **IDU-TI staff** to engage the family members in the treatment process.	
14.	Efforts are made for psychosocial and occupational rehabilitation of stabilised OST clients by the counsellor of the OST centre and by the **IDU-TI staff.**	
15.	The **IDU-TI** staff ensures provision of NSEP and other harm reduction services for clients unable to continue treatment or not stabilised on OST.	
16.	Is the **nurse** able to correctly project stock requirement and indent fresh stocks in time?	
17.	The **nodal officer** periodically reviews the functioning of the OST centre.	

Knowledge of staff members

Item	Doctor	Nurse	Counsellor	Projectmanager-TI	Outreach worker-TI
ASSESSMENT					
1. Essential criteria for assessing the suitability of the client for OST (a) Diagnosis of opioid dependence (b) Current IDU (c) Logistics and feasibility (d) Written consent					
Clinical Practice of OST					
2. Process of induction					
3. Frequency of follow-up and parameters assessed during follow-up					
4. Importance of adequate dose of OST medication					
5. Assessment of optimum dose					
6. Importance of adequate duration of treatment					
7. Assessment of optimum duration of treatment					
8. Awareness of conditions requiring postponement or need to review dispensing (such as intoxication or other physical conditions)					
9. Dispensing procedures					
10. OST with comorbidity (mental/physical – on anti-retroviral treatment(ART)/ anti-tubercular treatment(ATT);awareness of drug interactions for doctor					
11. Involuntary termination of treatment					
12. Treatment re-entry for those who were lost to follow-up or relapsed after treatment completion					
13. Other conditions to be periodically assessed/investigated (HIV and sexually transmitted infections testing)					
Psychosocial interventions					
14. Psycho-education about OST					
15. Knowledge about various motivation/enhancement techniques					
16. Knowledge about various relapse prevention techniques					

Note: If a particular item is not applicable to a staff member, the corresponding box has been shaded.

SECTION 4: IMPLEMENTATION OF OST

(Information collected through interaction with the staff as well as from records)

Item	Respons	
What is the timing during which the OST centre is functional?	_____AM/PM to ____AM/PM	
What is the timing for dispensing of OST medicines to the clients?	_____AM/PM to ____AM/PM	
Is the OST centre functional on all days of the week?	(Yes/No)	
If there is a holiday for the OST centre in a week, please provide details.		
OST target assigned to the centre by the SACS/NACO in the current year		
Total number of clients registered into the OST programme till now(cumulative)	From IT	
	From other sources	
	Total	
Any issue in initial recruitment of clients into the OST programme? If yes, please provide details,including possible reasons as well as suggested measures to improve recruitment.		
Is there a waiting list of clients interested in the initiation of OST? If yes, how many clients have been kept in waiting list? What are the reasons for keeping the clients in waiting list?		
What is the usual opioid drug injected by majority of clients?		
Are clients counselled (prepared) before initiating on OST in the field?		
Is the counselling (in the field) adequate?		
Usually, who does the initial assessment of clients for initiation on OST? Please tick one.	1.Counsellor only 2.Doctor only 3.Both	
Usual time taken to stabilise a client on OST (in days)		
Maximum dose of buprenorphine dispensed to any client (in mg/day)		
Minimum dose of buprenorphine dispensed to any client (in mg/day) – as maintenance treatment(not during induction/while tapering is on)		

Item	Respons
Average dose of buprenorphine at the centre (for maintenance clients)	
Is the client involved in decision-making about the dose of buprenorphine that is provided to him?	
Are there any side effects reported by clients? If yes, what are the side effects? How are these managed?	
Are regular follow-ups are being conducted by the doctor?	
What is the average frequency of follow-ups by the doctor?	
What is the maximum duration for which any client has been dispensed medications without follow-up/renewal of prescription?	
Are regular follow-ups being conducted by the counsellor?	
Whether the follow-up proforma of doctor/counsellor exists and reflects an improvement in the client after initiation on OST? If yes, provide details.	
Is the dose of buprenorphine changed after stabilisation depending on the client's symptoms (e.g. increase in dose, if the client reports discomfort after initial stabilisation)	
Are dispensing-related protocols being followed by the nurse during the dispensing of buprenorphine? Specifically, the following issues:	
• Confirmation of client's ID before giving the dose • Confirmation of the client's dose and validity of prescription before giving the dose • Confirmation that the client is not intoxicated before giving the dose • Entry of tablets and signature of the client in the dispensing register • Crushing the tablets before administration • Sublingual administration under supervision • Making the client wait for 5–10 minutes after giving the dose • Confirming that the buprenorphine powder has dissolved after 5–10 minutes of waiting	---------- ---------- ---------- ---------- ---------- ---------- ----------
Are clients being counselled about regaining socio-occupational functioning after stabilisation on OST?	
Are the family members contacted and involved in the treatment process? If yes, how is this done?	

Item	Respons
Number of clients who usually come to the centre for receiving their daily dose of OST on a given day in the preceding month (from the daily dispensing register)	Minimum number on a day: _____ Maximum number on a day: _____
Number of clients who usually come to the centre for follow-up with the doctor and the counsellor on a given day (from thefollow-up register)	Minimum number on a day: _____ Maximum number on a day: _____
Are the clients referred for HIV testing after OST stabilisation? If yes, what is the proportion of clients who are referred for testing (calculated as number of clients who have been tested in last 6 months/total number of clients initiated on OST)?	
Are the HIV-positive OST clients referred for ART services? If yes, what is the proportion of clients who are referred for ART (calculated as number of clients who are registered with ART services/number of HIV-positive clients currently on OST)?	
Are OST clients referred to any other services? If yes, please provide details of the same.	
Are there any other services being provided by the centre for increasing the retention of clients on OST? If yes, please provide details.	
Has there been any instance of diversion by any OST client? If yes, please provide.details.	
Are there any requests for take-home doses? If yes, has any client been given a take-home dose? What are the protocols followed for take-home dispensing?	
Are the clients who drop out of OST followed up in the field by the TI staff?	
Impression of the mentor on the following OST-related outcome among OST clients (may be recorded as a yes or no, along with remarks,if any)	

OST-related outcome	Yes/No	Remarks
Decrease in injecting drug use among OST clients		
Decrease in other drug/alcohol use among OST clients		
Decrease in high-risk sexual behaviour among OST clients		
Improvement in physical health among OST clients		
Improvement in socio-occupational functioning among OST clients		

SECTION 5: RECORD KEEPING-RELATED DETAILS

(Information collected through interaction with the staff as well as from records)

Are the following records being maintained at the OST centre? (Yes/No)	
• New client register	Yes/No
• OST client register	Yes/No
• Follow-up client register	Yes/No
• Client file containing:	Yes/No
o Client intake form (counsellor)	Yes/No
o Client intake form (doctor)	Yes/No
o Consent form	Yes/No
o Side effects checklist	Yes/No
o Prescription slips	Yes/No
o Follow-up forms (clinical)	Yes/No
o Follow-up forms (psychosocial)	Yes/No
o Client dose sheet	Yes/No
o Transfer-out and transfer-back forms	Yes/No
o Additional notes (take-home dosages, provision of OST in prison, clients meeting other outcomes, etc., if applicable)	Yes/No
• Referral register	Yes/No
• Counselling register	Yes/No
• Group discussion register	Yes/No
• Referral register	Yes/No
• Other services register (for government hospital-runOST centres only)	Yes/No
• Daily dispensing register	Yes/No
• Daily stock register	Yes/No
• OST centre stock register	Yes/No
• Central stock register	Yes/No
• Copies of monthly report sent	Yes/No
• Minutes of the meetings between the OST centre and the TI	Yes/No
Is there a prescription by the doctor available before every dose change?	Yes/No
Is the consent form signed by the client?	Yes/No
Are there details of the progress of the client during serial follow-up?	Yes/No
Do the records between the client file, client dose sheet, dispensing register, follow-up register, etc. match?	Yes/No
Are there any issues in record maintenance? Please provide details.	

SECTION 6: FEEDBACK FROM OST CLIENTS AND THEIR FAMILIES

Feedback from OST clients
Feedback from families of OST clients:

SECTION 7: STOCK MAINTENANCE AND PROGRAMME MANAGEMENT

Item	Respons
Are the daily stock and central stock segregated?	Yes/No
Is the central stock being kept in hospital pharmacy/NGO head office?	Yes/No
Is there a clear protocol regarding who would be handling the medicines (such as collecting medicines from the central stocks, possession of keys for the OST centre stock, etc.)?	Yes/No
Is there overwriting in the entries made in the dispensing and stock registers?	Yes/No
Do the entries between the dispensing register, daily stock register and central stock register match with each other?	Yes/No
Does the doctor/nodal officer (PM or project director in the case of an NGO-OST centre) verify for the correctness of the entries made in the dispensing and stock registers? Are these verifications signed by the doctor/nodal officer?	Yes/No
Is the nurse able to manage different strengths of stock properly?	Yes/No
Has there been any instance of stock out?	Yes/No
Is back-up staff available to ensure that medicines are available for dispensing when the nurse is on leave?	Yes/No
Please write below any issue related to stock maintenance.	Yes/No

Item	Respons
How frequently does the nodal officer (project director in the case of an NGO-OST centre) visit the OST centre to oversee the functioning of the OST centre?	
Is the nodal officer (project director in the case of an NGO-OST centre) involved in the OST centre functioning?	
Is there regular meeting held between the OST centre staff and the TI staff to discuss operational issues?(applicable only to government hospital-run OST centres)	
Are monthly reports regularly sent by the OST centre? Are the reports accurate, on time and in the prescribed format?	
Are the problems encountered in the OST centre functioning promptly addressed by the nodal officer/doctor in-charge (PM or project director in the case of an NGO-OST centre)?	
Does the hospital provide ancillary support to the OST centre in terms of back-up staff, class IV workers, guards, etc.?(applicable only to government hospital-run OST centres)	

SECTION 8: GAPS IDENTIFIED AND ADDRESSED DURING THE VISIT

Gaps identified and addressed during the visit:

SECTION 9: IMPRESSION ON THE QUALITY OF THE OST CENTRE

S.No.	Item	Scores			Scores obtained	Remark
		3	2	1		
1.	OST uptake*	More than 40% of registered clients by TI(s) have ever been started on OST	20-40% of registered clients by TI(s) have ever been ever on OST	<20% of registered clients by TI(s) have ever been ever on OST		
2.	Recruitment and training of staff	All of the staff is recruited and trained as per prescribed norms	Staff is recruited and trained but not as per prescribed norms/Some of the staff is not recruited or trained	Few/none of the staff is recruited/trained; doctor is not available/trained		

S.No.	Item	Scores			Scores obtained	Remark
		3	2	1		
3.	Knowledge and confidence of staff on OST-related issues	Staff is knowledgeable and confident on most of the issues related to OST	Staff is knowledgeable and confident on some of the issues related to OST	Staff is not knowledgeable and confident on most of the issues related to OST		
4.	Role clarity	Staff is clear on most roles entrusted to them	Staff is clear on some roles entrusted to them	Staff is not clear on most roles entrusted to them		
5.	Initial assessment of clients before OST initiation	Both doctor and counsellor conductassessment before initiating a client on OST in most of the instances	Only doctor/ counsellor conducts assessment before initiating a client on OST in most of the instances	Baseline assessment before initiating a client on OST not done in many instances		
6.	Stabilisation dose of buprenorphine	Most clients are stabilised on optimal doses of buprenorphine (>8 mg/day)	Most clients are stabilised on suboptimal doses of buprenorphine (6–8 mg/day)	Most clients are stabilised on low doses of buprenorphine <6 mg/day)		
7.	Follow-up of OST clients	Most clients are regularly followed up by both doctors and counsellor as per the guidelines	Some clients are regularly followed up by both doctors and counsellor	Most clients are not regularly followed up by both doctors and counsellor		
8.	Changes in dose of buprenorphine	Only the doctor changes the dose of buprenorphine for all the clients	-	Changes in the dose of buprenorphine are made by someone other than the doctor (even if occasionally)		
9.	Duration of maintenance phase of treatment *	Most clients continue maintenance treatment for more than 12 months	Buprenorphine is tapered between 9 and 12 months for many of the clients	Buprenorphine is tapered between 9 and 12 months of treatment for a majority of the clients, and even before 9 months for some clients		
10.	Follow-up of LFU/irregular clients in the field	Most LFU/irregular clients are followed up by the TI	Some LFU/irregular clients are followed up by the TI	Few/None of the LFU/irregular clients are followed up by the TI		
11.	Dispensing-related protocols	The nurse follows all the protocols for most clients	The nurse follows a part of the protocol for most of the clients/Protocol not followed for some clients	The nurse does not follow any protocols for dispensing/Other staff dispenses buprenorphine frequently		

S.No.		Scores			Scores obtained	Remark
		3	2	1		
12.	Record maintenance	Most of the records are well maintained	Some of the records are well maintained	Few/None of the records are well maintained		
13.	Stock management	Most stock-related issues are well managed	Some stock-related issues are well managed	None/Few stock-related issues are well managed		
14.	Satisfaction of clients and family members	Most of the clients and their families are satisfied with the OST-related services	Some of the clients and their families are satisfied with the OST-related services	Few/None of the clients and their families are satisfied with the OST-related services		
15.	Client retention (from the latest monthly report)*	More than 60% clients are retained	40–60% clients are retained	Less than 40% clients are retained		
16.	Proportion of very regular clients (from the latest monthly report)*	More than 70% are very regular	50–70% are very regular	Less than 50% are very regular		
OVERALL SCORE						
QUALITY GRADING						

Notes: The mentor may rate the above aspects of OST centre functioning on a scale of 1–3: 1 = poor quality, 2 = average quality, 3 = good quality.
**Items 1, 9, 15 and 16 are applicable only to those centres which are functional for more than 6 months.*

F. OST quality assurance visit report – Proforma

- Name of the OST mentor: _____
- Date of visit: _____
- Name and address of the OST centre visited:

_____

_____

_____

OBSERVATIONS/FINDINGS AND SPECIFIC RECOMMENDATIONS THEREOF ON THE FOLLOWING AREAS OF OST IMPLEMENTATION

1.Recruitment of clients into OST
2.Staff knowledge and discharge of responsibilities by staff
3.Staff attitude towards OST clients
4.Implementation of OST, including initiation, maintenance and tapering of OST
5.Psychosocial support provided to OST clients
6.Record maintenance
7.Stock management

8.Satisfaction of clients and their family members
9.Operational issues related to the management of the OST centre
10.Infrastructure-related issues
11.Coordination between the OST centre and TI, and referrallinkages
12.Grading of the quality of OST centre

ANY OTHER SPECIFIC INPUTS PROVIDED FOR IMPROVEMENT OF THE OST CENTRE FUNCTIONING BY THE SUPERVISOR

ISSUES FOR CONSIDERATION BY SACS/NACO

(Signature of the visiting mentor)

Annexure 1: List of common problems and possible solutions

Here, some common problems which may be encountered/voiced by the OST centre staff to the mentors/facilitators have been listed. For each of the problems, solutions which can be offered/explained by the mentors have also been suggested.

Problem:'IDUs do not agree to initiate OST'

- Possible solution: It must be remembered that OST is a treatment for opioid dependence. An individual can be offered this treatment and can be motivated to take this treatment. However, in order to succeed, the treatment must be purely voluntary in nature. If it is found that a large proportion of potential clients refuse to accept this treatment, the following strategies can be adopted:
  - o Motivation/Enhancement
  - o Using peers as rolemodels who are on OST (if they are themselves seen as doing well on treatment and benefiting from OST)
  - o Using outreach workers (ORWs) to contact the families of client so that the family members can also be brought into the picture for enhancing motivation. (This step should be advised, however, only if the client explicitly agrees to it and it is logistically feasible to meet the family.)
  - o Organising community events and hotspot-level group discussions to generate information and benefits of OST. Focus should also be on dispelling ofmyths/misconceptions associated with OST ('if I continue to take drugs on OST, I will die', 'OST can cause impotency', etc.). The doctor and the counsellor of every OST centre should make periodic field visitsand actively participate in such activities.
  - o Increasing attractiveness and accessibility of OST services by measures such as extended hours of dispensing and linking OST clients with nutrition, shelter, vocational training and rehabilitation services. For the latter, OST centres should establish linkages with schemes/agencies offering such services in the area.

Problem: 'IDUs continue to take drugs even while on OST'

- **Possible solution:** The most common reason of this is inadequate dose. It must be remembered that smaller doses of buprenorphine may be enough to counter the withdrawal symptoms, but in order to block the effects of other opioids, higher doses of buprenorphine are often required. Thus, dose adjustments, along with psychosocial interventions, may be employed as a strategy to address this.

  However, it must be remembered that factors other than inadequate dose may be responsible for continued drug use in many clients. Such factors may include strong peer group influence, cue-related cravings, familial or psychosocial distress, comorbid

psychiatric/medical conditions, etc. The doctor and the counsellor should undertake a detailed physical and psychosocial assessment in all cases where the client is continuing to inject himself/herselfdespite being prescribed reasonably good dose of buprenorphine.

It must also be enquired whether IDUs on OST were also dependent on other drugs, such as benzodiazepines and/or alcohol, besides opioids. If that is the case, OST with buprenorphine alone is not sufficient to take care of the dependence on other drugs. This may have to be separately and specifically treated.

Finally, it must be remembered that OST is being offered in the context of 'harm reduction'. Thus, even if OST succeeds in reducing the amount/frequency of illicit opioids and stopping injections, it may be a worthwhile outcome.

Problem:'Should clients be allowed to avail needle-syringe exchange facility from the TI, even if they are on OST?'

- **Possible solution:** This situation is related to the situation described above. While it is not an absolute contraindicationto allow simultaneous dispensing of OST and needles and syringes, it does indicate that the current dose of OST is not able to help the client fully stop injecting drugs. Additionally, although the OST dose may be enough to address opioid needs of the client, if the client needs other categories of drugs (such as benzodiazepines), they may have to be additionally prescribed (in the oral form) and dispensed.

  The dangers of mixing excessive amounts of brain depressants and the consequent risk of overdose must be clearly explained to such clients. In other words, such a situation calls for additional work by the staff of the OST centre and TI, but being on OST should not be a criterion to deny provision of sterile needles and syringes. Such clients should also continue to receive other TI services such asbehaviour change communication (BCC) on safe injecting, abscess prevention and management, etc.

Problem: Some IDUs ask whetherthey may be 'allowed to try the medication (buprenorphine) once, asonly afterthey experience the effects, will they be able to decide whether or not to initiate OST.'

- **Possible solution:** While it is likely that many IDUs may be curious to know the effects of buprenorphine, the strategy to take buprenorphine on a trial basis should be avoided. The specific messages that can be given in such situations may be:

'It will not be possible to judge the effect of the medication in terms of reduction in craving, amelioration of withdrawal symptoms, blockade of effect of externally administered opioids after a single dose of buprenorphine. You can judge whether the medicine is suitable for you only after taking it for a few weeks at least.'

'Even after you start this treatment, it will not be forced upon you. Anyone on OST may choose not to take the medicine and discontinue treatment as and when they choose. Such a decision would not affect the availability of treatment at a later stage should you wish to restart it.'

'If you are really curious to know the effects of medicine, you may talk to other patients who are on OST. They will be able to describe you that this medicine works almost like the injections you are taking, controls the withdrawals and does not let the craving get the better of you.'

Problem:'IDUs are not willing for wait for 2hours on the first day (to observe the effects of the first dose)'

- **Possible solution:** It must be firmly explained to the clients that since they are willing to take a treatment which is likely to continue for longterm, it is very important that they invest this much time (2 hours on the first day). This duration will allow them to report any untoward effect of the first dose of the medication. It will also allow the doctor to increase the dose in the case the first dose was not effective in controlling the withdrawals.

  Such concerns occur during the initiation of the OST programme in a given centre. It must be explained to the OST staff that most clients would be willing to wait for 2 hours on the first day; experience thus far in all the other OST centres shows that it has been possible to initiate clients on OST toobserve the proper protocol laid down.

Problem:'IDUs often ask for take-home medications with the excuse that they are going out of town for 2or 3days.'

- Possible solution: The OST programme is a daily supervised treatment programme; take-home medications are allowed only in special circumstances. In such situations, like the one mentioned above, if the client is travelling to a city where OST services exist, he may be asked to take medicines from that city's OST clinic (e.g. a client from Batala, travelling to Amritsar for 3 days). In the case this does not appear to be possible, the client may be given prescription for a shortterm of buprenorphine 2 mg + naloxone 0.5 mg combination tablets (if

available in the market). The dose should be approximately similar to the dose the client is currently being maintained upon.

Problem: 'Some clients often come very late – almost at the clinic's closing time.'

- **Possible solution:** The timings of the clinic should be decided, prominently displayed and then adhered to. In general, it is always advisable to have timings for dispensing to be shorter than timings for clinic opening. Similarly, timings for clinical services, for new clients, may be limited to only a few hours. For instance:

  - Clinic time: 8.00 AM to 4.00 PM
  - New patient registration time: 8.00 AM to 12:30 PM
  - Dispensing time: 8:30 AM to 3:30 PM

  This is important because, new patients, if registered after 12:30 PM, would require about an hour for evaluation, consent and dispensing of the first dose. Consequently, there will be little time left for their observation period of about 2 hours and any subsequent dosing if required. Similarly, in the morning and in the evening, the nursing staff and data manager may require about half an hour for stock and record maintenance purpose.

Problem: 'How often should a patient followup with the doctor? Is this a pre-defined frequency or should it be need based?'

- Possible solution: Each client should follow-up with the doctor once every week for the first month, then fortnightly for 2 months and every month after the first 3 months. Besides this, additional follow-ups can be need based, especially for clients who are coming irregularly or have difficulty maintaining abstinence from injecting while on treatment.

Problem: 'Can the staff nurse or counsellor change the dose of OST medicine in the absence of the doctor?'

- **Possible solution:** It is very important that the doctor aloneshould change the dose of OST medicine. This should not be done by any other staff. In case the doctor is absent on a given day, and the other staff is not able to contact the doctor telephonically, the dose change should be deferred to the next day when the doctor is available at the centre.

Problem: 'Can the counsellor dispense OST medicine in the absence of the nurse?'

- **Possible solution:** Here too, the dispensing of the medicine should be done by the nurse only. In case the staff nurse is not available on a given day, services of the back-up nurse or the TI nurse who has been trained on OST should be utilised.

Problem: 'Can non-IDUs be given OST in NACO-funded OST centres?'

- **Possible solution:** OST is not only a harm reduction measure, but also a long-term treatment strategy for opioid dependence. If a person fulfils the criteria of opioid dependence syndrome and is using opioids through the non-injecting route for a long period of time (such as chasing heroin or using cough syrups/dextropropoxyphene capsules orally), he/she can also be given OST. However, the current strategy of NACO prioritises IDUs and hence OST is not available for non-IDUs under the NACO scheme presently.

ANNEXURE 2: Steps for Planning and Managing QA Visits

Suggested steps for RTTCs for planning and managing QA visits to OST centres under project Hifazat

Step			
1.	Prepare a quarterly calendar for QA visits	RTTCs	• Each RTTC will prepare a calendar for field visits to OST centres located in their catchment area on a quarterly basis. • The calendar to be prepared on the format developed by the National Technical Training Centre(NTTC) and should include a list of OST centres to be visited during the quarter, the name of the OST mentor who will visit the centre and tentative dates of the visit. • The calendar will be made such that each functioning OST centre is visited at least once in 6 months. • Provision to be made for visits to OST centres which may become functional during the period for which the calendar is being prepared. • The calendar should ensure efficient use of the pool of OST mentors available with each RTTC.
2.	Share the tentative calendar with OST mentors	RTTCs	• Each RTTC will share the tentative visit calendar with the pool of OST mentors identified for its catchment area. • OST mentors will review the calendar and provide inputs on the dates and centres chosen for their visits. • Based on the inputs received, RTTC staff will revise the tentative calendar.
3.	Finalise the calendar with feedback from SACS and TSU	RTTCs	• Each RTTC will share the revised quarterly calendar with each of the SACS and TSU/ NACO Northeast Regional Office(NERO) in itscatchment area for feedback. • The calendar will be finalised after incorporating inputs received from the SACS and TSU/NERO. • SACS/TSU/NERO officers to highlight OST centres in need of priority visits in their respective states. • SACS/TSU officers should be requested to review dates keeping their availability to accompany the mentor in view. • SACS officers to also highlight if any of the OST centres have been omitted from the calendar and the number of OST centres likely to become functional in the state during the quarter.
4.	Share the finalised calendar with the pool of mentors and the SACS/TSU	RTTCs	• Each RTTC will share the finalised visit calendar with the pool of OST mentors and the SACS/TSU/NERO. • Any final inputs from OST mentors may be entertained at this stage. No changes in OST centre allocation should ordinarily be made to the calendar after this.
5.	Monthly tracking of QA visits	RTTCs	• The responsibility of ensuring completion of the QA visits as per the quarterly plan will lie with the concerned RTTC. • Each RTTC will maintain regular communication with the pool of mentors and monitor the progress of QA visits to OST centres in its catchment area on a monthly basis. • Any deviation from the monthly plan or delay in conducting the visit should be brought to the notice of the concerned mentor.

Step			
6.	Submission of reports		• After each visit, RTTCs will ensure that the mentor submits the filled QA tool and report within 1 week of the visit. • Each RTTC shall review the tool and report to ensure that they are complete in all respects. • RTTCs will submit the finalised reports (not the tool) to the concerned SACS and TSU/NERO within 2 weeks of the field visit. • RTTCs will submit all filled tools and visit reports to the NTTC on a monthly basis.
7.	Reimbursement of expenses	RTTCs	• The expenditure incurred by the mentors in carrying out QA visits shall be reimbursed as per norms established for this activity under project Hifazat. • The reimbursement should be done on receipt of original bills, vouchers, tickets, etc., and the filled tool and report for the QA visit. • Any exceptions to the established norms of the grant can only be made with prior permission of the Project Management Unit (PMU). The concerned RTTC should write to the PMU and seek specific exemption in such instances.
8.	Quarterly review and feedback	NTTC	• The NTTC will track the progress of the activity on a quarterly basis and provide feedback in the case of delays. • The NTTC will also review selected reports received from other RTTCs and provide feedback as required. • Further orientation/training of the identified mentors will be undertaken during visits of NDDTC faculty to other RTTCs.

ANNEXURE 3:Steps in planning and conducting a QA visit to an OST centre

Step 1: Each mentor should review the finalised quarterly calendar prepared by the RTTC and identify OST centres to be visited by him/her during the quarter and the tentative schedule for the same.

Step 2: At least 10days before the visit, the mentor should write to the JD/DD/AD-TI and TL-TSU of the concerned state, informing them about the upcoming visit and requesting them to accompany during the visit.

Step 3: The mentor should finalise the dates of the visit in consultation with SACS/TSU officers. Once the dates have been finalised, he/she should request the SACS/TSU officers to inform the concerned centre. The TI/TSU officers should also be briefed about the prerequisites for such a visit and requested to ensure cooperation from and availability of entire staff during the visit.

Step 4: The OST mentors will be responsible for making arrangements for their travel, boarding and lodging (if needed). They may request SACS/TSU officers for assistance in the same.

Step 5: The mentor should conduct the visit to the OST centres. If required, he/she should make a visit to the linked IDU-TI. The mentor should try and interact extensively with SACS/TSU officers and concerned PO during the visit.

Step 6: The mentor should prepare the report of the visit (filled tool and reporting format) and submit it to the concerned RTTC preferably within 1 week of the visit (maximum 10 days). If any clarifications/revisions are sought by the RTTC, he/she should revise the report accordingly and re-submit within 3–4 days.

Step 7: The mentor should submit bills, vouchers, tickets, etc. in original to the RTTC for reimbursement of the expenditure and payment of the honorarium. The RTTC shall issue the cheque only after receipt of the final report and all requisite documents pertaining to the expenses incurred.

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