Rolling out of Opioid Substitution Treatment (OST) in Tihar Prisons, India

Scientific Report
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A collaborative project of UNODC- ROSA, AIIMS & Tihar Prisons
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Supported and Implemented by: UNODC- ROSA under Project RAS H/71

Technical Support: National Drug Dependence Treatment Centre (NDDTC), Ghaziabad
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Implemented in Tihar Prisons, Delhi, India

The study was possible thanks to the support from Swedish International Development Agency- SIDA
Opiate dependence is a complex chronic relapsing disorder and a single episode of treatment seldom leads to prolonged abstinence from drugs. Opioid Substitution treatment based in an agonist drug like methadone and buprenorphine has established itself as a widely accepted harm reduction and treatment measure for opioid dependent individuals in the community in many countries (Council of Europe, 2001). It can decrease the high cost of opioid dependence to individuals, their families and society at large by reducing heroin use, associated deaths, HIV risk behaviours and criminal activity.

This pilot study was done to test the feasibility and effectiveness of buprenorphine as medication for long term treatment for opioid dependence in Tihar prisons, India. This study was also done to develop a manual/protocol of guidelines for implementing OST in prisons settings. A total of 220 opioid dependent inmates were recruited for the study from November, 2008 through March, 2012. Assessments were done at baseline and at every 3 months thereafter after initiating treatment with buprenorphine.

A major proportion (94.3%) of the dependent inmates was repeat offenders. For most patients (95.3%), heroin was the primary drug of abuse. 50.3% were currently (1 month prior to imprisonment) injection drug users. Among the injectable users sharing of syringe/needle was reported by 70% and paraphrenalia by 49% in their drug using careers.

After starting treatment in form of OST, there was a concurrent decrease in high risk behaviors. No other illicit drug use was reported at follow up. This was corroborated by the results of urine screening suggestive of minimal or no drug use at follow up during imprisonment. A statistically significant reduction was found in severity of dependence, craving for drugs and withdrawl symptoms at follow up. Recognition of co-morbid health problems and appropriate treatment of the same was provided to the prisoners on OST. In qualitative assessments, most prisoners expressed satisfaction with treatment and reported that this was their first ray of hope that treatment is possible.

In keeping with international literature, the feasibility and effectiveness of OST in prison settings was demonstrated through this pilot project. Additionally, a standard operating guideline was developed for implementation of OST in prison settings. An upscale of Opioid substitution treatment in prison both, as a drug treatment and harm reduction strategy, is advisable subject to policies that exist in respective member countries in the region. I am confident that the evidence reported from the report shall motivate more prison administrations to allow for and introduce opioid substitution services.

Cristina Albertin
Regional Representative
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This pilot study was done to test the feasibility and effectiveness of buprenorphine as medication for long term treatment for opioid dependence in Tihar prisons, India. This study was also done to develop a manual/protocol of guidelines for implementing Opioid Substitution Treatment (OST) in prisons settings. A total of 220 opioid dependent inmates were recruited for the study between November 2008 to March 2012. After initiating buprenorphine treatment on the subjects (selected prison inmates for the study), assessments were done at baseline and at every three months thereafter.

For the purpose of carrying out this intervention, opioid dependent inmates fulfilling the eligibility criteria of the study were lodged in a separate ward to ensure coordinated delivery of both pharmacological and psychosocial interventions. The study sample mostly comprised pretrial remand prisoners (95.3%). A major proportion (94.3%) were repeat offenders. For most patients (95.3%), heroin was the primary drug of abuse. 50.3% were currently (1 month prior to imprisonment) Injecting Drug Users (IDUs). Among the IDUs, sharing of syringe/needle was reported by 70% and paraphernalia by 49% in their drug using careers. Treatment was initialed with buprenorphine and the mean dose (in mg) of buprenorphine was 4.3± 2.0, 4.6± 1.9, 4.3 ±1.4, 4.3 ±1.5 given on 3, 6, 9 & 12 months respectively. The median dose of buprenorphine at all follow up points was 4 mg, retention in the prison arm was excellent (98%) and compliance among those retained in prison was 100%. In the prison, during the course of the study, 10, 3, 1 prisoners reported injecting drug use at 3, 6, 9 months respectively. No reporting of injecting drug use was obtained at 12 months and thereafter. There was concurrent decrease in high risk behaviour. No other illicit drug use was reported at follow up. This was corroborated by results of urine screening suggestive of minimal or no drug use at follow up during imprisonment. A statistically significant reduction was found in severity of dependence, craving for drugs and withdrawal symptoms at follow up. Recognition of co-morbid health problems and appropriate treatment of the same was provided to the prisoners on OST. In qualitative assessments, most prisoners expressed satisfaction with the treatment and reported experiencing OST treatment as their first ray of hope in their lives.

Major challenges in implementation of this project was the unpredictable duration of stay of these inmates as overwhelming majority were pretrial remand prisoners. Although community linkages were secured at the start of the project, there was a high rate of attrition post release. Models and mechanisms to ensure post release follow up is necessary and requires urgent perusal. Frequent rotation of staff implementing the OST project in Tihar prisons necessitated frequent refresher trainings and also a review of internal coordinating mechanisms in the prison to ensure smooth delivery.

In keeping with international literature, the feasibility and effectiveness of OST in prison settings was demonstrated through this pilot project. Additionally, a standard operating guideline was developed for implementation of OST in prison settings. An upscale of Opioid Substitution Treatment in prisons, both as a drug treatment and harm reduction strategy is advisable, subject to local policy issues in the region.
Opiate dependence is a complex chronic relapsing disorder and single episode of treatment seldom leads to prolonged abstinence from drugs. Opioid Substitution Treatment on agonist drugs like methadone and buprenorphine has established itself as a widely accepted harm reduction and treatment measure for opioid dependent individuals in the community in many countries (Council of Europe, 2001). OST can reduce the serious repercussions of opioid dependence on individuals, their families and society at large by reducing heroin use, associated deaths, HIV risk behaviour and criminal activity.

There are strong links between opioid use and dependence, and criminal behavior. Studies from around the world reveal that many prisoners have a history of problematic drug use and that drug use, including injecting drug use, occurs in prisons in a large scale (WHO, 2007). Prisoners are also one of the four key populations which have a higher prevalence of HIV infection than the general population (Hellard & Aitken, 2004; UNAIDS, 2006). These drug dependent prisoners may then go on to share drug injecting equipment and have unprotected sex, both inside prison and back in the community (Estebanez et al., 2002; UNAIDS, 2006), thus posing a grave threat to public health. On release, opioid dependent prisoners are at high risk of relapse and overdose (UNAIDS/WHO/UNODC, 2004) and rates of reoffending amongst this group of prisoners are extremely high (Hough, 2002). To address these problems, pure criminal justice interventions, without associated opioid dependence treatment, have been found to be inadequate and have very limited impact on drug-using behavior and re-offending among individuals with drug dependence. (UNAIDS/WHO/UNODC, 2004).

Hence, providing both drug dependence treatment and harm reduction programmes in prisons is therefore essential (Stöver et al. 2007). Consequently, an increasing number of prison systems are offering substitution treatment with methadone and buprenorphine to opioid dependent prison inmates, worldwide.

In recent years, evaluation of prison substitution treatment programs have provided clear evidence of their benefits. Evidence suggests that OST is feasible in a wide range of prison settings. The benefits of opioid agonist maintenance in prisons include less injecting drug use while in prison, increase in uptake of treatment on leaving prison, and reduction of rates of return to prison (WHO, 2009). The risk of transmission of HIV and other blood-borne viruses among prisoners is also likely to be decreased. OST has shown to have a positive effect on institutional behaviour by reducing drug-seeking behaviour and improving prison safety. While prison administrations have often initially raised concerns about security, violent behaviour and diversion of methadone, these problems have not emerged or have been addressed successfully where OST programmes have been implemented (WHO, 2007). OST can also increase attendance of general health care services, which would be desirable especially with respect to the often diverse physical and psychological health problems common amongst chronic drug users (EMCDDA, 2003).

Drug-free treatment approaches continue to dominate interventions in prisons in most countries (Zurhold, Stöver, Haasen, 2004). Despite being widely accepted as an effective intervention or opioid dependence elsewhere, OST remains controversial in many prison systems. Prison administrators have often not been
receptive to providing OST, due to philosophical opposition to this type of treatment and concerns about whether the provision of such therapy will lead to diversion of medication, violence, and/or security breaches (Magura et al., 1993).

Hence, there still prevails a huge gap between prisoners requiring substitution maintenance treatment and those receiving it (Stöver, Casselman & Hennebel, 2006). This gap denotes not only a shortcoming of treatment options and harm reduction chances for the individual prisoner patient but also a threat to public health. This pilot study attempts to address this gap in South Asia by testing the feasibility and effectiveness of Opioid Substitution Treatment (OST) with buprenorphine in prison settings in India. Despite extensive experience with methadone worldwide, buprenorphine has been used here because at the time of implementation, only buprenorphine had approval as a maintenance or substitution treatment in India. This pilot study is funded by the UNODC, ROSA’s project RAS/H71 titled “Prevention of Spread of HIV amongst Vulnerable Groups in South Asia- ‘Advocating for and Provision of Oral Substitution Treatment in Prisons of South Asia’.”
This pilot study was conducted with the following objectives:

1. To initiate UNODC ROSA’s first ever Opioid Substitution Treatment (OST) among opioid dependent prisoners as a HIV prevention measure in Tihar prisons, India.

2. To develop a manual/ protocol of guidelines for implementing OST in prisons settings.
3.1 Study intervention site

Delhi Prisons comprise of nine Central Prisons at Tihar Jail Complex and one District Prison at Rohini Complex. The study intervention site was the de-addiction centre located in Jail no.3 at Tihar Jail complex of Delhi Prisons. It is normal practice that all prisoners reporting drug abuse are admitted to the de-addiction centre in Jail no. 3 for detoxification before discharge to their respective prisons. Opioid dependent prisoners were identified and screened according to inclusion and exclusion criteria in de-addiction centre in Jail no. 3 and eligible prisoners selected for the study were lodged in a separate ward earmarked for OST in this centre.

3.2 Training

Prior to conducting the pilot study, selected categories of staff of Tihar prisons (identified by prison authorities) were trained for delivery of Opioid Substitution Treatment with buprenorphine by technical experts from AIIMS. These included:

- Health staff (doctors and nurses)
- Counselors to deliver psychosocial interventions (from NGOs working in Tihar prisons)
- Personnel from the prison administration identified by the prison authorities. These included senior prison managers as well, like Superintendent, Jail No.3.

A. Sensitization training

UNODC- ROSA organized a two-day sensitization workshop and a two-day training for the rollout of OST in Tihar prisons. The sensitization workshop had representation at the highest level, with the Joint Secretary from Ministry of Social Justice and Empowerment (MSJ&E); Chief, National Drug Dependence Tihar prisons. Sensitization training was provided to the staff of Tihar prisons (mentioned above), who had to implement the OST intervention in Tihar prisons. Key issues covered in the training programme were:

- Treatment options for drug dependence treatment in the prison
- Overview of substitution therapy
- Minimum standards of practice and best practices in delivery of OST
- Safeguards in OST: prevention and minimization of diversion
- Issues related to implementing OST in the prison settings
- Participative group sessions to enable and encourage participants clarify doubts and misconceptions regarding OST.
B. Training on Oral Substitution Treatment (OST)

The workshop focused on conceptual clarity of OST for opioid dependence and skill building exercise of the personnel involved in implementing OST in Tihar prisons. This training covered both theoretical and practical aspects as outlined below:

(i) Theoretical Aspects

- Role definition—doctors, nurses, prison managers and NGO staff were apprised of various activities to be carried out under the project and their roles were defined (see Appendix-1)
- Detailed pharmacology of buprenorphine and its use as a maintenance agent
- Psychosocial interventions
- Dispensing related aspects to be clarified both to doctors and nurses.
- Safeguards in OST: management of overdose and clarifying issues relating to diversion
- Records keeping which included maintenance of stock as well as clinical records
- Brainstorming on issues relating to implementation of OST in a particular prison. These included identification of space, separate wards, assigning staff for the project etc.

(ii) Practical aspects: Onsite sensitization at AIIMS community centre

Onsite sensitization of the participants was conducted by making them interact with patients already receiving OST in community clinic Trilokpuri, AIIMS so that the participants could get a first hand feel of the benefits of OST and clarification of their doubts regarding various treatment processes. Actual role play/demonstrations were carried out for psychosocial interventions.

Onsite suitable training at Tihar prisons on Opioid Substitution (buprenorphine) for core staff (doctors, nurses and counselors), as and when required, was carried out. Additionally, doctors were provided training at AIIMS in case of transfer of existing doctors working in the project.

Refresher cum sensitization trainings: Periodic retraining of both administrative as well as health staff had to be done due to frequent rotation/transfer. Periodic rotation of staff in Tihar is a norm and presented itself as an inherent challenge in implementation of the project.

C. Training of lab personnel

The testing of biological specimens for the presence of drugs is the most objective means of determining drug exposure and for validating self-reported drug use. This helps to confirm the clinical history of drug intake, plan intervention, monitor compliance following treatment and contribute to the clarification of the medico-legal problems.

Training of three laboratory personnel and physicians from Tihar jail was carried out at the National Drug Dependence Treatment Centre, Ghaziabad, AIIMS in the month of October 2008. Following aspects were covered in their training as under:

- Introduction to drugs of abuse
• Pharmacology of drugs of abuse
• Pertinent clinical information required for drug abuse testing
• Types of body fluid
• Sample handling (sample collection, sample storage, transportation and sample preparation)
• Analytical procedures
• Practical demonstration & training on cassette test for testing drugs of abuse in urine.
• Interpretation of results and factors affecting interpretation of results
• Precautions and quality control.

During their training, hands on training on cassette test were provided. Each individual was also asked to carry out cassette test on urine samples of opiate dependent patients under supervision of the responsible technical consultant.

3.3 Study design

The study was based on a pre-post test design where identified and eligible opioid dependent inmates from Tihar prisons were offered pharmacotherapy with buprenorphine and psychosocial intervention. Assessments were conducted at baseline, 3, 6, 9 and 12 months by trained staff of Tihar prisons. Institutional ethic clearance was taken by the ethics committee of the All India Institute of Medical Sciences. Signed voluntary informed consent for treatment was obtained before initiating the intervention.

(i) Sample recruitment

At the initial stage of the project, it was decided that 50 subjects with opioid dependence and fulfilling inclusion and exclusion criteria (Box 1 & 2) would be identified and recruited from Tihar prisons complex by social workers from NGOs working in Tihar jail and by identified doctors at Tihar prisons, Delhi. However with extension of the project, the funding agency decided to continue the process of further recruitment and a total of 220 subjects were recruited between November 2008 to March 2012.

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**Box-1**

**Inclusion criteria**

a. Age more than 18 years.
b. Likely to stay in prison for one year.
c. Inmates meeting ICD-10 [International Classification of Diseases-10] diagnosis for opioid dependence (as per self report) at the time of incarceration with history of injecting drug use (ever use) and current users (last one month). Preference given to those Injecting Drug Users (IDUs) who are known to be HIV/ hepatitis B/ hepatitis C positive.
d. History of opioid dependence for a period of 5 years or longer.
e. Inmates who are from East Delhi (where it would be easier to provide pos release care as both Government Organisations and NGOs providing buprenorphine are located in these areas only).
f. Persons willing to participate voluntarily and provide informed consent for the project.
Exclusion criteria

a. Patients with serious medical conditions like acute respiratory failure, acute hepatic disease, delirium tremens, current dependence on alcohol
b. Female Patients who are pregnant or breast-feeding
c. Known hypersensitivity to buprenorphine
d. Presence of major psychiatric illness or physical illness due to which patient is unable to cooperate for interview.

This study was performed on newly received opioid dependent prisoners (on entry into prison). For identification of criteria like inmates staying for a longer duration and inmates who were from East Delhi, helpm was taken from the prison authorities.

Based on experiences and learning from the project, the inclusion criteria were modified. As majority of our patients were pretrial remands, criteria ‘b’ of inclusion criteria was difficult to operationalize and hence was omitted from the list. Criteria ‘c’ was also modified to include non injecting drug users or those who were taking smack by chasing route to extend the benefit of treatment to this important group. This group is as vulnerable to the harms of continued drug use including repeat criminal offences, total disruption of social, occupational, physical and economic aspects of their life. Criteria ‘e’ was modified and inmates who were opioid dependent and were willing to follow up in one of the designated treatment centers post release were included in the study. Modification in the inclusion criteria in the form of recruitment of non injecting opioid drug users was made in consultation with UNODC. Necessary approval for these modifications was taken from the AIIMS Ethics Committee. Hence the modified inclusion criteria of the project were:

Box-2
Revised inclusion criteria

a. Age more than 18 years.
b. Inmates meeting ICD-10 diagnosis for opioid dependence (as per self report) at the time of incarceration with or without history of injecting drug use (ever use) and current users(last one month). Preference given to those Injecting Drug Users (IDUs) who are known to be HIV/ hepatitis B/ hepatitis C positive.
c. History of opioid dependence for a period of 5 years or longer.
d. Inmates who are willing to follow up in designated post release follow up centers
e. Persons willing to participate voluntarily and provide informed consent for the project.

The exclusion criteria of the project remained the same.

(ii) Intervention

At the initiation of the project, it was decided that after an initial period of stabilization(around two weeks), where buprenorphine(sublingual, directly observed) will be dispensed daily, the selected subjects will be put on sublingual buprenorphine 2-24 mg/day on alternate days (as directly observed therapy)by identified doctors at Tihar prisons.

However, as the patients were uncomfortable with alternate dispensing and reported distressing withdrawal symptoms and craving, this schedule was revised and patients were then dispensed buprenorphine daily as directly observed therapy through the sublingual route of administration.
Lodging: All stakeholders and technical experts decided that prisoners on OST would be lodged in a special ward created within the drug de-addiction centre in Jail no.3 so that it would:

- Make it easier for prison administration to coordinate and deliver OST services from one single point
- Enable easy movement for daily dispensing of medication
- Enable the inmates on OST to easily access both the medical and psychosocial intervention
- Help minimize issues related to diversion of prescribed medication.

Time of dispensing: Buprenorphine was administered early in the morning (7a.m-9a.m) as directly observed therapy so that it does not interfere with other activities of the prisoner throughout the day like court dates, family visits, visit to other outpatient departments and other allotted work etc. Psychosocial interventions were carried out after 9 a.m.

Storage of medicines: There was an agreement that bulk stock of medication should be stored in the head office of the prison. A two-three days stock of medicine (including holidays) was maintained at the dispensing site with the designated doctor and nurse. This 2-3 days stock of medication was transferred from the head office to the prison by a designated official of the prison administration.

Psychosocial intervention were administered as per predetermined guidelines in four group sessions and four individual sessions (by identified and trained NGOs operating at Tihar prisons). This psychosocial intervention was mainly focused on clarifying goals of maintenance treatment, improving treatment compliance, reducing the rate of dropout from treatment, relapse prevention, improving coping and problem solving skills and addressing high risk behavior.

However with the progress of the project, it was decided that a broader scope of psychosocial interventions is needed to address treatment process and recovery in greater detail, enhancing motivation, self efficacy and optimism, planning lifestyle changes and rehabilitation

Methods to prevent diversion: Diversion was noted in the initial stages of the project. It was then decided that prisoners should be dosed separately or in small batches of 3. The tablets should be crushed before dispensing and the dispensing team should comprise officials from the prison administration. Diversion was not noted after these measures were put in place.

For prisoners on OST who were released from prison, community linkage to centres providing OST on buprenorphine post release was established with the following four centres:

1. National Drug Dependence Treatment Centre, Ghaziabad
2. Community clinic, Trilokpuri, AIIMS
3. Mobile clinic, Sundarnagari, AIIMS
4. De-addiction clinic, AIIMS

All these centers provided pharmacotherapy with buprenorphine and psychosocial intervention for the released prisoners.
(iii) Assessments

a. Quantitative

Assessments were done at baseline and at 3, 6, 9 and 12 months follow up. The baseline interview schedule covered basic demographic characteristics crime record, drug use history, high risk behavior, physical and psychological health prior to entry in the prison. At follow up, inmates were evaluated on drug use, severity of dependence, retention compliance, and craving, opioid withdrawal symptoms, any side effects with buprenorphine treatment, high risk behavior, health and psychological status and qualitative inputs.

**BOX-3 (Appendix -2)**

**Instruments and Tools**

1. Drug abuse monitoring system proforma which includes socio demographic profile (baseline)
2. Crime record (baseline)
3. Drug use questionnaire (baseline)
4. Drug use questionnaire (follow up)
5. Severity of dependence scale (sexual)
6. Follow up assessment form (psychological)
7. SOWS –Subjective Opioid Withdrawal Scale (for assessment of opioid Withdrawal)
8. OOWS – Objective Opioid Withdrawal Scale (for assessment of opioid Withdrawal)
9. Visual Analog Scale (for craving)
10. Medication information questionnaire
11. Side effect check list for buprenorphine
12. Assessment of high risk behavior (Injecting, sexual)
13. Assessment of health status (physical and psychological)

14. Process indicators

**Laboratory/biochemical parameters:** Urine screening was done by using cassette test for morphine at baseline, 3, 6, 9 and 12 months to validate self report and obtain information about concurrent drug use if any. Haemogram and Liver Function Test were the mandatory investigations. In addition, HIV status, hepatitis screens and other investigations as indicated (e.g. T.B) were also carried out at Tihar prisons to assess biochemical impact of OST on the subjects.

*Refer to Appendix 2 on instruments and tools used for quantitative assessments.*
b. Qualitative

Qualitative data was obtained through process indicators on implementation of oral substitution with buprenorphine by documenting the experience of staff and patients. This was done using qualitative methods such as In-depth Interviews. Focus Group Discussions were also held with all key stakeholders for qualitative inputs.

(iv) Monitoring

Technical experts from the AIIMS team made weekly site visits to hand hold the provision of OST and monitor the difficulties encountered and solve operational problems during the first 6 to 8 months of the project. Intensive mentoring inputs were required from the technical experts from AIIMS during this period. Regular meetings were held with the prison health staff, counselors and patients to solve implementation issues.

The following parameters were monitored:

1. Patients’ satisfaction with the treatment- adequacy of dose, addressing doubts/ misconceptions about OST, duration and goals of the treatment
2. Whether training conducted earlier was adequate
3. Difficulties in recruitment
4. Ensuring procedural coordination between health staff, counselors and prison administration
5. Medication- dispensing, safe-keeping and diversion
6. Psycho-social intervention- satisfaction of patients
7. Adequacy of record keeping
8. Management of prisoners with co-morbid medical disorders
9. Difficulties or challenges faced.

The period of weekly visits was followed by fortnightly visits that were made by the technical team for another 6 months and monthly visits thereafter. Further, telephonic contact was always available when needed, so as to maintain constant monitoring and support.

(v) Post release follow up

On release, all those prison inmates who had participated in the study were provided with referral details (referral slip) to the appropriate community centre indicating the date of commencement of opioid substitution therapy and current dose of buprenorphine.

To enhance post release outcome, a two day supply of medicines(OST) (buprenorphine-naloxone combination tablet) was given to allow the released prisoners ample backup time and medicines to locate their follow up centre for further dispensing of buprenorphine and also provide cover for holidays(for prisoners released on Fridays/Saturdays). This was done to prevent relapse to drug use immediately upon release. Released prisoners were also encouraged to follow up by telephonic contact and conduct field visits to their homes and follow up centers. Efforts to involve their families in treatment by meeting them on their visits to Tihar jail or field visits to their homes post release formed an integral part of the follow- up process.
3.4 Data Analysis

Data was manually checked by the experts from All India Institute of Medical Sciences, New Delhi. Coding of the questions was done, based on the responses before data entry was made in the computer. The data was scrutinized at an intensive level prior to analysis. Validity checks were applied and corrections were made accordingly. The information from qualitative data collected side by side during the survey was used to fill the missing data. Gaps were also filled using information from other related questions in the questionnaire itself. Data was then analysed using a software SPSS-11.0. Appropriate statistical tests were applied to find out the significance of the findings. Analysis of variance was also used to test the difference between the results at different point of time.
The study was conducted from November 2008 to March 2012 and the results have been reported for the aforesaid period. This section of the report presents observations and assessments obtained at different phases of the study which includes baseline, 3, 6, 9, 12 months and follow-up. Besides ‘quantitative assessment’, the results given below also present ‘qualitative assessment’ derived by the end of the study.

Box 3 below presents a quick glance at the sample size and study outline, followed by quantitative and qualitative assessments in detail:

The results are reported for the period 7.11.08 to 24.3.2012
Total no. of prisoners included in the study 220
Total no. of prisoners released 186
Total no. of prisoners whose assessments are complete 193
Median duration of stay of prisoners in the prison 83 days (minimum=2, maximum=715, s.d. =138)

| Total sample of prisoners assessed in the study at different follow-up time |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Month 0 3 6 9 12 15 18 21 24 27 30 |
| N 193 98 51 27 12 10 7 7 4 2 1 |

A. Quantitative assessment

A1 : Baseline(0 months)

Baseline study was performed on selected sample of newly received opioid dependent prisoners on their entry into the prison. Baseline information was obtained immediately after the recruitment of the selected sample of prisoners in the treatment program also called as 0 month of the treatment. Baseline information was collected for a total of 193 prisoners (i.e, n=193).

I. Socio - demographic parameters

The socio-demographic profile of the prisoners selected for the study, in terms of their age. Marital status, employment status and family profile can be understood from the figures given ahead:
a. Age-wise distribution:

As depicted through figure 1 above, maximum prisoners (41.5%) were in the age group of 26-35 yrs. and a substantial number were young (37%). The mean age of the sample was found to be 30.2 ± 8.9yrs.

b. Marital status:

Fig. 2 above presents the marital status of the sample selected for study. Most of the drug users were unmarried (55.4%) followed by the married (29.5%) ones. Around 11.4% of the prisoners were either divorced or separated from their spouses due to drug abuse.

c. Educational status:

Fig.3 above shows that maximum prisoners in the study were illiterate (47.7%), followed by those who were literate/educated up to only the middle level (44%). Only 8.3% had moved up to 10th/12th standard.
d. Distribution by employment status:

**Fig 4. Distribution of prisoners by employment status**

![Distribution of prisoners by employment status](image)

Majority of the drug users in this study were either presently unemployed or never employed (70%). Only a few (8.3%) could sustain full time employment and 9.3% were self employed, as can be understood from figure 4 above.

e. Family structure:

**Fig 5. Distribution of prisoners by family structure**

![Distribution of prisoners by family structure](image)

Most of the drug users belonged to either joint family (32.1%) or nuclear family (25.9%). Nearly 38% of drug users were either living alone or with friends. Figure 5 above represents the different categories of prisoners by their family structure.

II. Crime record of selected sample

a. Status of prison inmates:

**Fig 6. Status of Inmates included in the study**

![Status of Inmates included in the study](image)

Fig 6 shows that the study sample mostly comprised of prisoners who were pre-trial remandees or under trials (95%).
b. Previous arrest status:

![Fig 7. Distribution of prisoners by No. of previous arrest](image)

Fig. 7 above represents the distribution of selected sample by number of their previous arrests prior to the study. As many as 94.3% of prisoners in the study sample were repeat offenders. Nearly 30% of prisoners were arrested 6-10 times on previous occasions. Around 4.1% had been arrested more than 10 times before the current imprisonment.

c. Commitment of offence to support drug abuse:

![Fig 8. Commitment of offences by prisoners supporting their drug habits(%)](image)

Prison inmates selected for the study were enquired about their main reason for committing the offence. Figure 8 clearly shows that a significant majority of the prisoners (97%) admitted to the fact that the offences for which they had been arrested were actually done to support their expensive drug habit.

d. Frequency of arrests for drug related offence:

![Fig 9. Distribution of prisoners by No. of times apprehended for drug related offence](image)

Most of prisoners were not arrested under the drug control act in India (Narcotic Drug and Psychotropic Substances act, 1985) but rather for other crimes like theft, robbery etc. As can be understood from figure 9 above, drug related offence was not the prime reason for repeated imprisonment of a majority of prisoners.
III. Drug Use Parameters

Prison inmates selected for the study were assessed for their drug use parameters in terms of the most common or frequently used drug/drugs taken by a majority of the inmates and figures were reported on the status of drugs taken one month prior to imprisonment and expressed in percentage as given in table 1 and fig. nos. 10 to 13 below:

Table 1: Percentage of inmates by drug use

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Ever Use(%)</th>
<th>1 month prior to imprisonment(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heroin</td>
<td>96.9</td>
<td>95.3</td>
</tr>
<tr>
<td>Opium</td>
<td>55.5</td>
<td>16.1</td>
</tr>
<tr>
<td>Other opioids</td>
<td>79.2</td>
<td>64.8</td>
</tr>
<tr>
<td>Cannabinoids</td>
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<td>67.9</td>
</tr>
<tr>
<td>Sedatives/hypnotics</td>
<td>71.4</td>
<td>56.0</td>
</tr>
<tr>
<td>Alcohol</td>
<td>77.1</td>
<td>34.7</td>
</tr>
<tr>
<td>Volatile Solvents</td>
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<td>8.8</td>
</tr>
<tr>
<td>Tobacco</td>
<td>87.0</td>
<td>85.0</td>
</tr>
</tbody>
</table>

**Fig. 10 Drug use among the prisoners**

a. Fig. 10: A significant majority of the inmates (95.3%) reported heroin being the primary drug of abuse. This was followed by cannabinoids (67.9%) and other opioids (64.8%).

b. Fig. 11: Nearly half the prisoners recruited were using heroin by injectable route in the month prior to imprisonment. Mean number of people shared with was $2\pm4$ people.
c. Fig. 12: It was found that the mean age of initiation of primary drug is 18±6 yrs. A substantial proportion of inmates (35%) reported early onset of opioid use i.e. before 15 years of age.

d. Fig. 13: Around 44% of the total sample of prisoners in OST program were using the drugs from 10 to 20yrs. and the percentage of those prisoners using drugs for more than 20 yrs. was found to be 8.8%. The mean duration of regular use was observed to be 11±6yrs.

A2: Follow up results

a. Dispensing of dose

The patients were usually inducted on 2 mg of sublingual buprenorphine (s/l). Dose increments were made every three days till the withdrawal symptoms subsided. Adequate medication was given to reduce craving for drug use.

Fig. 14 Mean dose of Buprenorphine dispensed in last three months

Fig. 14 Shows minimum, maximum and mean dose at different time of assessments. The mean dose (in mg) of buprenorphine was 4.3±2.0, 4.6±1.9, 4.3±1.4, 4.3±1.5mg at 3, 6, 9, 12 months respectively. The median dose of buprenorphine at all follow up points was 4 mg.
The optimum dose of buprenorphine is considered that dose at which the patient discontinues or markedly diminishes use of other opioids and experiences no withdrawal symptoms, minimal or no side effects, and no uncontrollable cravings for drugs of abuse. As demonstrated by the graphs below, patients recorded a decrease in severity of dependence scale, craving, withdrawal symptoms and side effects on institution of buprenorphine therapy.

Retention in prison arm was excellent (98%). Compliance to buprenorphine on those retained for treatment in the prison was 100%. 2% (4 prisoners) dropped out of prison arm voluntarily and another 2% (4 prisoners) were discharged due to disciplinary reasons and 1% (2 prisoners) were discharged due to medical reasons.

b. Drug use

During the course of the study in the prison, 10, 3, 1 prisoners reported injecting drug use at 3, 6, 9 months respectively. No reporting of injecting drug use was obtained at 12 months and thereafter. No other illicit drug use was reported at follow up. This was objectively confirmed by urine for screening (also see section i).

c. Severity of Dependence Scale

The Severity of Dependence Scale (SDS) is a 5-item questionnaire that provides a score indicating the severity of dependence on opioids. Each of the five items is scored on a 4-point scale (0-3). The total score is obtained through the addition of the 5-item ratings. The higher the score, the higher the level of dependence.

![Fig. 15 Mean score of severity of dependence of the inmates over time](image)

As depicted through the graph in Fig. 15 above, a significant decrease (F=9.806, df=10, p<.001) in severity of dependence of drug use was reported by the inmates over time.

d. OOWS – Objective Opioid Withdrawal Scale (for assessment of opioid withdrawal)

The Objective Opiate Withdrawal Scale (OOWS) provides an objective measure (range 0-13) of the severity of opiate withdrawal symptoms. It contains 13 physically observable signs, rated present or absent, based on a timed period of observation of the patient by a rater.

![Fig. 16 Mean Objective opioid Withdrawal Scale score over time](image)

The graph in Fig. 16 above shows that a highly significant decrease (F=24.34, df=10, p<.001) in the mean OOWS score was observed over time among the inmates who were included in the OST program.
e. Subjective Opioid Withdrawal Scale (SOWS)

The Subjective Opiate Withdrawal Scale (SOWS) contains 16 symptoms whose intensity, the patient rates on a scale of 0 (‘not at all’) to 4 (‘extreme withdrawal’) (range 0 – 64).

![Fig. 17 Mean Subjective Opioid Withdrawal Scale score of prisoners](image)

Fig. 17 demonstrates that a highly significant decrease (F=196.32, df=10, p<.001) was observed over time in the mean subjective opioid withdrawal (SOWS) score of the prisoners under OST.

f. Visual Analog Scale (for Craving)

Prisoners on OST rated their craving on a 10 point scale (i.e, 0-10), where 0 represented minimum or no craving and 10 indicated maximum craving.

![Fig. 18 Mean Visual Analog Scale (VAS) score of prisoners over time](image)

Fig. 18: A highly significant decrease (F=110.55, df=10, p<.001) in the mean VAS score was observed among the prisoners over time.

g. Side effects of buprenorphine

![Fig. 19 Side-effects reported by prisoners(%)](image)

Fig. 19 clearly depicts that the most commonly reported side effects at 3 months were weakness by 16(16.8%), headache by 14(14.7%), drowsiness by 12(12.6%) prisoners, and light headedness by 10(10.5%) prisoners. These side effects were minimally reported at subsequent follow up.
h. Health and psychological status

Most inmates reported that they were satisfied with the fact that they were being screened for their medical problems and were being provided treatment. 5% of inmates reported that they had chronic medical problems at baseline while at follow up till 12 months, 8-17% of inmates had chronic medical problems. 6.7% of prisoners at baseline and 7 – 18.5% of prisoners till 12 months follow-up thought it was important for them to take treatment. Two prisoners received Anti Retroviral Therapy and 3 prisoners received treatment for Tuberculosis. There were 10 prisoners who received treatment for hepatitis B & C.

![Fig. 20](image)

Fig. 20 indicates the rating of psychological health status (anxiety, depression, emotions and feelings) by prison inmates. A significant decrease (F=2.389, df=10, p=0.01) was observed over time as far as psychological status is concerned.

i. Laboratory test

Urine screening of 220 patients who were on OST intervention was performed during the course of study. A total of 232 urine samples were screened at different point of time i.e, at baseline, 3, 6, 9 and 12 months. Test results showed that out of 232 urine samples, 212 (91.4%) samples were tested negative and 20 samples (8.6%) were tested positive for morphine by the Cassette test. Further test results showed that out of 232 urine samples, 95 (40.9%) urine samples were tested at baseline, 63 (27.2%) samples were tested at 3 months, 34 (14.6%) samples were tested at 6 months, 27 (12%) samples were tested at 9 months and rest of the samples (5.3%) were tested beyond 9 months.

Out of 40.9% baseline samples, only 11.76% samples were found to be morphine positive by Cassette test and majority of them were found to be negative. This is suggestive of the time gap (96hrs) between the last use of opioid and the recruitment into the study. It was also observed from records that the urine sent for screening and recruitment procedures used to take a week’s time.

On follow up at 3 months, 6 months, 9 months, none of them were tested positive. Only one sample (4.3%) was found to be positive at 12 months. Thus, a high proportion of patients were abstinent, suggestive of no illicit drug use during imprisonment. Thus, urine screening provides an objective evidence of the compliance to the prescribed medication.

j. Assessment of High Risk Behavior

Injecting risk behavior

It was reported by 2-4 prisoners that 2 inmates were injecting in their barracks at 3 months, 6 months and at 9 months assessment period. No further instances of injecting drug use was reported thereafter.
As observed in Fig. 21, at baseline, one fourth of the sample reported injecting more than 3 times a day and 22% injected 2-3 times a day. During the course of the study in the prison, a total of 10 prisoners reported injecting drug use at 3 months follow up at varying frequencies. This number decreased to three at 6 months and one at 9 months. No reporting of injecting drug use was obtained at 12 months and thereafter.

Fig. 22 provides the information on the number of times a subject had used a needle after someone else had used it. Before imprisonment, a total of 30% of the prisoners reported the use of already used needle and in the last month before imprisonment, 11.8% of the inmates reported 6-10 instances when they used a needle after someone else had used it. During imprisonment, 1-3.7% of subjects reported sharing at 3, 6, 9 months follow up. No reports of sharing were obtained at 12 months and thereafter.

As observed in Fig. 23, at baseline, 12.3 percent of the prisoners on OST reported that only one person had already used the needle before their use. There were 6(3.1%) prisoners who reported the sharing of needle by more than 10 people before their use of the same needle at baseline. Sharing with one person was reported at 6 and 9 months follow up and no such reports were obtained at subsequent follow ups.
As observed in Fig. 24 above, the sharing of needle/syringe for more than 10 times by others after their use was reported by 14(7.2%) prisoners and 22(11.3%) prisoners reported two times sharing of the needle after their use in the last month before imprisonment. At follow up, such an instance was reported one to two times by 3%, 8% and 3.7% prisoners at 3, 6, 9 months of follow respectively.

Fig. 25 provides the information that only 11.8% drug users ‘always clean’ and 12.3% ‘sometimes clean’ the needle/syringe before reusing them at baseline. However, at follow-up, amongst those prisoners who used injectables, most of them reported that they did not reuse the needle and by the end of the 12th month none of them reused the needle.

Amongst the prison inmates selected for the study, those who shared needles for injecting drug use, were enquired about the method of cleaning the needle for their use, it was found (as shown in Fig. 26), that at baseline, most of the prisoners who shared the needle, reported the cleaning of the needle/syringe with water (37.1%) and only 0.8% cleaned with bleach before using it. At follow up, where applicable, the prisoners either reported cleaning with water or did not clean.
Sexual risk behavior

**Fig. 27** No. of inmates known to have sex with other inmate in the barrack

![Bar chart showing the percentage of inmates known to have sex with other inmates in the barrack over time.](chart1)

Fig. 27 depicts that approximately 13 – 15% of inmates were reported to be involved in sexual activities at 3, 9 and 12 months. A larger number (35%) was reported to be involved in sexual activities at 6 months follow up. The reporting of sexual behavior among the prisoners decreased over time.

**Fig. 28** Percentage of prisoners by No. of sexual partners

![Bar chart showing the percentage of prisoners by the number of sexual partners at different follow-up times.](chart2)

Fig. 28 provides the information that at baseline, 23% of the prisoners had sex within last one month while only a small number of prisoners ranging from 4-7% reported having sex with other inmates at 3, 6 and 9 months of follow up. No sexual activity (with partners) was reported during subsequent follow ups.

**Fig. 29** Percentage of prisoners by kinds of their sexual activity

![Bar chart showing the percentage of prisoners by kinds of sexual activity at different follow-up times.](chart3)

Fig. 29 shows that at baseline, 13 (6.7%) persons reported having masturbation while 6, 3 and 3 persons reported this activity at 3, 6 and 9 months of follow up respectively. Anal sex was also reported by 2 prisoners at 3 months follow up.
As given in Fig. 30, it was observed that 14.5 percent of prisoners reported the use of condom before imprisonment. While in the prison during under OST program, only 8.2%, 10% and 11.1% reported using condoms at 3, 6 and 9 months respectively. In fact, almost all of them reported of ‘not having penetrative sex’ by 12th month follow up.

Fig. 31: 11 prisoners reported having anal sex at baseline and 3, 1, 1 prisoners reported anal sex at 3, 6 and 9 months follow up respectively. By the 12th month, none of them reported of having anal sex.

**Other skin penetration practices**

a. It was observed that at the recruitment time (baseline), 24 (13.6%) persons reported that they had come into contact with another person’s blood ‘once’. e.g., through fights, slash-ups, self-mutilation, accidents, blood-sports, occupational, pimples, blood nose, etc. This number decreased to 6, 4 and 3 at the 3, 6 and 9 month follow up respectively.

b. Prisoners who reported to be pierced once by someone were found to be 10, 5, 3, 3 at the baseline, 3, 6 and 9 month follow up respectively. No reporting of this activity at 12 months follow up was observed.

c. Fig. 32: It was observed that 15-18% of inmates reported the use of another inmate’s razor/blade at 3, 6 and 9 months. However, this was not reported at 12 months and thereafter.
d. Fig.33: In the prison, sharing a toothbrush occasionally seemed to be common at 3, 6, 9 and 12 months and decreased thereafter.

*e. Fig.34: It was observed that using another person’s personal hygiene equipment seemed to be common at 3,6,9 and 12 months follow up and decreased thereafter.*

k. **Post release follow up:**

High rates of attrition were noted in the post release follow up in the designated community centres. Patients on regular follow up ranged from 5-17 % at various follow up times.
B. Qualitative assessment results

Qualitative assessment was carried out on the outcome of process indicators built into the project as well as Focus Group Discussions carried out on all stakeholders. The results obtained are presented below-

(i). Benefit/ satisfaction with OST-

All stakeholders unanimously agreed about the benefits of OST. Most prisoners expressed satisfaction with treatment and expressed that this was their first ray of hope that they could ever leave drugs.

(ii). Changes noted in patients’ behavior by the staff-

- Marked improvement in personal hygiene
- They are calmer and also do not involve in gang activities or try to procure drugs inside the jail
- Are amenable to counseling
- Listen to what the staff members are saying
- Are more productive and do the work they are told to do

The staff reported that these benefits start becoming obvious in the first three months of treatment. Rapport between patients and prison health staff takes time to get established. As most of these prisoners were repeat offenders, the staff also took time to overcome their doubts/skepticism about their behavior. As benefits of OST started showing, the prisoners and staff gradually and increasingly became comfortable with each other.

(iii). Attitude of staff -

As the rapport between the staff members and prison inmates/patients improved and as the benefits of treatment started becoming obvious, there were fewer disciplinary problems amongst the prisoners. The patients perceived the staff attitude as supportive and encouraging.

(iv). Dosage–

Most prisoners reported that they were satisfied with the dosage that was being given to them and that they were involved by the doctors in the decision regarding the dosage of their medication. However as initially planned in the project, prisoners expressed their dissatisfaction with alternate day dispensing and reported withdrawal symptoms on the second day. Hence all patients were subsequently shifted to daily dispensing. Patients reported a decrease in craving and withdrawal symptoms and consequently reported a decrease in drug seeking behavior. Patients were satisfied with the dose of OST they were receiving though some of them reported mild withdrawals prior to the morning dose. Most patients felt that they would require the medication for at least 1-2 years to give up their dependence.

(v). Diversion-

Some prisoners from the OST program tried to sell medicines to prisoners who were not in the programme for monetary benefit, to help other addicts not in the program and satisfy their curiosity. Prisoners reported that crushing of tablets in powder really helped to control incidents of diversion. No diversion was reported at the staff level. .
(vi). Psychosocial intervention-

The patients expressed a need for more intensive psychosocial intervention both in the prison and post release. In addition to counseling related to OST and relapse prevention, they wanted skills training to be provided inside the prison. This would also help them to structure their time while in prison.

Most prisoners also expressed their desire for rehabilitation post release as they felt that going back into the same environment would aggravate their risk of relapse.

(vii). Post release follow up-

All stakeholders agreed that post release follow up is not satisfactory and urgent persual like tie up with some NGO is necessary to ascertain post release follow up mechanisms.
This pilot study had a pre-post test design with assessments at baseline (on entry into prison), and at every 3 months thereafter. A total of 220 subjects were recruited in the study from Nov2008 to March 2012. These assessments were done on standard instruments by trained personnel of Tihar prisons. Illicit drug use was measured by self report as well as objective measurement (urine cassette test for morphine).

The subjects recruited in the study comprised a high risk marginalized population vulnerable to the extensive harms of drug use. All subjects in the study were male, mostly unemployed (70%) and illiterate (48%). More than a third (38%) of drug users were either living alone or with friends. 95.3% of the subjects reported heroin as their primary drug of abuse. Most were also polydrug users and commonly reported the use of cannabinoids, sedative hypnotics, tobacco and alcohol along with heroin. Most of them were chronic users. Mean duration of regular use was found to be 11±6yrs. Nearly half the subjects recruited were using heroin by injecting route (50.3%) in the month prior to imprisonment. At baseline, one fourth of the sample reported injecting more than 3 times a day and 22% injected 2-3 times a day. Among the Injecting Drug Users sharing of syringe/needle was reported by 70% and paraphernalia by 49% in their drug using careers, suggesting that a high proportion had indulged in risky injection use practices.

An overwhelming majority of these subjects were pretrial remand prisoners (95.3%). While most of them were arrested for crimes like theft, robbery, violence; only a minority were arrested under law criminalizing drug possession, use and trafficking. Most admitted to committing crimes to support their drug use. Median duration of stay in prison was 83 days suggesting that most prisoners on OST were released within a short duration of time. This suggests that time for therapeutic intervention is often limited. They were also repeat offenders (94.3%) and this points to the fact that repeated contact with criminal justice system was made creating a kind of revolving door between prison and community. These findings are consistent with international literature which suggests that a lifetime history of incarceration is common among Intravenous Drug Users (IDUs); 56% to 90% of IDUs have been imprisoned previously [Jurgens, 2009]. Imprisonment of drug users for crimes they commit—often to support their addiction—contributes to prisoners’ high prevalence of drug dependence [European commission, 2008].

A daily dispensing regimen for buprenorphine was preferred by inmates on OST. Buprenorphine was administered as directly observed therapy. Diversion was noted in the initial stages of the project and especially when buprenorphine was dispensed in the tablet form. Crushing the tablets, dispensing in small batches of 2-3 prisoners at one time and including an official from the prison administration in the dispensing team was effective in controlling diversion. No problems related to diversion were faced after these modifications were made.

OST was found to be effective in key parameters related to drug use and marked reduction of illicit drug use as demonstrated by both subjective self report and objective testing by urine cassette test for morphine was observed. There was a statistically significant reduction in severity of dependence, craving for drugs and both subjective and objective withdrawal features after initiation of therapy. Similar to experiences worldwide, OST with buprenorphine demonstrated itself to be safe as no major adverse events were reported during implementation.
The mean dose (in mg) of buprenorphine was 4.3±2.0, 4.6±1.9, 4.3±1.4, 4.3±1.5 at 3, 6, 9 and 12 months respectively. The median dose of buprenorphine at all follow up points was 4 mg. In community settings, dosages prescribed in Indian patients have been in the range of 4 mg to 8 mg per day (Dhawan A, 2007). In general, dose requirement for Indian patients have been found to differ and are much lower than their western counterparts. The reasons for this are not known although postulated reasons may be genetic differences, difference in potency of illegal opioids, difference in the usual dose of opioids dependent persons etc.

The retention rate in prison was high (95.5%) and compliance among those retained in prison was 100%.

Patients expressed satisfaction with the dosage, dispensing procedure and attitude of the staff. Minimal injecting drug use and associated risk behavior was reported in prison at follow up. This may reduce risk of transmission of HIV and other blood-borne viruses among prisoners. The reporting of sexual behavior among the prisoners decreased over time although due to the sensitive nature of this information, it may not be entirely reliable. However, sharing personal hygiene equipments like razors, toothbrush, comb etc. was a common activity among these prisoners.

A significant decrease (F=2.389, df=10, p=0.01) was observed over time as far as psychological status is concerned. However this decrease was apparent only after 15 months at follow up. Although, prisoners on OST reported being satisfied with the treatment, many prisoners expressed distress if their family members did not visit them/try to arrange bail for them.

This study found a low rate of retention post release in the community (5-17%) at various follow up points. Various factors identified for this high rate of attrition were:

- Transportation charges
- Financial difficulties and unemployment
- Follow up centres very far and need time to locate follow up centres
- Peer pressure to take drugs and involvement in criminal activities
- Lack of family support. Most families want patients to continue criminal activities as source of income while others are involved in drug peddling.
- Being homeless

This may imply that in order to prevent relapse into crime and drug use, people additionally need adequate support with overall social integration (Mourino, 1994). There was a strong expressed need for rehabilitation both in prison and on release. A liaison with a Non Government Organization with a strong focus on rehabilitation would require urgent perusal to increase the post release follow up.

Periodic rotation of staff necessitated regular retraining and the need for refresher trainings every 6 months was strongly expressed by all categories of staff involved in implementation of the OST programme in the prison.
The implementation of OST with buprenorphine was found to be feasible in the prison. Further, this intervention was found to be effective in key parameters like reduction in illicit drug use, retention in prison, reduction in severity of opioid dependence, craving, withdrawal and drug seeking behavior. Diversion did not come up as a major issue and was effectively prevented by making simple modifications. It took an initial 3 months for coordination mechanisms inside the prison to get established. Thereafter the staff did not face any difficulties in implementation of the project although frequent rotation of staff necessitated refresher trainings. All stakeholders found the interventions beneficial for prisoners on OST. Based on the project, a Standard Operating Guideline for implementing OST in prison was drafted. However there was marked attrition in post release follow up. This underscores a need for more intensive psychosocial and rehabilitative intervention.
Rolling out of Opioid Substitution Treatment (OST) in Tihar Prisons, India: Scientific Report
• This study had a single arm pre-post test design and no control group was included.

• Dealing with under trials is always a challenge due to unpredictable duration of stay (mostly short) and unplanned release. That means time available for therapeutic interventions is often limited.

• Strengthening the post release arm of treatment, i.e., psychosocial and rehabilitative components is essential for dealing with this population.
• Need to scale up Opioid Substitution Treatment in other prison sites in India and mainstream it under National AIDS Control Programme (NACP) to maximize coverage and treatment potential.

• Standardize provision of psychosocial intervention to optimise impact.

• Develop an in-prison rehabilitation model in collaboration with prison administration once patients are stabilized on OST.

• Develop post release models of care to ensure continuity of treatment through OST treatment centres available in the community.
REFERENCES


APPENDIX

APPENDIX-1: DEFINED ROLES

Roles of each staff

a. Role of Doctors

- Confirmation of recruitment and signed informed consent
- Obtain signed therapeutic contract
- Baseline proforma to be filled-
  i. Drug Use Questionnaire (includes Physical Examination)
  ii. Severity of Dependence Scale
  iii. Visual Analog Scale for Craving
- Supervise administration of medication
- Conduct relevant investigations
- Identification and treatment of associated illness TB, HIV, Hepatitis B.
- Dispensing of drug in doctor’s chamber – Directly observed treatment
- Follow up proforma (3, 6, 9, 12--- months)-
  i. Follow-up Assessment (weekly)
  ii. Drug Use Questionnaire (includes Physical Examination)
  iii. Severity of Dependence Scale
  iv. Visual Analog Scale for Craving
- Keep diary record of information related to process indicators
- Coordinate between NGO, prison manager and medical staff.
- Maintain stock of medicine to be procured daily/alternate day except holiday
- Conduct periodical bio chemical/ lab monitoring
- Conduct periodical training of all prison staff regarding issues related to OST
b. Role of NGOs

- Assessment for inclusion criteria- Identifying recipients for the project.
- Explanation of OST and motivating him/her to volunteer for it.
- Reading patient information sheet, obtain signed informed consent.
- Trust building/ rapport.
- Baseline proforma to be filled -
  i. Drug Abuse Monitoring System (Baseline)
  ii. Crime Record (Baseline)
  iii. Subjective Opiate Withdrawal Scale (SOWS).
  iv. High Risk Behaviour Scale
  v. Health and Psychological Status
- Psychosocial intervention- 4 individual and 4 group sessions
- Observation and constant monitoring of patients
- Maintain date of next assessment
- Follow-up proforma-3 and 6 months
  i. Subjective Opiate Withdrawal Scale (SOWS).
  ii. High Risk Behaviour Scale
  iii. Health and Psychological Status
- Ensuring regular follow up
- Post release rehabilitation
- Maintain diary record of psychosocial interventions, process indicators and difficulties in patient retention.

c. Role of Nurses

- Dispensing of medication daily in the first 2 weeks and on alternate days thereafter.
- Maintain record of medicines dispensed
- Inform Social Worker in case patient misses even one visit
- Baseline proforma-
  1. Objective Opioid Withdrawal Scale
• Follow up proforma (3, 6,9,12--- months) to be filled-
  • Medication information proforma
  • Side effect check list
  • Objective Opioid Withdrawal Scale
• Keep record of next assessment
• As a participant for in-depth-interview for process indicators

d. Role of AIIMS
• Responsible for carrying out the staff training, and monitoring of data collection, data analysis, compilation and the formulation of the report.

e. Role of Prison Managers
1. Identification of target population on the basis of cases: U/S IPC, address (East Delhi) with expected date of release to be distributed to Prison Head Quarters(PHQ) and concerned staff and NGOs
2. Providing infrastructure i.e.
   a. storage of medicine at Prison Head Quarters(PHQ)
   b. specific room at OPD with adequate furniture and fixtures
3. Issues related to lodging in designated barrack
4. Office orders deputing specific staff i.e. Doctors, Pharmacist, Nurse
5. Monthly meeting of OST team
6. Frequent monitoring by the Jail Superintendent I (SCJ )-3
7. Maintain vigilance in the operating system
   • Trial and error
   • Overall supervision- and motivation to NGOs etc.

Overall logistics and implementation of the study were looked after by UNODC.
# APPENDIX- 2: INSTRUMENTS AND TOOLS

## Drug Abuse Monitoring System (Baseline)

### A. Socio-demographics (Enter appropriate code given under each item)

1. **Subject ID. No**
2. **Date of Registration**

3. **Age (Actual Years)**
4. **Sex**
   - 1. Male
   - 2. Female
5. **Marital Status**
   - 1. Never married
   - 2. Married
   - 3. Divorced / Separated
   - 4. Widow / Widower
   - 5. Separated due to drug abuse
6. **Education**
   - 1. Illiterate
   - 2. Literate (read & write)
   - 3. Primary (upto 5th)
   - 4. Middle (upto 8th)
   - 5. upto 10 & 12
   - 6. Graduation
   - 7. PG/ Tech/Prof.
7. **Employment status**
   - (prior to imprisonment)
   - 1. Never employed
   - 2. Unemployed
   - 3. Full time employed
   - 4. Part time employed
   - 5. Self employed
   - 6. Student
   - 7. Housewife/ Girl
   - 8. Any Other
8. **Living arrangement**
   - (prior to imprisonment)
   - 1. Joint family
   - 2. Nuclear family
   - 3. Alone
   - 4. With friends
   - 5. Any other

### B. Substance of abuse (Enquire for all substances listed below)

<table>
<thead>
<tr>
<th>Substance of abuse</th>
<th>Last 1 month (prior to imprisonment)</th>
<th>Last 1 month (during imprisonment)</th>
<th>Ever use</th>
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<tbody>
<tr>
<td>9.1 Alcohol</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.2 Heroin (Smack, Brown sugar, No. 4 etc.)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.3 Opium (Opium, Doda etc.)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.4 Other opioids (Norphin, Proxyvon, Parvon forte, ParvonPlus, Parvon, Parvon-N, Spasmoproxyvon, Parvodex, Fortwinetc)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance of abuse</th>
<th>Last 1 month (prior to imprisonment)</th>
<th>Last 1 month (during imprisonment)</th>
<th>Ever use</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.5 Cannabinoids (Ganja, Charas etc.)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.6 Sedatives / hypnotics e.g. Valium, Nitravet, Tablet No.10 etc.)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.8 Volatile solvents</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.9 Tobacco</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.10 Any other</td>
<td>[ ]</td>
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<td>[ ]</td>
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</tbody>
</table>

(Enter code as: 1. Yes  2. No  9. NA)
10. Ever had any of the following symptoms suggesting STI
   a) Genital ulcer growth
   b) Urethral discharge
   c) Vaginal discharge
   d) Burning urination
   e) Itching around genital organs
   f) Rectal pain, discharge

11. Ever had Jaundice
    (Enquire symptoms suggestive of Hepatitis)

12. Ever had sex with sex workers

13. Ever had HIV screening
    Result, if available  1. Positive  2. Negative

14. Ever had HBV screening
    Result, if available  1. Positive  2. Negative

15. Ever had HCV screening
    Result, if available  1. Positive  2. Negative

16. Previous treatment for Drug Abuse, if any

17. Ever hospitalized for treatment of drug abuse
## Crime Record (Baseline)

<table>
<thead>
<tr>
<th>Subject ID. No</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Are you a
   - 1. Convict
   - 2. Pre-trial remandee
   - 3. Detene

2. How long have you been in prison in the current imprisonment? months
   - [ ]

3. Section(s) IPC under which arrested? .................................................................

4. How many times arrested before this crime?
   - [ ]

5. Age at first imprisonment (yrs)
   - [ ]

6. Have you ever been convicted of any crime in the past i.e. before the current imprisonment? (1=Yes 2=No)
   - [ ]

7. Have you ever been apprehended for a drug related offence?
   - 1 = No.
   - 2 = Can’t say
   - 3 = Once
   - 4 = Twice or more

8. Were any of the offences for which you are in prison committed to support your drug habit? (1=Yes 2=No)
   - [ ]

9. Aggression /Violence/Disciplinary problems related to drug use for which received punishment in Jail.
   - .............................................................................................................................
## Drug Use Questionnaire (Baseline)

**Subject ID. No**

**Date**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Before imprisonment</th>
<th>Current use in prison</th>
<th>(last one month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Name of opioid used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Route of Administration (opioid)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Chasing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. IDU</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Age of First Use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Duration of Regular Use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Last Dose of Primary Drug (Date)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>if Injecting drug use</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a) Route of administration (1. I.V. 2. I.M. 3. S.C.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>b) Sharing of Syringe/Needle/Injection. Paraphernalia</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>c) No. of people shared with</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>d) Name of the injectable compound(s), if known-Mention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>IDU use last one month prior to imprisonment 1. Yes 2. No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IDU in PRISON (EVER USE)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Ever injected in prison (code 1. Yes 2. No)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Ever shared syringes in prison (code 1. Yes 2. No)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>No. of people shared with in prison</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Months since shared syringes in prison</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Medical Illness (ever) : (list)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>...........................................................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Medical Illness (current) : (list)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>...........................................................................................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Patient on:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ARV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment for Hepatitis B &amp; C</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment for T.B</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment for any other list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>15. Comorbid psychiatric illness (lifetime)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Psychosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>Comorbid Psychiatric problems (current) :</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Psychosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Depression</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
18. Previous attempts to achieve abstinence, if any and results:

<table>
<thead>
<tr>
<th>Specify time period</th>
<th>Duration of abstinence (months)</th>
<th>Self/medical help Code 1. self 2. medical</th>
<th>Reasons of relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

18. General physical examination

a. Pulse rate:  

b. Blood pressure  Systolic/ Diastolic  

c. Weight  

(Enter code as 1. Yes  2. No)

d. Pallor:  
e. Cyanosis:  
f. Jaundice:  
g. Edema:  
h. Clubbing:  
i. Lymphadenopathy:  
j. Skin  
  i) Needle marks  
  ii) Abscess  
  iii) Open wounds  

19. Systemic examination:

Chest  Abdomen  Neurological

20. Urine report (cassette test) ...........................................................................................................................................

21. Lab investigation

Haemoglobin (gm%)  

TLC  DLC(B)  

DLC(L)  DLC(E)  

DLC(M)  DLC(N)  

Billirubin (mg%)  Alkaline phos.  

AST  ALT  

22. Any other relevant investigation __________________________________

23. Clinical diagnosis ____________________________________________
# Drug Use Questionnaire

(Follow up) (for past four weeks)
(at 3 Months - at 6 Months……)

Subject ID. No .......................... Date ..........................

Record the average amount on a using day and number of days substances used in each of past four weeks

<table>
<thead>
<tr>
<th></th>
<th>Week 4</th>
<th>Week 3</th>
<th>Week 2</th>
<th>Week 1</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Alcohol</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-28</td>
</tr>
<tr>
<td>b. Opium</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-28</td>
</tr>
<tr>
<td>c. Heroin</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-28</td>
</tr>
<tr>
<td>d. Other opioids</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-28</td>
</tr>
<tr>
<td>e. Others (except tobacco)</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-7</td>
<td>0-28</td>
</tr>
</tbody>
</table>

Name .....................................................................................................

1. Last dose of primary drug (opioid)     Date ..........................
(Enter code as: 1. Yes 2. No 9. NA)

2. Health problems (current) : (list)

..................................................................................................................................................................
..................................................................................................................................................................

3. Comorbid Psychiatric problems (current) :
   *Psychosis
   *Depression

4. Patient on:
   ARV
   Treatment for Hepatitis B & C
   Treatment for T.B
   Any other .................................................................

5. General physical examination
   c. Weight ........................................
(Enter code as 1. Yes 2. No)
   d. Pallor: .......................... e. Cyanosis: ..........................

Rolling out of Opioid Substitution Treatment (OST) in Tihar Prisons, India: *Scientific Report*
f. Jaundice: ☐  g. Edema: ☐

h. Clubbing: ☐  i. Lymphadenopathy: ☐

j. Skin
   i) Needle marks ☐
   ii) Abscess ☐
   iii) Open wounds ☐

6. Systemic examination:
   Chest  Abdomen  Neurological

7. Urine report (cassette test) .................................................................

8. Lab investigation
   Haemoglobin (gm%) ☐
   TLC  ☐  DLC(B)  ☐
   DLC(L)  ☐  DLC(E)  ☐
   DLC(M)  ☐  DLC(N)  ☐
   Billirubin (mg%)  ☐  Alkaline phos.  ☐
   AST  ☐  ALT  ☐

22. Any other relevant information........................................................................................................
Severity of Dependence Scale (SDS)  
(Gossop, 1995)  
(Baseline - 3 Months - 6 Months - 9 Months ---------)

Subject ID. No  
Date 

For each of the five questions, please indicate the most appropriate response, as it applied to your drug use in the last 30 days.

[Note: When reading out the questions below, replace “(drug)” with the name of the principal opiate for which treatment is currently being received, e.g. heroin, opium, etc.]

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Question</th>
<th>Never / almost never</th>
<th>Sometimes</th>
<th>Often nearly</th>
<th>Always/always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Do you think your use of (drug) was out of control?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2.</td>
<td>Did the prospect of missing a fix (or dose) make you anxious or worried?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3.</td>
<td>Did you worry about your use of (drug)?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4.</td>
<td>Did you wish you could stop?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5.</td>
<td>How difficult did you find it to stop or go without (drug)?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

SDS TOTAL: ..........................
Follow Up Assessment
(Weekly)

Subject ID. No

Date

1. Treatment compliance-
   Number of times to be visited
   Number of times visited

2. Drug use

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of drug use</th>
<th>Frequency</th>
<th>Amount</th>
<th>Last Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Side effects of medication, if any.

........................................................................................................
........................................................................................................

4. Treatment

   Dose prescribed
   Craving (code 1. Yes 2. No)
   Withdrawal (code 1. Yes 2. No)

5. Referral

........................................................................................................

6. Offence/Disciplinary problems in the prison related to drug use

........................................................................................................
........................................................................................................

7. Any other comment

........................................................................................................
### Subjective Opiate Withdrawal Scale (SOWS)

*(Handelsman L, 1987)*

(Baseline - 3 Months - 6 Months - 9 Months ------------)

*(Before morning dose of medication)*

<table>
<thead>
<tr>
<th>Subject ID. No</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No (0)</th>
<th>Mild (1)</th>
<th>Mod (2)</th>
<th>Sev (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel anxious</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I feel like yawning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I am perspiring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. My eyes are tearing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. My nose is running</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. I have a goose flesh</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I am shaking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. I have hot flash</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. I have cold flash</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. My bones and muscles ache</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Feel restless</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Feel nauseous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Feel like vomiting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. My muscles twitch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Have cramp in my stomach</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Feel like shooting up now</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total scoring for every day**

Min. 0.

Max. 48.
### Objective Opiate Withdrawal Scale (OOWS)

(Handelsman L, 1987)

(Baseline - 3 Months - 6 Months……)

(Before administering medication)

<table>
<thead>
<tr>
<th>Subject ID. No</th>
<th>Date</th>
</tr>
</thead>
</table>

**Item (Score 1 for present and 0 for absent for each Item)**

1. Yawning. (One or more)
   (Frequency = # of yawn per observation period).

2. Rhinorrhea (Running nose)(Three or more)
   (Frequency = # of sniff per observation period).

3. Piloerection.
   (Goose flesh = observe patient’s arm)

4. Perspiration

5. Lacrimation.

6. Dilated pupils

7. Tremors (hands).

8. Hot and cold flashes.
   (Shivering and huddling for warmth)

9. Restlessness.

10. Vomiting.

11. Muscle twitches.

12. Abdominal cramps.(holding stomach)

13. Anxiety (Range mild to severe)

**Total Score**

- **Mild:** Observable manifestation- foot shaking, fidgeting, finger tapping.
- **Moderate to severe:** agitation, unable to sit, trembling, panicky, complaints of difficulty in breathing, choking sensation, palpitations.

**Total scoring for everyday**

- **Min. Score** 0.
- **Max. Score** 13.
Visual Analog Scale for craving
(Baseline - 3 Months - 6 Months - 9 Months -

Subject ID. No. [ ] [ ] [ ] [ ] [ ] [ ] Date [ ] [ ] [ ] [ ] [ ] [ ]

Client's rating of Craving for drug (opioids)

<table>
<thead>
<tr>
<th>Minimum</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medication Information Questionnaire
(3 Months - 6 Months - 9 Months -

Subject ID. No. [ ] [ ] [ ] [ ] [ ] [ ] Date [ ] [ ] [ ] [ ] [ ] [ ]

1. Dose of Buprenorphine dispensed in last 3 months
   (Range including minimum and maximum dose in mg)
   a) Minimum dose
   b) Maximum dose

2. Current dose dispensed at time of follow-up of Buprenorphine (in mg)

3. Dose received most of the time in last 3 months (in mg)

4. Weekly chart of buprenorphine

<table>
<thead>
<tr>
<th>No. of Weeks</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
<th>Week 8</th>
<th>Week 9</th>
<th>Week 10</th>
<th>Week 11</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose dispensed (min-max dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of days received</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of days was supposed to receive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Side Effects Check List

(Handelsman L, 1987)
(3 Months - 6 Months……)

Subject ID. No  
Date  

(Please put a tick mark where ever applicable)

<table>
<thead>
<tr>
<th>No.</th>
<th>Effect</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Sedation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Diplopia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Giddiness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Headaches</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Confusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Light Headedness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Blurred vision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Hallucination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Drowsiness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>In coordination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Slurred speech</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Itching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Oral Ulceration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Constipation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Weakness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>Sexual problem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>Any other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
High Risk Behaviour
Adapted from Ward, Darke & Hall, 1990
(Injecting and sexual practices)
(Baseline - 3 Months - 6 Months……)

Subject ID. No □□□□□ Date □□□□□□

These questions are about the way you use drugs, and your received sexual behaviour.

I emphasize again that any information that you give me is completely confidential.

Part 1: Drug Use

1. How many inmates do you know injected drugs in the last 4 weeks in your barrack?

2. How many times have you injected any drugs in the last month.
   - No times .......................................................... 0
   - Once a week or less ...................................... 1
   - More that once a week (but less that once a day) .......... 2
   - Once a day .................................................. 3
   - 2-3 times a day ........................................... 4
   - More than 3 times a day ................................ 5

4. How many times in the last month have you used a needle after someone else had already used it?
   - No times .......................................................... 0
   - One time ...................................................... 1
   - Two time ....................................................... 2
   - 3-5 times ...................................................... 3
   - 6-10 times .................................................... 4

5. How many different people have used a needle before you in the last month?
   - None .............................................................. 0
   - One person .................................................. 1
   - Two people ................................................... 2
   - 3-5 people ...................................................... 3
   - 6-10 people ................................................... 4
   - More that 10 people ..................................... 5
6. How many times in the last month has someone used a needle after you have used it?
   - No times ................................................................. 0
   - One time .............................................................. 1
   - Two times ............................................................. 2
   - 3-5 times .............................................................. 3
   - 6-10 times ............................................................ 4
   - More than 10 times ............................................... 5

7. How often, in the last month, have you cleaned needles before reusing them?
   - Doesn’t re-use ....................................................... 0
   - Every time ........................................................... 1
   - Often ..................................................................... 2
   - Sometimes .......................................................... 3
   - Rarely .................................................................... 4
   - Never ..................................................................... 5

8. The last time you injected and shared with others, how did you clean the needle/syringe?
   1. Cleaned with water
   2. Cleaned with bleach
   3. Any other mode (pls. Specify)
   4. Did not clean
   5. Not applicable

Part 2: Sexual Behaviour

9. How many inmates do you know had sex with another inmate on your barrack in the last 4 weeks?

10. How many people, have you had sex within the last month?
    - None .................................................................. 0
    - One person ....................................................... 1
    - Two people ......................................................... 2
    - 3-5 people .......................................................... 3
    - 6-10 people ......................................................... 4
    - More than 10 people ........................................... 5
11. What kinds of sexual activity have you had in this prison?
(Please tick in front of the item-whichever applicable)

- None
- Masturbation
- Masturbation with a partner
- Oral sex
- Anal sex
- Any Other

12. How often have you used condoms when having sex with your partner in the last months?

- No reg. Partner/No penetrative sex ............................................................ 1
- Every time .................................................................................................. 2
- Sometimes ................................................................................................. 3
- Rarely ........................................................................................................ 4
- Never ......................................................................................................... 5

13. How many times did you have anal sex in the last month?

- No times .................................................................................................... 0
- Once time ................................................................................................... 1
- Tow times .................................................................................................. 2
- 3-5 ............................................................................................................. 3
- 6-10 ........................................................................................................... 4
- More than 10 times .................................................................................... 5

General Comments or HIV Risk-taking behaviour

..........................................................................................................................
Part 3: Other Skin Penetration Practices


Record your responses to each of the following questions by circling the answer option that you think is most relevant to you. Please remember that “in the last month” refers to the month before you commenced current drug treatment.

1. In the last month, how many times have you come into contact with another person’s blood (eg. through fights, slash-ups, self-mutilation, accidents, blood-sports, occupational, pimples, blood nose, etc)?
   - No times
   - Once
   - Twice
   - 3 - 5 times
   - 6 - 10 times
   - More than 10 times

2. In the last month, how many times have you been pierced (eg. ear or body) by someone else who was not a professional tattooist?
   - No times
   - Once
   - Twice
   - 3 - 5 times
   - 6 - 10 times
   - More than 10 times

3. In the last month, how many times have you used another person’s used razor (eg. disposable razors, razor-blades)?
   - No times
   - Once
   - Twice
   - 3 - 5 times
   - 6 - 10 times
   - More than 10 times

4. In the last month, how many times have you used another person’s toothbrush?
   - No times
   - Once
   - Twice
   - 3 - 5 times
   - 6 - 10 times
   - More than 10 times

5. In the last month, how many times have you used another person’s personal hygiene equipment (eg. nail file, nail scissors, nail clippers, tweezers, comb, brush)?
   - No times
   - Once
   - Twice
   - 3 - 5 times
   - 6 - 10 times
   - More than 10 times

Please make sure that you have answered all relevant questions correctly
Health (Addiction Severity Index) and psychological status
(Baseline - 3 Months - 6 Months)

MEDICAL STATUS

Subject ID. No       Date

1. How many times in your life have you been hospitalized for medical problems?
   (Include o.d.’s, d.t.’s, exclude detox.)

2. How long ago was your last hospitalization for a physical problem?

3. Do you have any chronic medical problems which continue to interfere with your life?

4. Are you taking any prescribed medication on a regular basis for a physical problem

5. N.A.

6. How many days have you experienced medical problems in the past 30 days?

FOR QUESTIONS 7 & 8 PLEASE ASK PATIENT TO USE THE PATIENT’S RATING SCALE

7. How troubled or bothered have you been by these medical problems in the past 30 days?

8. How important to you now is treatment for these medical problems?

INTERVIEWER SEVERITY RATING

9. How would you rate the patient’s need for medical treatment?

CONFIDENCE RATINGS
Is the above information significantly distorted by:

10. Patient’s misrepresentation? 0 - No 1 – Yes

11. Patient’s inability to understand? 0 - No 1 – Yes

Psychological health status

a. Client’s rating of psychological health status (anxiety, depression and problem emotions and feelings)

<table>
<thead>
<tr>
<th>Poor</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Good</th>
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Process Indicators for Staff  
(3 Months - 6 Months)  
(Focus Group Discussion)

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<tr>
<th>Subject ID. No</th>
<th>Date</th>
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1. Recruitment of Subjects
   a) Method used for recruitment ............................................................
      .............................................................................................................
   b) Difficulties in recruitment .................................................................
      .............................................................................................................

2. Training of Staff (Confidence of staff in performing duties assigned to them before and after training) about self and others
   .............................................................................................................

3. a) Dispensing related aspects (timing etc., patient needs)
   .............................................................................................................
   b) Reports of diversion/misuse of medication
   .............................................................................................................
   c) Medicine safe keeping
   .............................................................................................................

4. Need for additional medication (for alcohol related problems, comorbid depression if it emerged during treatment)
   .............................................................................................................

5. Additional psychosocial interventions or input made
   .............................................................................................................

6. Efforts made to retain subjects (difficulties, suggestions)
   .............................................................................................................

7. Difficulties encountered by staff- (e.g. Disciplinary problems)
   .............................................................................................................

8. Issues related to record keeping (difficulties, suggestions)
   .............................................................................................................
### Process Indicators for Patients

(3 Months - 6 Months……)

(Focus Group Discussion)

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**Focus Group Discussions : three with patient**

1.  
   a) Dose related Issues (adequacy of dose prescribed, how much say or influence the patient had in regulating dose prescribed)

   ............................................................................................................................................................

   b) Dispensing related aspects (timing etc, patient needs)

   ............................................................................................................................................................

   c) Reports of diversion/misuse of medication

   ............................................................................................................................................................

2.  
   Difficulties in coming for regular follow up

   ............................................................................................................................................................

3.  
   a) Satisfaction with treatment/improvement

   ............................................................................................................................................................

   b) Difficulties or barriers in treatment

   ............................................................................................................................................................

4.  
   a) Efforts made by staff to retain subjects (what was done, suggestions)

   ............................................................................................................................................................

   b) Feedback about psychosocial intervention (was it beneficial, difficulties, suggestions)

   ............................................................................................................................................................

5.  
   a) Attitude of staff

   ............................................................................................................................................................

   b) Difficulties encountered by staff- (e.g. disciplinary problems)

   ............................................................................................................................................................

6.  
   How has this treatment helped you?

   ............................................................................................................................................................
Rolling out of Opioid Substitution Treatment (OST) in Tihar Prisons, India: Scientific Report