National Standard Operating Procedure for Opioid Substitution Therapy in Bangladesh

April 2022

জাতীয় এইডস/এসটিডি কন্ট্রোল
স্বাস্থ্য অধিদপ্তর, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়

DEPARTMENT OF NARCOTICS CONTROL BANGLADESH
মাদকদ্রব্য নিয়ন্ত্রণ

Save the Children

National Standard Operating Procedure for Opioid Substitution Therapy in Bangladesh

April 2022

Developed by

Dr. Ingrid Alida Van Beek, MD

Conjoint Professor, Kirby Institute, University of New South Wales, Sydney, Australia
- International Consultant

Dr. Muhammad Kamruzzaman Mozumder PhD

Associate Professor, Department Clinical Psychology, Dhaka University
- National Consultant

Reviewed by

AIDS/STD programme (ASP), Directorate General of Health Services (DGHS)
Dr. Md. Abdul Wadud, Programme Manager
Dr. Ziaul Bari, Medical Officer

Departments of Narcotics Control (DNC)
Dr. Md. Rahanul Islam, Resident Psychiatrist, Central Drug Addiction Treatment Centre

Save the Children in Bangladesh
Ezazul Islam Chowdhury, Technical Advisor, HIV/AIDS Programme, Health & Nutrition Sector

icddr,b
Dr. Tanveer Khan Ibne Shafiq, Senior Medical Officer, programme for HIV

UNAIDS
Dr. Saima Khan, Country Director, UNAIDS Bangladesh (As member of National OST Coordination Committee)

Approved by:

AIDS/STD Programme (ASP), DGHS and Department of Narcotics Control (DNC)

Supported by

HIV/AIDS Programme of Save the Children in Bangladesh, under the Global Fund NFM2 Grant

Publications

First version: 2016
Revised through this technical assistance: July 2020 to June 2021
Second version: April 2022

Cover Design

Ezazul Islam Chowdhury

Printed by

Printfusion Company, Tongi

Table of Contents

Forward

Bangladesh, though not a drug producing country, is vulnerable for illicit drug use for its geographical location, close proximity of drug producing zones, rapid urbanization, increase of population, effect of internet, lack of social awareness etc. As magnitude is huge, Government of Bangladesh has been trying to tackle the problem, however, evidence suggest that no single approach has been proven to be effective to reduce the consequences of drugs. Therefore, along with supply and demand reduction, harm reduction approach is similarly important to Government of Bangladesh. With this reality, collaboration has been established among Department of Narcotics Control (DNC) and other law enforcing agencies, ministries and departments as well as development partners and NGOs.

Drug use itself a severe problem and the problem increases when HIV and other blood borne infections get linked with drugs. Globally, drug users, particularly people Who Inject Drugs (PWID) are very much vulnerable to HIV and HCV infection. In Bangladesh, this vulnerability is due to unsafe injection practices. Although, issues of HIV are dealt with AIDS/STD programme under DGHS, as a nodal body of narcotics control, DNC is also aware of the severity of the problems amongst the drug users. It is providing support to ASP and its GO-NGO stakeholders to prevent HIV under harm reduction approach. With this consideration and total support from DNC, National Narcotics Control Board (NNCB) approved Methadone (a narcotics drug) for OST services in Bangladesh in 2008. DNC is continuing its support in rapid scale up of OST by providing smooth regulatory support and guidance.

DNC is happy to see that the Global Fund has taken the initiative to review the OST programme in Bangladesh for the first time with support from ASP, relevant stakeholders including community organizations. In each step of the process, DNC was engaged and provided its support for proper completion.

I thank ASP for its stewardship role, Save the Children for providing financial and other necessary support for completion of the assignment and other OST implementers including icddr,b, CARE Bangladesh, UNAIDS and UNODC for supporting technical assistance team. I hope that this SOP will support OST project staff in Bangladesh to run the OST centres properly with maintaining quality.

Md. Abdus Sabur Mandal
Director General
Department of Narcotics Control
Ministry of Home Affairs

Forward

HIV prevalence among the People Who Inject Drugs (PWID) was 22% in Dhaka city, which has come down to around 4.1% overall, however, prevalence is still more than 5% in Dhaka and Narayanganj (IBBS 2021, ASP). It seems interventions for PWID are successful, as a result of efforts from ASP and its NGO implementers. As HIV risk behaviour is still common among this KP and concentrated level of epidemic among this populations still persists in some areas, high coverage and comprehensive services including Needle/Syringes Programme (NSP), Opioid Substitution Therapy (OST), HIV Testing Services (HTS) and ART are essential services and required in adequate scale.

World wide, OST has already demonstrated results in HIV risk reduction amongst PWID and the services are available in more than 80 countries including Bangladesh. Currently, implementers under the Global Fund NFM3 Grant are operating 16 OST centres. Health Sector Programme is planning to start four new centres soon. However, the coverage is still below the lower limit of WHO (20%). With support from development partners like Global Fund, Department of Narcotics Control and NGO implementers including Save the Children, icddr,b, CARE Bangladesh, ASP is working to enhance the service coverage and quality of the intervention through monitoring and supervision. ASP is lead the National OST Coordination Committee and also member of the OST National Steering Committee, thus playing an important role in OST design and overall implementation.

I take this opportunity to thank the Global Fund for it's initiative to assess/review the OST programme in Bangladesh and accordingly provide technical support to develop various SOPs and action plan including this one. I also thank to Save the Children for providing financial and other assistance and to make the development process comprehensive by engaging all relevant GO (ASP and DNC), NGO (icdd,b, CARE Bangladesh), community based organizations (APOSH, KP networks), international experts (Save US, Global Fund), UN offices (UNAIDS, UNODC) in the process. In the review process, ASP took lead by forming the committee and participated in the review of this document. As it was a gap in the country, ASP believes that this updated SOP will support OST project staff in Bangladesh to run the OST centres properly with maintaining quality.

Dr. Md. Khurshid Alam
Director, DGHS and Line Director, TB-Leprosy & AIDS/STD Programme,
Directorate General of Health Services (DGHS)
Ministry of Health and Family Welfare

Message

Opioid Substitution Therapy (OST) is an evidence based and effective bio-medical intervention for People Who Inject Drugs (PWID). This intervention started in Bangladesh in 2010 through the UNODC project RAS/H13 ROSA as a part of pilot study, conducted by icddr,b in Central Drug Addiction Treatment Centre (CTC), DNC, Dhaka. Although the pilot study was approved by the National Narcotics Control Board (NNCB) in three sites (CTC and two DICs), implementation was started at the DIC in 2012 under Save the Children Grant with funding from the Global Fund. Currently, there are two PRs (icddr,b and Save the Children) implementing OST through 16 centres (SC-11 and icddr,b- 5). Along with the coverage, efforts to enhance the quality is also under consideration of implementing agencies. Thus, various efforts have been taken so far.

In February 2020, UNODC and the Global Fund Country Team (CT) conducted a joint mission in Bangladesh and generated a report, where along with other issues, gap areas also were identified in OST. Based on that, Save the Children commissioned two consultants: Dr. Ingrid Van Beek (International Consultant) and Dr. Kamruzzaman Mozumder (National Consultant) to run an assessment and accordingly develop SOP/Manuals and action plans to address the gap areas. The team started its assignment in July 2020 and continued till June 2021. In the assessment process, they worked with all implementing agencies (CARE Bangladesh, icddr.b, APOSH), nodal body of HIV (ASP) and regulatory body (DNC). In addition, they consulted with UN offices in Bangladesh (UNODC and UNAIDS). The entire process of TA has been regularly followed by a joint team consisting of Save the Children Bangladesh, Save the Children US and the Global Fund.

From the beginning of the planning, ASP was on board and provided support through forming review committee and also took part in the review process. DNC was involved in the total process and provided feedback during the development as well as part of the review team. Technical and field team of implementing agencies including Save the Children, CARE Bangladesh, icddr,b were engaged in the total process and provided their support to complete the assignment. On behalf of Save the Children, I wish to express my profound gratitude to all those who have tirelessly worked on this module.

My gratitude to the Global Fund CT for funding this assessment to identify the gaps. Thanks to Save the Children US on giving us technical support, Lastly, but not the least, my sincere gratitude to our two consultants Dr. Ingrid Van Beek and Dr. Kamruzzaman Mozumder for their hard work, particularly during the peak time of COVID 19 and they also dedicatedly addressed the review comments even after the contract period.

I hope that this SOP will provide adequate support to concerned technical staff of OST centre including doctor, counsellor, nurse and other relevant staff to operate OST service with quality.

Dr. Lima Rahman
Director – Health and Nutrition Sector
Save the Children in Bangladesh

Message

We would like to thank all the stakeholders who participated in this assignment including the UNODC, UNAIDS, the implementing partners, community-based organisations, the OST Clinic staff and their clients for the support we received in undertaking this assignment.

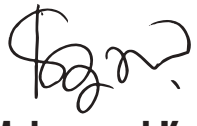
Everyone went out of their way to assist us. Especially the OST Clinic staff who amidst their busy schedules gave us time for the interviews and accompanied us on the clinic and field visits. We are also grateful to the three technical focal from the implementing partners, Dr. Md Shahidul Islam from SCI, Dr. Tanveer Khan Ibne Shafiq from icddr,b and Dr. Rehana Ahmed Mita from CARE Bangladesh for their assistance throughout the TA period.

We thank the various Government officials from the Department of Narcotics Control (DNC), AIDS/STD Programme (ASP), DGHS and Divisional Health Office who travelled out of Dhaka to attend the National Consultation meeting organised at short notice. Gratitude to Director General (DG), DNC to hear the recommendations from the Technical Assistance team and participants in the National OST Stakeholders Meeting and gave his commitment to consider the issues positively from his office. Also, sincere thanks to Line Director, ASP to form an expert review committee from National OST Coordination Committee and proceed for approval of the document.

The officials from UNAIDS, UNODC and the community-based organisations (NPUD, APOSH) all demonstrated a keen interest in the successful completion of the assignment and implementation of the upcoming recommendations.

We were also supported by Palani Narayanan of the Global Fund, and Ezazul Islam Chowdhury and Dr Imran Muhammad of SCI who provided feedback throughout. And finally, we'd like to thank Dr Lima Rahman who supported the whole team in carrying out the assignment's various activities.

Dr. Ingrid Alida Van Beek, ***MD***
International Consultant



Dr. Muhammad Kamruzzaman Mozumder ***PhD***
National Consultant

Acronyms

ART	Anti-Retroviral Therapy/Treatment
ASSIST	Alcohol, Smoking and Substance Involvement Screening Test
ATS	Amphetamine-type substance
BAL	Blood Alcohol Level
BBI	Blood Borne Infections
BSMMU	Bangabandhu Sheikh Mujib Medical University
CBO	Community Based Organization
CBT	Cognitive Behaviour Therapy
CNS	Central Nervous System
COWS	Clinical Opiate Withdrawal Scale
DIC	Drop-in Centre
DOT	Directly Observed Treatment/Therapy
DSM	Diagnostic and Statistical Manual of Mental Disorders
EAR	Expired Air Respiration
ECG	Electrocardiogram
GCS	Glasgow Coma Scale
GoB	Government of Bangladesh
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh
IEC	Information Education Communication
KP	Key Populations
MI	Motivational Interviewing
MMT	Methadone Maintenance Treatment/Therapy
MOHA	Ministry of Home Affairs
MOHFW	Ministry of Health and Family Welfare
NRTI	Nucleoside reverse transcriptase inhibitors
NNRTI	Non-nucleoside reverse transcriptase inhibitors
NSP	Needle Syringe Program
NSP	National Strategic Plan
OST	Opioid Substitution Treatment/Therapy
OW	Outreach worker
PMR	Progressive Muscle Relaxation
PWID	People who inject drugs
PWUD	People who use drugs
SCI	Save the Children International in Bangladesh
SHG	Self Help Group
STI	Sexually Transmitted Infection
TAS	Treatment as Prevention
TB	Tuberculosis
UDS	Urine Drug Screen
UNAIDS	United Nations Joint Programme on HIV/AIDS
UNODC	United Nations Office of Drugs and Crime
WHO	World Health Organization

A: Background and guiding principles

Opioid substitution therapy (OST) as a public health intervention

There is strong evidence that opioid substitution therapy (OST) is effective in enabling people to reduce or cease injecting drug use, greatly reducing their risk of HIV infection (Joint United Nations Programme on HIV/AIDS, 2016). Methadone maintenance therapy has been associated with a 54% reduction in the risk of HIV infection among people who inject drugs (MacArthur et al., 2012). OST has also been found to have wider health, economic, psychological and social benefits.

The World Health Organization (WHO), the United Nations Office on Drugs and Crime (UNODC) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommend that OST be provided as part of an evidence-based public health response for people who inject drugs (PWID) with a comprehensive package to include the following interventions[1]:

1. Needle and syringe programs (NSPs)
2. Opioid substitution therapy (OST) and other evidence-based drug-dependence treatment
3. HIV testing services (HTS)
4. Antiretroviral therapy (ART) for people living with HIV
5. Prevention and treatment of sexually transmitted infections (STIs) (and sexual and reproductive health services)
6. Condom programs for people who inject drugs and their sexual partners
7. Targeted information, education and communication (IEC)
8. Prevention, vaccination, diagnosis and treatment of viral hepatitis B and C
9. Prevention, diagnosis and treatment of tuberculosis (TB)
10. Community distribution of naloxone for prevention and treatment of opioid overdose.

Methadone has also been included on the WHO List of Essential Medicines for the treatment of substance dependence since 2003. (A subset of WHO's List of Essential Medicines for use in OST Clinics in Bangladesh is at Annex 4 of this document.)

OST is an effective, safe and cost-effective medical treatment that is also proven to reduce the frequency of injecting heroin or other opioids and the associated risks of overdose (by 50%), infection and transmission of other blood borne viruses including hepatitis C (HCV), as well as reducing criminal activity ("HARM REDUCTION FOR HIV PREVENTION," 2020).

Alongside its effectiveness in preventing HIV, OST has also been shown to increase adherence to HIV and TB treatment. Many PWID first makes contact with health care through OST programs then go on to access other services (Joint United Nations Programme on HIV/AIDS, 2016; Kermode, Crofts, Kumar, & Dorabjee, 2011).

The benefits of OST are far reaching and have been demonstrated in a variety of low-, middle- and high-income countries. It is estimated that 130,000 new HIV infections outside

[1] UNODC et al. (2017)

of sub-Saharan Africa could be prevented every year if access to OST was sufficient (Joint United Nations Programme on HIV/AIDS, 2016).

To achieve optimal OST program coverage (considered by WHO to be 40%) and treatment outcomes, OST should be accessible to anybody in need of treatment who meets the criteria for inclusion, whether or not they inject, and needs to be affordable.

The importance of achieving high OST retention rates

Research has shown that longer-term methadone at higher dosages (> 60 mg) leads to better long-term health and social outcomes than shorter-term programs aimed at detoxification, and treatment plans should take a long-term perspective. However, retention rates remain low in many countries. A 2014 evidence review found OST programs in low- and middle-income countries had an average one-year retention rate of around 50% (Feelemyer, Des Jarlais, Arasteh, Abdul-Quader, & Hagan, 2014).

Key principles for OST retention in therapy

The use of illegal drugs while in OST should never be a reason for excluding a client from the program. This could indicate the need for a clinical adjustment of the treatment. However, the medication dosage must never be adjusted as a reward or punishment for behaviour.

Safety: The OST program should ensure the safety of clients, staff and medication. Clear information should be given to clients on the rules and regulations within the centre.

Openness and flexibility: Rules and regulations surrounding entry and retention in OST should not be overly burdensome on the client. Long waiting times, limited dispensing hours and compulsory urine testing are not recommended. Offering same-day treatment upon registration is a good practice.

Respect: High-quality care that is non-stigmatising and non-discriminatory is a cornerstone of effective and principled treatment. For opioid-dependent people with TB, viral HBV, HCV or HIV, it is recommended that methadone be administered in conjunction with medical treatment.

There is no need to wait for abstinence from opioids to start treatment for these conditions. Treatment services should offer hepatitis B vaccination to all opioid-dependent clients. Care settings that provide OST should initiate HIV testing and start and maintain ART for all people living with HIV, according to national guidelines.

The importance of creating a welcoming OST Clinic environment

Treating clients with respect and dignity and making OST Clinics as pleasant and relaxing as possible will make daily clinic visits more tolerable for clients and afford the staff safety. Putting up bars or screens to separate clients and service-providers inevitably creates mistrust. Similar attention must be paid to the external amenities of the clinic. Signage on the outside of the building should be discreet in order not to attract unwanted attention and to allow clients anonymity.

OST should be provided as a holistic treatment encompassing the following:

1. Help with social integration:

Individual or group counselling and self-help groups can help OST clients develop communication and socialisation skills. Peer support groups have also been an important emotional resource for people who inject drugs in many settings.

2. Work with peer advocates so that client feedback informs services:

Community organisations/network led by people with lived experience of injecting drugs can help OST providers by providing information to PWID, OST clients, parents and relatives, as well as to doctors and the general public. Through training and orientation (with support from intervention), CBO and community network will develop clients to become peer advocates/ counsellors for OST.

3. Work with family and relatives for a supportive environment:

To ensure the effectiveness of OST and the quality of clients' lives, programs should offer psychological and social services to families and friends of program participants (and especially to children, ensuring that they are kept with the parents and family wherever possible). However, it is essential that clients retain their right to confidentiality.

4. Advocate for OST and clients' rights:

It is important to engage in advocacy for clients' rights to access high-quality and sustained OST, and expanded programs. Advocacy by program providers can be done alongside peer advocacy networks and family groups, who can also help mobilise national campaigns for access to treatment.

The role of 'low threshold' OST Clinics

The most successful OST programs are 'low-threshold', i.e. easy to enrol in, harm-reduction oriented, offering a range of treatment options, and actively attracting PWID into services.

- Needed to ensure that the most high-risk part of the injecting population is attracted to OST, gains access to OST and is retained in OST
- Their emphasis is on achieving lifestyle stability versus being 'drug-free' per se – although this can also be achieved
- Their main aim is to achieve regular clinic attendance and treatment retention for the 'chronic relapsing condition' of opioid dependence
- The need to reach therapeutic dose (> 60 mg) should be actively promoted among OST Clinic clients in low threshold OST programs – but can be challenging in the presence of intercurrent drug use but this should be manageable (see later section on approaches to intercurrent drug use during OST).

Features of High-quality OST Clinics

- Sited in community locations close to where PWID already dwell to minimise the need for travel
- Integrated in targeted primary health care settings or DICs with outreach and peer workers targeting high risk PWID for HIV prevention. This helps demystify and promote OST and also enables a holistic approach to other health and psychosocial issues among complex/high needs groups. Opportunities provided by integrated "one-stop-shop" low threshold OST Clinics include:
  - Regular health and psychosocial review
  - Monitoring and/or treatment of complex/chronic health issues
  - Co-administration and monitoring of other treatments e.g., HIV, TB, psychiatric medications
  - Sexual and reproductive health provision e.g., STI diagnosis and treatment, Pap smears, contraception, pregnancy/antenatal support

  - The means of HIV and other blood borne infections (BBI) prevention to include access to NSP and condoms

- Clients have a sense of ownership of their program given opportunities have a say in how it is designed and provide feedback about their experience as a clinic client
- Physical security barriers, CCTVs, mirrors etc are minimised (within safety requirements) to avoid and 'us' versus 'them' (who can't be trusted) atmosphere and to enable face to face client rapport
- The client spaces are warm and user-friendly - not sterile or 'clinical' and staff do not need to be too formally dressed (white coats with stethoscopes around the neck to be avoided!)
- Clients understand and have agreed to a Code of Conduct and consequences for non-compliance upfront (which should be publicly displayed). Clients also have an important role in developing and reviewing these rules
- All frontline staff are able to provide 'brief interventions', crisis counselling, aggression & critical incident management
- Professional demarcations are minimised, and nursing roles are extended to the extent possible - so that medical and counselling staff are preserved for the assessment of more complex clinical and psychosocial matters
- All staff have a non-judgemental attitude, treating clients with dignity and respect at all times
- The Clinic has a proactive approach to debriefing staff post-incident and managing staff stress and 'burn out'
- Professional development and staff training are embraced

Flexible Dosing Protocols

- Dosing protocols should be flexible within national guidelines enabling clients to increase/decrease their own dose within a safe range (e.g., 10 mg per week) without requiring medical review
- Dosing hours are extended as far as possible to enable employment, study etc
- Intercurrent drug use is assumed, so there is limited need for routine drug testing - unless the client repeatedly presents for dosing with signs of intoxication and disputes this, insisting on their usual dose
- Intoxicated presentations are approached in a way that focuses on client safety – and not in a punitive way
- Split or delayed dosing later that day is also considered to avoid missed doses and need to decrease below therapeutic dose, affecting OST retention
- Ideally, a methadone prescriber is on call by phone at weekends to assess the dose for those who have not attended for several days to avoid accumulation of missed doses
- Clinic has an 'Open Door policy' where clients not being 'exited' from the program until it is ascertained that they no longer wish to remain in treatment, and know that they are always welcome back. However, for reporting purposes: OST clients who have not received OST for one month should no longer be regarded as part of the OST client population

Beyond the Drug

An 'intensive case management approach' is recommended to achieve treatment goals among the most marginalised high-risk clients with complex issues

Consider allocating 'case managers' based on what the main issues are for that OST client. For example, if they have mostly physical issues a clinic nurse may be best versus someone with complex psychosocial issues, in which case a counsellor may be best

Treatment goals need to be realistic and achievable, reviewing and adjusting these over time as required to ensure they remain relevant

Underlying psychosocial issues affecting clients' stability, particularly their accommodation stability and employment situation, should be prioritised in a proactive, comprehensive way.

Relevant quality indicators for low threshold OST Clinics

The following indicators should be monitored and incorporated into OST Clinic reporting requirements to the extent feasible.

- Number of new enrolees and daily attendances
- Proportion of HIV positive OST clients - reflecting the prevalence in local area (ideally over-represented among OST Clinic clients)
- Uptake and adherence to ART and other relevant treatments (e.g., HCV and TB) over time
- Proportion of 'high risk' PWID including 'hidden' populations e.g., female, younger, street based and unemployed PWID
- Proportion of OST clients tested for HIV and other transmissible infections annually
- Proportion of OST clients receiving therapeutic dosage level (> 60 mg)
- Proportion of OST clients retained in OST at 6,12 and 24 months
- Reduction in HIV risk behaviours
- Reduction in illicit opioid and other drug use / reduction in intoxicated presentations for OST
- Reduction in criminal behaviour and rate of incarceration
- Clients' achievement of treatment goals with emphasis on social outcomes including gaining stable accommodation and a legal source of income
- Number of OST clients successfully withdrawn from OST upon reaching their treatment goals
- Number of 'released' OST clients who re-enrol in OST within 6, and 12 months

OST Program outcome indicators

- Increasing OST coverage to reach 40% PWID population coverage
- Reduced annual incidence (new cases) of HIV and other transmissible infections (HBV & HCV) among PWID
- Reduction in the prevalence of HIV and other transmissible infections among PWID in Bangladesh over time

References

Feelemyer, J., Des Jarlais, D., Arasteh, K., Abdul-Quader, A. S., & Hagan, H. (2014). Retention of participants in medication-assisted programs in low- and middle-income countries: an international systematic review. Addiction, 109(1), 20-32. doi: 10.1111/add.12303

HARM REDUCTION FOR HIV PREVENTION. (2020). Retrieved 29 November 2020, from https://www.avert.org/professionals/hiv-programming/prevention/harm-reduction

Joint United Nations Programme on HIV/AIDS. (2016). Do no harm: health, human rights and people who use drugs: UNAIDS.

Kermode, M., Crofts, N., Kumar, M. S., & Dorabjee, J. (2011). Opioid substitution therapy in resource-poor settings: SciELO Public Health.

MacArthur, G. J., Minozzi, S., Martin, N., Vickerman, P., Deren, S., Bruneau, J., . . . Hickman, M. (2012). Opiate substitution treatment and HIV transmission in people who inject drugs: systematic review and meta-analysis. BMJ : British Medical Journal, 345, e5945. doi: 10.1136/bmj.e5945

UNODC, INPUD, UNAIDS, UNDP, UNFPA, WHO, . . . PEPFAR. (2017). Implementing comprehensive HIV and HCV programmes with people who inject drugs Practical Guidance for collaborative interventions (the "IDUIT"). Viena.

B: Clinical Management Standard Operating Guidelines

Methadone Induction, Stabilisation and Maintenance Therapy

Key considerations to ensure OST achieves its aim of preventing HIV and other blood borne infections (BBIs) including hepatitis B (HBV) and hepatitis C (HCV) among PWID

- the need to achieve adequate coverage of the population of opioid dependent people who inject drugs (PWID): towards WHO target of 40%
- the need for those PWID who drive HIV epidemics to be over-represented
    - HIV positive PWID and those most likely to engage in high levels of injecting and sexual risk behaviours i.e., younger, female PWID
- that retention in OST is ALL important to achieve adequate population coverage
- that the strongest predictor of OST retention is the ability to reach therapeutic methadone dose of > 60 mg.

The most socially marginalised PWID are the most at risk of HIV and other BBIs. Characteristics of this sub-population include the following.

- younger
- transient, with itinerant lifestyles, dwelling on the streets
- low levels of education and literacy, limited employment opportunities, unreliable/ illegal sources of income
- high levels of criminal involvement, periods in prison
- fragmented social and family support systems
- other physical and mental health conditions
- poor access to health care including the means of HIV prevention including NSP, condoms and OST

It should be recognised that this most socially marginalised sub-population of PWID has the most to gain from the day-to-day stability afforded by OST- but is often the least able to gain access or be retained in methadone treatment due to their 'chaotic' lifestyles. For this reason:

- this group needs to be specifically targeted for enrolment at OST clinics to achieve HIV prevention among PWID at the population level
- this should occur alongside prioritising those who have already acquired HIV and other BBIs, OST also providing the stability needed for anti-retroviral therapy (ART) to achieve its therapeutic and secondary prevention ("Treatment as Prevention" - TaS) benefits
- "hidden" populations - such as younger, female and transgender PWID, also need to be specifically targeted
- the involvement of 'peers' with lived experience of HIV and or illicit drug use is key to ensuring that the most marginalised sub-populations of opioid dependent PWID gain access and are retained in OST.

Implications for client assessment

- While PWID need to be assessed to be opioid dependent for a duration of time, 12 months is a reasonable benchmark. But can be flexible about this if the opioid dependent person is at particularly high risk;
- While repeated "failure" in other treatment types may indicate dependence, this should not be an essential criterion, also keeping in mind their limited access to health care options will also have affected their access to other drug treatment options;
- It is known that high risk marginalised PWID are very unlikely to successfully detoxify from all drugs in the short to medium term;
- Opioid detoxification reduces clients' opioid tolerance, which increases their risk of opioid overdose in the likely event of relapse to drug use post-detoxification. For this reason, opioid detoxification shouldn't necessarily be seen as a 'first-line of treatment' and should arguably even be avoided in high risk marginalised PWID;
- Opioid dependence is recognised to be a 'chronic relapsing condition' with a natural course that can extend over many years, which is well-matched with methadone maintenance treatment;
- For these reasons, methadone treatment should not be considered a 'treatment of last resort' among HIV positive PWID and those engaged in HIV risk behaviours, and may well be an appropriate 'first line of treatment' for opioid dependence for these key priority populations
- The key criterion for OST eligibility is being opioid dependent.

The Assessment of Opioid Dependence

The Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) and the International Classification of Diseases, 10th edition (ICD 10) are both considered 'gold standard' in the assessment of opioid dependence. Clinicians can choose which of these two to apply in their assessment of this key criterion among PWID seeking to commence OST.

DSM-5 criteria for Opioid Use Disorder

- Using larger amounts of opioids or over a longer period than was intended
- Persistent desire to cut down or unsuccessful efforts to control use
- Great deal of time spent obtaining, using, or recovering from use
- Craving, or a strong desire or urge to use substance
- Failure to fulfil major role obligations at work, school, or home due to recurrent opioid use
- Continued use despite recurrent or persistent social or interpersonal problems caused or exacerbated by opioid use
- Giving up or reducing social, occupational, or recreational activities due to opioid use
- Recurrent opioid use in physically hazardous situations
- Continued opioid use despite physical or psychological problems caused or exacerbated by its use
- Tolerance (marked increase in amount; marked decrease in effect)
- Withdrawal syndrome as manifested by cessation of opioids or use of opioids (or a closely related substance) to relieve or avoid withdrawal symptoms

The severity of opioid dependence disorder is rated according to how many of these symptoms are present as follows.

Mild	2-3 symptoms
Moderate	4-5 symptoms
Severe	6 or more symptoms

ICD-10 Criteria for Opioid Dependence Syndrome

Opioid dependence syndrome is defined by the presence of three or more of the following features present simultaneously at any one time in the preceding year:

- a strong desire or sense of compulsion to take opioids
- difficulties in controlling opioid use
- a physiological withdrawal state
- tolerance
- progressive neglect of alternative pleasures or interests because of opioid use
- persisting with opioid use despite clear evidence of overtly harmful consequences

Further assessment of opioid dependent clients commencing OST

1. Comprehensive clinical and psychosocial history

The prescribing doctor should obtain a comprehensive clinical and psychosocial history including corroboration from other sources as necessary. The history should include:

a. types of drugs used (including alcohol) and duration of use; their mode of administration and level of injecting risk practices. Scales such as the Injecting Risk Scale (IRS) (at Annex 1) can be used to standardise injecting risk data and enable more objective risk monitoring over time.

b. history of drug overdose and other injecting related disease and injury (including BBIs)

c. previous drug treatment/rehabilitation attempts and outcomes

d. co-morbidities (including mental health, sexual health and chronic pain and other conditions)

e. current accommodation situation, employment status and sources of income; criminal history (including time spent in prison) and outstanding legal matters

f. assessment of family situation (including number of dependants), and level of social support. The appropriateness of involvement of family or other potential supports should also be considered at this time

The doctor should discuss the treatment goals with the client (and other supports as appropriate), ensuring that these are realistic and achievable. Once agreed, these should be recorded in the client's medical file.

The doctor should also assess whether the client would benefit from an intensive case management approach led by a nurse and or a counsellor, depending on what issues need to be closely monitored to achieve the treatment goals.

2. Physical and mental state examination:

General physical and mental state examination should be conducted based on the medical history and presenting circumstances.

Clients should be assessed for opioid intoxication and withdrawal, taking account of reported last drug use, noting that intoxication with central nervous system (CNS) depressants such as benzodiazepines and alcohol increase the risk for overdose in combination with methadone. The Intoxication Scale at Annex 2 should be used for this.

Opioid withdrawal severity indicates dependence severity and may inform the timing and amount of first dose of methadone. There are several scales available to measure withdrawal severity including the Clinical Opioid Withdrawal Scale (COWS) at Annex 3. However, observation of withdrawal symptoms prior to OST commencement should not be mandatory and should only be required if there are good reasons to doubt that the person is opioid dependent.

Full examination should include inspection of potential injecting sites including the cubital fossae, neck and groin areas.

3. Laboratory investigations should include:

- Full blood count and biochemistry screen including liver function testing (poor liver function affecting methadone metabolism)
- HIV, HBV, HCV and TB screening
- Sexual health screening if indicated by clinical history and examination
- Chest X-Ray (to screen for TB and tobacco-related harms if relevant)
- Baseline ECG (to exclude pre-existing QT prolongation – see later section)
- Urine drug screening (UDS) is useful to corroborate client history and establish recent opioid and other substance use but should not be mandatory. Delays in obtaining UDS results should also not delay treatment initiation where the diagnosis of opioid dependence can be clearly established. Also be aware of the potential for an adversarial relationship with the client if the use of UDS is poorly communicated as being due to a lack of trust in what the client is reporting.
- Investigations for other conditions, either related to the presenting condition or to the client's drug use should also be undertaken as needed.

  All of this information should be systematically recorded in the client's medical file.

Phases of methadone treatment

1. Methadone Induction - initiation: +/- 6 weeks (1 – 3 months)
2. Methadone stabilisation and maintenance therapy: variable and case dependent

1. Methadone Induction:

Goal:

To safely achieve an adequate dose of methadone, stabilise the client's opioid use, and to address co-existing conditions.

Key Objectives:

- reduction of withdrawal symptoms
- reduction of cravings

- reduced non-medical opioid and other drug use
- client satisfaction and engagement in treatment

Induction Dose of methadone:

The calculation of the starting dose should take the following factors into account:

- The right dose varies from person to person and from time to time
- Illicit heroin varies in purity from area to area and from time to time
- The characteristics of the various medications vary e.g. methadone is a long-acting opioid
- Too much medication can be fatal and too little is unlikely to be effective

The general guideline is: **START LOW AND GO SLOW**

Day 1	The initial dose generally ranges between 10 and 20mg. • If tolerance to opioids is high, the usual dose is between 25 and 40mg • In cases where tolerance is low or uncertain, a dose between 10 and 20mg is more appropriate
Day 1 to 3	• Same dose as the client will experience increasing effects from the methadone each day
Days 4 - 7	• Consider dose increments of 5-10mg every 3 days

The reason the dose is increased only after 3 days is that the client will experience increasing pharmacological effects from the methadone each day = "dose accumulation".

The dosing in the first week might proceed like this if only started on 10 – 20 mg dose:

Methadone 10 to 20 mg/day	days 1 to 3
Methadone 25 mg/day	days 4 to 6
Methadone 30 mg/day	days 7 to 9

The total increase in Week 1 should not exceed 20mg.

Clients do not need to be re-assessed by their medical prescriber until the end of the first week of methadone dosing unless there are particular concerns such as intoxicated presentations.

Dose increments of 5–10 mg every 3–5 days will result in most clients being on doses of between:

- 30 and 50 mg by the end of the first week
- 40 to 60 mg by the end of the second week

Typical reasons for dose increase include:

- Signs and symptoms of opioid withdrawal
- Amount and/or frequency of illicit opioid use not decreasing
- Persistent cravings for opioids
- Failure to achieve a dose that blocks the euphoria of short acting non-medical opioids

2. Methadone stabilisation and maintenance therapy

- It can take six weeks or more before the dose needed for stabilisation is reached
- While the level of opioid dependence may affect methadone's induction dose, lower doses being recommended when clients' opioid dependence is less severe – there is no evidence this affects their final stabilisation dose
- Methadone doses of 60 - 120 mg/day are known to be more effective than lower doses to achieve retention in treatment, reduction in non-medical opioid use and associated high-risk injecting behaviours. Achieving this therapeutic dosage range should be strongly encouraged
- In some instances, due to a client's high tolerance, metabolism or use of other medications (e.g. ART) higher doses may be required but this is unusual
- Clients should be re-assessed by their prescriber whenever their dose has increased by a further 20 mg
- It should be noted that doses > 100 mg also present additional risk for those receiving unsupervised takeaway doses
- Doses > 150 mg/day are generally associated with little additional benefit and may be associated with dose-related adverse events
- Increasing methadone dose > 200 mg should require a second medical opinion

Methadone's stabilisation phase can be considered to have reached:

- When the client feels comfortable throughout 24 hours
- When there is no subjective or objective withdrawal before doses
- When there is no sedation or euphoria after doses.

The stabilisation dose of methadone should only need to be adjusted, upwards if the client starts to experience withdrawal symptoms – or downwards is he/she starts to experience unwanted side effects e.g. drowsiness.

Stabilised OST clients should be allowed to adjust their own methadone dose within a safe range, for e.g. by up to 10 mg per week - in 5 mg increments - both upward and downward - with prior approval from their prescriber, providing they do not present in an intoxicated state. Prescriptions should be written accordingly.

Duration of methadone maintenance therapy (MMT)

- All clients should be continued on MMT for a period of at least one year and probably more, until the goals of the treatment have been reached
- All decisions regarding duration of treatment should preferably be taken jointly by the treatment team and the client
- The ongoing treatment status of all those on MMT should be thoroughly reviewed at least once every 12 months.

Frequency of client follow-up

- Should be decided on a case-by-case basis by the multidisciplinary team in consultation with the client and involve the client's case manager if one has been assigned

- The prescribing doctor should ensure the methadone dose continues to be adequate and attendance is regular to meet treatment goals - as well as assess and treat any other clinical issues as they arise
- The client should be specifically asked about any intercurrent drug use (against evidence of any intoxicated presentations), injecting risk behaviours, and any side effects of methadone being experienced. Potential injecting sites should only be examined if there is reason to believe the person is continuing to inject drugs; any injecting-related cutaneous problems identified should be actively treated
- The counsellor/social worker should assist in achieving stable accommodation and a legal source of income
- Complex clients should be assigned to a case manager where possible, who should be responsible for coordinating all aspects of their care, including referrals to other health and social welfare agencies. The case manager should also monitor their clients' treatment goals, and adjust these as appropriate
- Complex clients should also be reviewed by the multidisciplinary team at regular 'client case management' meetings, which should be held fortnightly and at least monthly. New and existing clients developing challenging issues should also be assessed for their need of case management at such meetings, thereby also sharing staff's respective clinical practice wisdom among the team
- Urine drug testing is only required if the client is engaging in problematic intercurrent drug use or if receiving unsupervised takeaway methadone dosing
- Other laboratory investigations should be undertaken as needed and include regular HIV and other BBI testing
- Annual ECG to screen for QTc interval prolongation is also recommended for some OST clients as follows.

QTc Interval Prolongation

- Varies depending on heart rate, age and gender (male)
- Influenced by electrolyte balance, medications (including methadone), and cardiac ischaemia
- Associated with increased risk of cardiovascular co-morbidities, including sudden cardiac death, increasing with age
- Evident in 10-15% of people on methadone maintenance treatment
- Although the evidence base for routine ECG screening is limited - it is recommended that a baseline ECG be obtained before initiation of methadone.

QTc interval (in milliseconds) risk levels based on gender

Normal (low risk)	Men ≤ 450 ms	Women ≤ 470 ms
Mildly elevated	Men 450 - 500 ms	Women 470 - 500 ms
Severe (high risk)	> 500 ms regardless of gender	

OST clients should have an ECG in the following circumstances:

- OST clients receiving > 100 mg methadone (annually)
- Previous personal or family history of QT interval prolongation
- Symptoms such as palpitations, syncope, dizziness and unexplained seizures

- Cardiac abnormalities such as ischaemia, endocarditis, valve disease
- Severe electrolyte disturbances resulting from infection, vomiting, diarrhoea
- Those OST clients also taking atypical antipsychotics, tricyclic antidepressants, certain antimicrobials, and antiretroviral agents.

Dispensing methadone

- The administration of methadone doses should always be supervised i.e. directly observed treatment (DOT) for the first few months until the client is stabilised
- Prior to administering the medication, the dispensing staff (nurse/pharmacist) must:
  - confirm client's identity and current, valid prescription
  - assess whether the client is intoxicated using the Intoxication Scale (as per later 'Assessment of Intoxication' section)
  - conduct the necessary documentation procedures i.e. entering the dispensing dose in the register, obtaining the signature of the client

Special Issues related to methadone dosage

Missed Methadone Doses:

- Methadone is a respiratory depressant
- Clients on daily dosing become tolerant to this effect, but on missing doses there is variable and unpredictable loss of this tolerance
- If the client loses tolerance to opioids and methadone is started again on the same stabilisation dose, there is risk of respiratory depression and even death

Generally, the following schedule is considered safe and effective providing the client is not re-presenting for dosing in an intoxicated state, requiring medical assessment.

If the client has missed:

One day	No change in dose
Two days	Administer normal dose
Three days	Administer half the last dose, only requiring consultation with a doctor if dosing staff member has particular concerns. This can be by phone.
Four days	Recommence at 40mg or half dose - whichever is the lower in consultation with a doctor. This can be by phone unless there are particular concerns.
Five plus days	Regard this as a new induction requiring re-assessment by prescribing doctor.

Deferred Dispensing

Clients should not receive methadone if they appear to be intoxicated, particularly with alcohol or benzodiazepines (see later sections re: 'assessment of Intoxication' and 'approaches to intercurrent drug use')

Mildly intoxicated clients may be asked to wait to be reassessed some hours later prior to administration of methadone.

Split Dosing

Split methadone dosing is rarely necessary and results in lower peak serum levels.

Split dosing can be useful with pregnant clients experiencing persistent nausea but can usually be discontinued within about four weeks.

Replacement of vomited doses

A physician or nurse may replace a vomited dose provided the vomiting was observed by a staff. The following schedule must be followed.

The vomiting occurred:

less than 15 minutes after ingestion	full replacement to be given
between 15 and 30 minutes	half the usual dose to be replaced
more than 30 minutes	no replacement to be given

Nausea / Vomiting

Clients reporting nausea/vomiting prior to dosing should be offered an anti-emetic (prescribed by the doctor and administered, preferably parenterally) such as metoclopramide and dosed 30 minutes later or once symptoms have settled.

Eating prior to dosing may reduce the incidence of nausea and vomiting.

Overdose of Methadone

- Methadone overdose can occur in clinic situations due to human error. Systems should be in place to detect such errors as soon as possible.
- All dosing errors should be immediately reported to the medical doctor in attendance and recorded as a “Critical Incident” in a Methadone Incident Register kept at the OST Clinic.
- All staff should be trained in the emergency management of opioid overdose at orientation and annually thereafter.
- All OST clinics should have a resuscitation trolley stocked with ambu bags, face masks, Guedel’s airways, plastic gloves and other equipment potentially needed in such an event.
- The risk to clients is directly related to their level of opioid tolerance, and their current dose relative to how much additional methadone was administered.
- Methadone’s long duration of effect should also be noted.

Clients within two weeks of commencing methadone treatment i.e. still in the early methadone induction phase who are administered a methadone overdose of ANY magnitude:

- require formal clinical observation for at least 4 hours because their opioid tolerance will be relatively low
- if signs of intoxication continue, more prolonged observation is needed
- this may require transferring the client to the nearest Hospital Emergency Department
- upon recovery - a more gradual induction at lower methadone doses should be commenced

Clients who have been receiving > 40mg methadone/day consistently for two months i.e. those who are stabilised on methadone treatment:

- will generally tolerate up to double their usual dose without significant symptoms.
- for an overdose of greater than double the usual daily dose the client will require clinical observation for at least 4 hours and be transferred to hospital observation if not fully recovered at this time.

Caution regarding Induced Vomiting

- Inducing vomiting may be dangerous and is contra-indicated if the client has any signs of CNS and depression due to methadone overdose. This is because of the risk of aspiration, CNS depression also suppressing the gag reflex.
- Emesis after the first ten minutes is an unsatisfactory means of dealing with methadone overdose anyway.
- However, in circumstances where medical help is not readily available, induction of vomiting (by mechanical stimulation of the pharynx) within 5-10 minutes of ingesting the dose may be appropriate as a first aid measure only.

Conditions warranting additional caution in methadone treatment in general

- Continuing high risk poly drug use
- Concurrent use of other sedating drugs or medications
- Co-occurring alcohol dependence
- Recent history of reduced opioid tolerance
- Medical conditions complicating opioid use
- Clients suffering with chronic pain
- People with serious mental illness
- Medications that affect methadone levels
- Concomitant medical problems

Assessment of Intoxication

Overview

To ensure OST Clinic staff effectively assess clients for intoxication, and do not proceed with methadone dosing where necessary and appropriate.

Considerations

Intoxication occurs when a person's intake of a substance exceeds their tolerance & produces behavioural and/or physical changes. Intoxication can be dangerous because it can increase the risk of opioid overdose and or mask serious illness or injury.

Intercurrent drug use among clients enrolled in OST is common, particularly among the most high-risk clients targeted by low threshold OST programs focused on HIV prevention.

Staff should be aware that intoxication may be as a result of both central nervous system depressant drugs (e.g. opioids such as heroin, buprenorphine, morphine or methadone,

as well as alcohol and benzodiazepines) as well as central nervous system stimulant drugs (e.g. methamphetamines such as yaba).

Accurate assessment of intoxication is crucial to ensure safe methadone dosing. Clients' level of intoxication should be quantified and documented on the Intoxication Scale form (at Annex A), which should be placed in clients' medical files.

Staff responsible for implementing this procedure should be familiar with the Glasgow Coma Scale and the operation of a breathalyser machine to measure blood alcohol levels.

Staff should follow appropriate procedures if clients presenting intoxicated are abusive, aggressive or begin to show signs of overdose.

Procedure

Taking adequate time to perform an intoxication assessment can be useful. Asking the client to wait in the client waiting room for a while can allow further essential observations to occur. This can provide the time to observe their posture/gait as they wait – for example, without the prompt of someone talking to them, do they sit or slump in the chair or 'nod off'?

The 'Intoxication Scale' form (at Annex 2) should be completed for all OST Clinic clients suspected of presenting for their daily methadone dose in an intoxicated state, in accordance with the following guidelines.

- **Speech**
  The way a person speaks is important. Slurred speech may indicate the presence of depressants such as alcohol, benzodiazepines, opioids or psychiatric medication. Agitated or pressured speech may indicate the presence of stimulants such as methamphetamines. This should be recorded on the Intoxication Scale.

- **Best verbal response**
  A person's verbal response should be noted – identical to the Glasgow Coma Scale. Are they speaking at all? If so, what is the content of what they're saying? Are they presenting as confused and disoriented? The most relevant response should be noted on the Best Verbal Response of the Intoxication Scale.

- **Alertness**
  Are they alert and responding normally, or are they drowsy, "nodding off"? If so, how drowsy are they? Do they respond to voice, or only to painful stimuli? Are they responding at all?

- **Best eye response**
  Person's best eye response should be noted – identical to the Glasgow Coma Scale. Is the person spontaneously opening their eyes, or only if you speak to them? While you're noting this, look also at their pupil size.

- **Pupil size**
  Pupil size is a very useful indicator in the assessment of intoxication and identification of drug type involved. 'Pinned' or pin-point pupils is a strong indication of opioid drugs involved, whereas dilated pupils indicate the possibility of stimulant drugs, such as methamphetamines. It should be noted, however, that withdrawal from opioids also produces dilated pupils.

- **Gait**
  Observe posture & stability whilst standing or sitting. Are they unsteady on their feet, or uncoordinated?

- **Orientation to time and place**

  This is a record of a person's verbal response in more detail. Ask them what day of the week it is, or what date it is, and if they know exactly where they are.

- **Blood Alcohol Level (BAL)**

  When a client presents as possibly intoxicated from alcohol, and/or there is a smell of alcohol present, the client should be breathalysed to determine their alcohol level. When a client shows signs of intoxication and their BAL is 0.05% or greater, they should be considered 'intoxicated', and managed as per guidelines below.

Where there is some doubt about a person's intoxication, the medical doctor in attendance should be consulted for second opinion.

Immediate management of persons presenting intoxicated

Performing the Intoxication Scale provides objective evidence of a client's level of intoxication. Clients who are assessed as intoxicated should not be dispensed any methadone that day, and should be managed according to the following guidelines.

- If the client is becoming less responsive staff should first assess the need for emergency medical treatment.
- When there are concerns for a client's safety (but emergency medical treatment is not required), the client should be given the option of remaining at the OST clinic for further clinical observations while alternative arrangements are made.

  All clients remaining on site should be regularly assessed by staff to ensure there is no deterioration in their level of consciousness or overdose occurring. The Intoxication Assessment can be repeated over suitable time intervals (e.g. every 20 minutes), as agreed by the medical doctor in attendance. This will provide clear, documented evidence of any change in the level of intoxication. All assessments and clinical observations should be documented in the clients' medical files.

- If an intoxicated client wishes to leave the Clinic, staff should make all reasonable attempts to ensure the client has somewhere safe to go and is accompanied by someone who is not intoxicated e.g. an outreach worker. If it is necessary, the nurse in charge may authorise a staff member to accompany client to a safe place, so long as sufficient staff remain on site for service operation.
- All intoxicated clients should be provided with relevant safety advice in relation to the risks of any further drug use.
- Any client assessed as being intoxicated who intends to drive a vehicle should be informed that this is dangerous and that the OST Clinic has a duty of care to take all reasonable steps to ensure this does not occur.

Client follow up

Clients re-presenting to the OST Clinic for dosing following a previous assessment of intoxication should be reviewed by a staff member prior to receiving their next methadone dose.

Clients should be counselled about this intoxicated presentation, any reasons behind it should be explored and their current mental state should be assessed and documented in their medical file. Interventions recommended should be discussed, including any referrals made to other services where appropriate.

Clients presenting in an intoxicated state on one or more occasions per week should be reviewed by their methadone prescriber to facilitate an appropriate and therapeutic course of action and have a case management plan implemented as needed.

Approach to Intercurrent Substance Use

For many different reasons, some clients continue to use alcohol or other drugs while enrolled in OST. Although some clients may be able to do this with minimal impairment to their health and wellbeing, others find even low levels of drug use can be sufficient to cause significant medical, psychological, or social harms.

Addressing patterns of substance use that are related to poor outcomes and harms is an important aspect of safe and effective OST. Some clients may inject buprenorphine or methadone to stop injecting other opioids (e.g. heroin). In this situation clients should be supported to move away from injecting these substances.

It is important to establish a therapeutic relationship that encourages open disclosure by clients without fear of recriminations. As with the management of any chronic condition, a partnership approach to addressing substance use should be fostered. This requires that service providers recognise the validity of self-autonomy in client decision-making, but also for the client to recognise the responsibilities of the service provider to ensure the safety of treatment and their role to encourage improvements in the client's clinical condition.

Substance use may be disclosed by clients and should be systematically addressed in clinical reviews. Urine Drug Screens (UDSs) and breath alcohol monitoring can also identify undisclosed substance use.

Continued high-risk intercurrent drug use may also be evidenced by:

- frequent presentations when intoxicated
- evidence of regular drug use on examination (e.g. breath alcohol, recent injecting sites)
- overdoses or other chaotic drug using behaviour
- deteriorating medical, psychological, or social wellbeing related to drug use.

Attempts should be made to stabilise such clients. A clinical review is required of the client's goals regarding their substance use, precipitants to continued drug use, participation in psychosocial interventions and supports, and frequency of clinical reviews and monitoring (including UDS).

Methadone dosing regimens should also be reviewed. This involves:

- ensuring an adequate dose of methadone is prescribed - increases in methadone doses are beneficial in addressing additional opioid use, but less effective in addressing additional alcohol, benzodiazepine or stimulant use - clients on low methadone (< 60 mg) should be encouraged to increase their dose. However, there are fewer benefits in raising dose for clients already on high methadone doses (> 150 mg).
- ensuring the client is taking the methadone as prescribed - review takeaway or unsupervised dosing conditions- clients with high-risk patterns of substance use may require a period of supervised dosing and restricting takeaway or unsupervised doses.

If the client's safety is not at risk from ongoing drug use in combination with their OST, it will generally be in the client's interest to persist with treatment. However, if the risks of combining methadone with other drug use outweigh the benefits of opioid agonist treatment to the client, arranging the client's gradual withdrawal from methadone may be indicated.

Benzodiazepine use disorders in OST populations

While it is estimated that approximately 30–60% of OST clients have used benzodiazepines in the preceding year, only a minority (estimated at 10–20%) are high dose or erratic dependent users. Particular safety concerns arise in clients using benzodiazepines in high doses or erratically, due to the increased risk of overdose, impaired memory and impaired cognition.

These individuals may also experience complications from their benzodiazepine use such as increased anxiety, sleep disorders, intoxicated presentations for dosing, seizures, delirium, overdoses and hospital admissions.

The management of benzodiazepine use disorders in OST clients is complex. It may take several consultations to comprehensively assess a client's benzodiazepine use and how it affects their OST.

Assessment of OST clients using benzodiazepines

1. **Pattern of benzodiazepine use - which involves asking about:**
   - the frequency and amount of use, and how it is administered (e.g. injected versus oral)
   - how benzodiazepine use is affected by other substance use (e.g. opioid or alcohol withdrawal, missed methadone doses)
   - the source of benzodiazepines (e.g. prescriber, or the illicit drug market)
   - the extent of benzodiazepine dependence, including withdrawal phenomena such as seizures, perceptual changes, anxiety or sleep problems.
2. **Adverse events or harms linked to benzodiazepine use Including:**
   - overdoses
   - high-risk behaviours whilst intoxicated (e.g. arguments, crime, injecting risk practices, falls, motor vehicle accidents)
   - memory and cognitive impairments
   - 'emotional blunting'.
   - Concomitant medical and mental health conditions Including:
   - anxiety and depression
   - neurological conditions (e.g. epilepsy)
   - sleep disorders.
3. **Review of OST treatment conditions including:**
   - frequency and attendance at appointments
   - urine drug screen (UDS) results
   - missed doses or intoxicated presentations
   - level of dosing supervision (access to takeaway methadone dosing)
   - adequacy of the methadone dose
   - participation in health and psychosocial services addressing comorbidities.

Is there a therapeutic role for benzodiazepines in OST clients?

As with all medications, potential therapeutic benefits must be balanced against potential adverse consequences, with recognition that risks are increased in particular subgroups.

Extra caution should be shown in clients with:

- current or previous benzodiazepine-related problems
- concomitant conditions that increase the vulnerability to benzodiazepine-opioid interactions (e.g. cognitive or memory impairment, respiratory depression, use of other sedatives, and those with reduced hepatic clearance of benzodiazepines, such as in those with cirrhosis and the elderly).

Benzodiazepines are primarily used for short-term management of sleep disorders and anxiety disorders. These conditions are often chronic for many OST clients so they are unlikely to respond to short-term benzodiazepine treatment. As such benzodiazepines should generally be avoided in OST clients, with greater emphasis on alternative non-pharmacological (e.g. relaxation training and sleep hygiene strategies, CBT for anxiety disorders) or pharmacological approaches for anxiety disorders (e.g. selective serotonin reuptake inhibitors). Specialist assessment and treatment may be indicated for those individuals experiencing severe anxiety or sleep disorders.

A common request by clients is for benzodiazepines to assist in agitation and sleep problems associated with withdrawal from methadone maintenance treatment. As OST withdrawal symptoms tend to last weeks to months, the development of benzodiazepine dependence is a genuine concern if they are used for such prolonged periods.

Additional risks include overdose in those who relapse to illicit opioid use following OST cessation. Nevertheless, there are OST clients without histories of problematic benzodiazepine use who may benefit from short courses (e.g. up to 2–4 weeks) of benzodiazepines, as an adjunct to psychosocial treatment approaches.

Managing benzodiazepine misuse in OST populations

Benzodiazepine misuse describes high-dose and/or binge patterns of use that are associated with adverse events or harms (e.g. overdoses, intoxicated presentations), but not meeting criteria for significant benzodiazepine dependence.

There is only a very limited role for prescribing benzodiazepines in OST clients with benzodiazepine misuse. Efforts should instead be directed to addressing concomitant psychological, medical and social conditions, and minimising the potential for harms arising from benzodiazepine-opioid interactions.

These clients should be subject to regular monitoring and clinical review, which should include education regarding the potential adverse consequences of benzodiazepine use. This should target potential ‘immediate’ effects of benzodiazepine co-intoxication (e.g. impairment of memory, cognition and judgement, and how this can in turn lead to high risk behaviours and harms such as needle sharing, unsafe sex, violence, crime and driving offences), as well as longer term disturbances in sleep and mood. The risk of seizure with sudden supply disruption for benzodiazepine-dependent clients should also be pointed out.

Generally, OST should not be discontinued for persistent benzodiazepine misuse. Instead, risk management strategies should be put in place. A contingency management framework can be incorporated into treatment conditions. For example, treatment conditions (e.g. takeaways, frequency of reviews) can be linked to benzodiazepine use (e.g. UDS results) and evidence of associated harms (e.g. intoxicated presentations).

Stimulant use in OST populations

It is not uncommon for OST clients to report using stimulants, particularly methamphetamine. This may be sporadic, infrequent or regular (including dependent use). As frequency of methamphetamine use increases so does the risk of health and social problems.

Unlike central nervous system (CNS) depressants (e.g. opioids, benzodiazepines and alcohol) - methamphetamine, or other stimulant use, is not associated with increased risk of sedative overdose.

The most common problems seen with methamphetamine use are mental health problems such an anxiety, agitation, misperception, delusions, paranoia, magical thinking, hallucinations and psychosis. Depression is also common in regular users. Regular and dependent users experiencing such mental health problems may require co-management with mental health services.

Common physical health problems include loss of weight and insomnia. Regular or intensive users may be at higher risk of blood borne and sexually transmitted infections due to risky injecting and sexual practices. Endocarditis can also occur in those who inject. Other health problems include cardiac arrhythmias and ischaemia, cerebral haemorrhages and stroke, and hyperthermia.

Regular or intensive methamphetamine use is associated with behavioural problems in clinical settings, such as aggressive behaviour clients attending for OST. Strategies should be in place to clinically assess for methamphetamine use and prevent and manage behavioural incidents.

Some OST clients who use methamphetamines also use sedatives (e.g. cannabis, benzodiazepines, alcohol) to negate feeling over-stimulated or to reduce anxiety or insomnia. Screening for problematic use of sedatives in this population may also be indicated.

Counselling is advised for OST clients experiencing problematic methamphetamine use, including approaches using Cognitive Behavioural Therapy and motivational interviewing.

Alcohol use disorders in OST populations

Particular safety concerns arise in people with alcohol-use disorders, due to the increased risks of overdose, impaired memory and cognitive performance, and altered pharmacokinetics (e.g. liver disease).

Specific strategies should be considered in alcohol dependent clients, including:

- treatment interventions for alcohol dependence (withdrawal, counselling pharmacotherapies with acamprosate or disulfiram)
- increased monitoring by dosing staff (including consideration of the need for regular breath alcohol readings)
- increased frequency of clinical reviews and UDS
- restriction of takeaway or unsupervised dosing

Note that methadone dose increases alone are often not effective in addressing alcohol use and may indeed increase risks of over-sedation.

Client Assessment for Takeaway Methadone Dosing

Studies show that OST programs with takeaway policies have better treatment retention rates than programs that restrict takeaways. The range of benefits of providing OST clients with takeaway methadone include:

- enhanced clients' integration into the community, also reducing their time and travel costs;
- promoting client responsibility for treatment, greater self-autonomy in the management of their condition being consistent with the principles of chronic disease management;
- facilitating OST engagement by enabling clients with travel difficulties, work or other commitments to maintain regular dosing;
- reduced stigma associated with regular attendance at OST clinics, particularly where there are concerns regarding confidentiality for the client;
- better treatment outcomes, by linking positive behaviours e.g. regular attendance for appointments or dosing, cessation of other drug use, to increased access to takeaway doses (consistent with the principles of Contingency Management); and
- reducing the inconvenience and staff cost of daily dispensing for the OST clinic.

However, there are also significant concerns regarding takeaway doses, which include:

- Risk of deliberate or accidental opioid overdose by the client or others, particularly by children and other non-tolerant individuals
- Injection of takeaway medication resulting in overdose, damage to veins or other health problems (all clients receiving takeaway doses should have an inspection of their veins at their regular clinical review)
- Diversion of methadone to others, resulting in poor outcomes for the client themselves, and abuse by others for whom methadone was not prescribed
- Risk of bringing the OST clinic and the OST program more generally into disrepute if seen to be poorly supervised.

Methadone takeaway guidelines should aim to strike a balance between recognition of clients' rights to autonomy, practitioners' duty of care, and public concerns about diversion of medication.

The safety of takeaway methadone is increased by:

- Careful selection of clients suitable for takeaway methadone through assessment and close monitoring by the prescriber and dispenser, and
- Education of clients about the risks.

The risk of diversion is reduced by:

- Clear communication - with the client and relevant others (e.g. family members) regarding the conditions for unsupervised doses, and the responsible storage and use of their medicine. Their explicit consent to verify this understanding should also be obtained and recorded in their medical file;
- Limiting the number of consecutive takeaway doses - especially higher doses of methadone (e.g. >80 mg methadone daily) which carry significant risks if used non-medically by a client or if diverted to others, not on opioid agonist treatment.
- Strict follow up by intervention staff: Intervention should have regular mechanism to follow up with clients and verify the doses taken already and remaining (over phone or home visit). During the home visit, project staff should review the condition along with engagement of caregiver, whether it is in line.

Other precautions to reduce diversion include:

- Dispensing methadone in liquid form; avoiding powder form, which is more readily injected
- Diluting takeaway doses of methadone with purified water to reduce the chance of an entire dose being accidentally swallowed, for example by a child. This also discourages injection (and makes it less harmful to veins if it is injected), and reduces its monetary value on the illicit drug market
- Diluting methadone doses greater than 25mg to 100ml, and smaller doses to 50ml volume
- Dispensing methadone in a child-resistant container
- Ensuring that clients are able to store their containers in a locked box, kept out of view and child reach, or a locked cupboard that is never left unlocked or open – the key stored safely elsewhere.

Assessment of OST client stability

Clients should be formally assessed for 'stability' before take-home methadone dosing is commenced, and focus on the following:

- At least 2 months since enrolment (preferably longer) and not before the client is fully induced and stabilised on a therapeutic methadone dose, needing few dosage adjustments
- Client's current adherence to daily supervised dosing (attending the OST clinic least 25 days a month) and keeping appointments with the treatment team
- Infrequent past use of additional illicit opioids or other drugs (no more than one 'intoxicated' presentation to OST clinic in the last month, which may or may not be confirmed by recent urine drug screen results)
- Stable mental health (e.g. no suicidality, severe anxiety or depression, psychosis)
- Stable accommodation - not street-based
- Client able to demonstrate that he/she has a secure area at home to store medication - particularly if there are children at home, and especially if they are < 5 years old.

Take-home dosing is not recommended in the following situations:

- Poly-substance use
- Recent overdoses or presenting in an intoxicated state for dosing
- Unstable psychiatric conditions
- Client is considered likely to inject take-home doses

Rating client 'stability'

After considering each of these risk factors, the prescriber should apply an overall risk rating as follows.

High Risk	the presence of one or more significant risk factors;
Moderate Risk	presence of some risk factors, but no significant high-risk factors;
Low Risk	no significant risk factors identified.

This stability risk rating recognises that each individual client may have different levels of risk for different factors.

It is recommended that prescribers should tend towards conservative takeaway prescribing, and where prescribers seek to prescribe a greater number of takeaways than is suggested within these guidelines, they should seek advice of a colleague, and clearly document their decision making.

Takeaway Risk Framework

Induction and stabilisation: usually the first 3 months of treatment: no takeaway doses (except in very special circumstances, which should be qualified and clearly documented in the patient medical record)

Maintenance phase: takeaway availability based on risk assessment

High risk	Supervised dosing - no takeaway doses except special circumstances
Moderate risk	0 - 2 takeaways per week
Low risk	2 - 4 takeaways per week

Take-home dosing might progress as follows:

- No take-home doses in the first 2 months of treatment
- Assess stability (once stabilised on methadone) - one take-home dose per week
- Assess stability over one month - two take-home doses per week
- Assess stability over one month - three take-home doses per week
- Assess stability over one month - four take-home doses per week

Weekly doses should only exceed four in exceptional circumstances e.g. COVID-19.

Regular clinical review is essential. All clients receiving unsupervised doses should have:

- a formal clinical review at least every three months by a member of the multidisciplinary team - and more frequently for clients with more complex treatment needs
- regular urine drug screening as part of the risk assessment process
- the reason for any missed appointments should be explored (may include problems with transport, childcare, work)
- clients at high risk (e.g. sedative use, risk of non-medical use of methadone) who routinely miss appointments should have their dosing conditions reviewed.

Management of Methadone Withdrawal

It is appropriate to consider withdrawal from methadone treatment once a client has met their treatment goals. Importantly, the client should be assessed to have been stable on OST for a considerable time (usually more than 1 – 2 years) with good support systems in place, as the withdrawal process itself risks destabilising the client, potentially losing the benefits gained as a result of OST.

Special care should be taken with HIV positive clients receiving ART, as their adherence to this crucial treatment may also be disrupted.

For these reasons a careful assessment of their reasons for seeking to withdraw from OST and the likelihood of a successful withdrawal at that particular time should be undertaken by the prescribing clinician and counsellors involved, in close consultation with the client to ensure that an informed decision about the value of proceeding with this can be made.

Approach to methadone withdrawal

The most common approach for ceasing OST is for the OST client to undertake a gradual tapering of their methadone dose over several months as an outpatient.

This enables time for the client to adjust to the necessary physiological, behavioural and social changes that arise during this process.

Withdrawal severity tends to increase as the dose approaches zero, with peak withdrawal discomfort usually described in the 1–4 weeks after cessation of dosing.

Low severity symptoms (e.g. poor sleep, mood disturbances, cravings) often persist for several months.

Careful monitoring is required to identify a relapse or deterioration in the client's condition, indicating the need to reconsider the treatment plan.

It is also noteworthy that clients' risk of opioid overdose starts increasing as their opioid tolerance is decreasing during methadone withdrawal. Specific safety advice about this increased overdose risk should be given to clients when they commence methadone withdrawal.

Reduction in Methadone daily doses

Most clients tolerate dose reductions of 5–10% decrements every 1 to 4 weeks over a 12-week period. The rate of weekly methadone withdrawal may proceed as follows.

Over 50 mg/day	5 - 10 mg
30-50 mg/day	2.5 mg
Less than 30 mg/day	1 - 2 mg

However, this may vary according to the indications and time frame for withdrawal, and the clinical stability of the client. There should be a flexible approach with dosage adjustments upwards and downwards made as needed.

Some clients may reach a dosing level (often between 20 and 60 mg) where they feel unable to attempt further methadone dose reductions - either due to withdrawal discomfort, increased use of other drugs, or deterioration in general health and wellbeing. Such clients may benefit from restabilising on a higher methadone dose, reconsidering withdrawal when they feel more ready to undergo this often personally challenging process.

Rapid detoxification (< 1 month)

There are some indications for more rapid withdrawal from methadone. This may include an imminent relocation to an area with no access to OST. In such instances, methadone dose can be reduced by 10 mg, every 3rd or 4th day until a dose of 20mg is reached. Methadone is then reduced by 5 mg every 3rd or 4th day. It should be noted, however, that relapse to opioid use is higher for such rapid withdrawal regimens than for the longer, more tapered regimens.

Psychosocial support

Providing additional psychosocial support for clients undergoing withdrawal from OST is important, and a 6 month after care plan should be developed at the outset of the withdrawal process.

This should include provision of:

- client information and engagement in treatment decision making
- supportive care, including withdrawal counselling (to maintain motivation, provide coping strategies, reduce risk behaviours), peer and self-help groups, family and community supports and securing of stable living arrangements
- regular monitoring and increased frequency of reviews as the withdrawal process becomes more arduous.

Role for ancillary medicines

There may be a role for symptomatic medicine to assist in the management of withdrawal symptoms such as nausea, aches and pains, and diarrhoea.

Caution should be used in prescribing sedatives such as benzodiazepines due to the long-term nature of the sleep problems (weeks to months), and the high risk of dependence or non-medical use of such medicine in opioid users.

Relapse prevention

Once the client has fully withdrawn from methadone, treatment with naltrexone may be considered to reduce their risk of relapse to opioid use. However, it should be noted that

naltrexone – an opioid antagonist – is only effective in blocking the psychoactive effects of opioids, and no other drug classes - the risk of relapse to non-opioid drug use remaining. Clients' continuing adherence to oral naltrexone regimens may also be negatively affected by the uptake of illicit non-opioid drug use.

Clients' risk of opioid overdose also returns as soon as they cease naltrexone treatment. Specific safety advice about this heightened risk should be given to clients when they commence naltrexone maintenance treatment.

For these reasons, clients should be assessed as being highly motivated to cease all illicit drug use and be very stable with strong and sustainable support systems in place - prior to embarking on methadone withdrawal regimens.

Clients should also be assured of re-enrolment in OST in the event of relapse to opioid use.

Emergency management of 'sudden collapse'/decreased level of consciousness

Aim

To ensure the effective assessment and treatment of clients with 'sudden collapse' or decreased level of consciousness.

Background

Opioid overdose is the most common cause of death among people who inject drugs. The immediate availability of emergency assistance is key to improving outcomes of drug overdose.

Common risk factors for opioid overdose include:

- the concurrent use of other central nervous system (CNS) depressant drugs such as benzodiazepines and alcohol
- reduced tolerance to opioids e.g. following detoxification/rehabilitation or incarceration in a closed prison setting

- larger quantity and higher than usual quality of opioids
- injection as a mode of drug administration
- having a systemic infection e.g. pneumonia

The signs of opioid overdose include:

- Pin-point pupils
- Reduced respiratory rate
- Hypotension
- Reduced consciousness/responsiveness

Assessment and Action

D - Danger: assess the scene

- Alert another staff member – ask them to stop further clients from entering the area Move other clients away from the immediate vicinity to the greatest extent possible
- Ensure that client is positioned such that they are easily accessible to resuscitation staff Ensure that sharps and other Worker Health Safety risks are safely removed from area

R - Response (Glasgow Coma Scale)

- Call the person's name, squeeze an earlobe or shoulder or rub their central chest.
- It is important to document a client's initial Glasgow Coma Scale (virtually the same as the Intoxication Scale at Annex 2) as well as their respiratory rate.
- It should be noted that apnoea (when a client is not breathing or making no respiratory effort at all) is a significant clinical indicator.

S - Send for help – call for emergency assistance

A - Assess the Airway

If the client is unconscious:

- Place in left lateral "recovery" position: chin forward to open their airway and mouth downwards to allow drainage of any fluids
- Make sure there is nothing in their throat blocking their airway: clear and open their airway
- Keep their airway open

D - Danger

R - Response (Glasgow Coma Scale)

S - Send for help

A - Airway

B - Breathing

C - Circulation

B - Assess Breathing

Roll the person onto their back and check for breathing:

- Look & feel for chest movements
- Listen & feel for sounds of air escaping from the mouth/nose

If the person starts breathing normally:

- Put them back into the recovery position and administer oxygen via a mask (10 litres/minute) and continue to observe

If the person is hypo-ventilating or not breathing at all:

- Commence Expired Air Respiration (EAR) using an ambu bag and mask

Only insert a Guedel's airway if unable to maintain a patent airway without one, noting the risk of aspiration during insertion in people with a decreased level of consciousness wherein the gag reflex is supressed.

C - Assess Circulation

- Palpate for the carotid pulse after initiating EAR
- Pulse present: continue EAR
- Pulse absent: commence external cardiac compression and continue EAR (= CPR): applying 2 rescue breaths after every 30 chest compressions.

Assess the cause of decreasing level of consciousness

- Check recent drug use history if available
- If opioid overdose is not confirmed, consider stroke, head injury, cerebral haemorrhage or any other relevant history and seek further medical assessment and advice.

Ongoing resuscitation

If the client does not respond after five minutes EAR and still has signs of opioid overdose

- Arrange for the client to be transferred to an emergency centre for further assessment and treatment
- Continue EAR protemp
- Replace all used resuscitation equipment immediately.

If client's breathing responds adequately i.e. breathing at least 4-5 breaths of reasonable depth per minute unassisted

- Gradually decrease oxygen i.e. from 8 litres/minute for 5 minutes to 6 litres/minute for 5 minutes.
- Reassess the client after a further 15 minutes without supplemental oxygen using GCS and oximeter (if available).
- The client should be breathing spontaneously and maintaining oxygen saturation levels of 95% or above on room air before being allowed to leave the premises.

If the client is **maintaining airway, but is still requiring supplemental oxygen** for longer than one hour **and remains hard to rouse**

- Consider involvement of other drugs such as benzodiazepines and or alcohol.

If the client is **unwilling to be transported to hospital** for further observation:

- Ensure they remain at the Clinic or in the company of someone who can summon help if required.

If the **client leaves the Clinic against clinical advice:** document this in their medical file.

- Strongly advise the client against administering any further drugs for at least six hours if they have overdosed on heroin and longer for methadone or benzodiazepines.

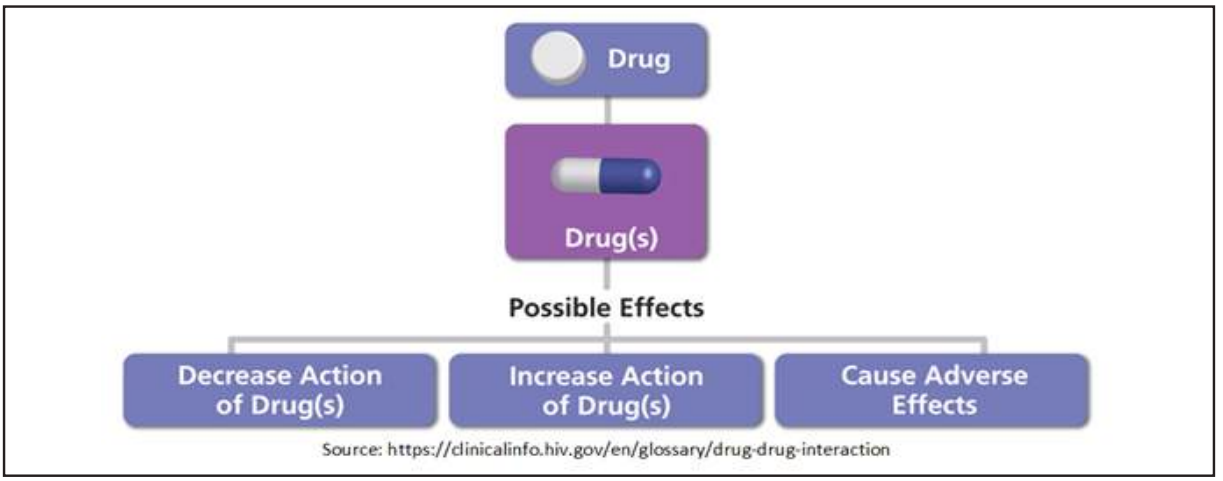
Follow up

- Document all actions taken in the client's file.
- Ensure the client's file is flagged so that further assessment and counselling can occur upon next presentation to the Clinic - prior to receiving their next methadone dose.
- The overdose should be discussed, exploring any reasons for it and ongoing risks.
- The client's mental health status should also be checked to exclude any level of suicidality.

Drug-Drug Interactions between Methadone and Other Drugs

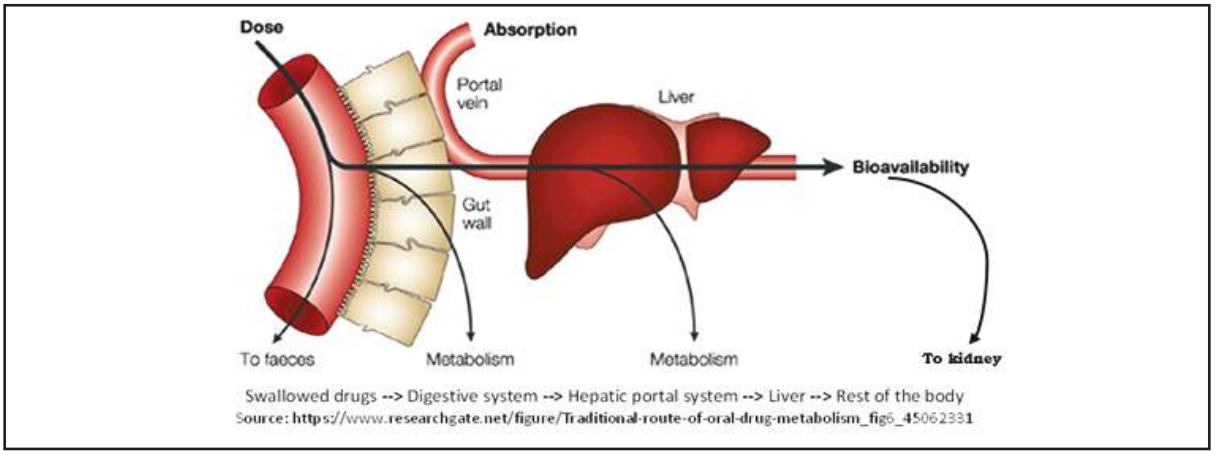
Drug interactions are a leading cause of morbidity and mortality worldwide. Drug interactions can occur through several mechanisms. One or more mechanisms may be involved in the expression of a clinically significant drug interaction. The primary mechanisms of drug interactions include effects of drugs on the hepatic metabolism of pharmaceuticals including effects on cytochrome P450 (CYP) enzymes or effects on glucuronidation; medication effects on the function of the drug transporter, P-glycoprotein, and effects on the absorption of drugs.

Pharmacodynamic interactions are also important. For example, some drugs when taken in combination exhibit synergism that can increase drug effects resulting in toxicity. Conversely, they can decrease drug effects resulting in subtherapeutic drug levels unless dose is increased accordingly. Or they can have direct adverse effects.



Source: https://clinicalinfo.hiv.gov/en/glossary/drug-drug-interaction

Pharmacokinetic and pharmacodynamic properties of drugs may be altered when ≥2 drugs are administered to a patient. Interactions largely occur at the level of drug metabolism but may occur at the level of drug absorption, distribution, or elimination. Also, drug-drug interactions may occur at the level of the receptor (through competitive antagonism); many of which are intentional and produce therapeutic benefit in patients (e.g., antihistamine reversal of histamine effects, naloxone reversal of opioid Central Nervous System depressant effects).



Swallowed drugs --> Digestive system --> Hepatic portal system --> Liver --> Rest of the body
Source: https://www.researchgate.net/figure/Traditional-route-of-oral-drug-metabolism_fig6_45062331

Drug interactions may also occur at a pharmaceutical level because of a physicochemical incompatibility of two medications when combined. Such interactions generally alter the chemical structure of one or both constituents thereby rendering them inactive and potentially dangerous. Alternatively, two drugs simultaneously administered orally may form a complex that can inhibit drug absorption.

Drug-drug interactions at the level of drug metabolism can be somewhat predictable based on prior knowledge of a given drug's biotransformation profile.

Despite these limitations, information pertaining to a drug's impact on drug-metabolizing enzymes (e.g., substrate, inducer, inhibitor) can be useful in understanding if the drug has the potential to compete for, induce, or inhibit the metabolism of another drug (e.g., enzyme inhibition enhanced effect vs enzyme induction → diminished effect) of a drug-drug interaction.

Methadone and buprenorphine are frequently prescribed for the treatment of opioid dependence. Patients needing treatment with these medications often have co-occurring physical and mental illnesses that require pharmaceutical treatment. The misuse of illicit substances is also common in opioid-dependent individuals. On the other hand, many drug users may have HIV and or other co-infections. Treatment with HIV antiretroviral therapy (ART) and other medications for co-infections are known to help people living with HIV to live longer, healthier lives and reduces the risk of HIV transmission. But drug-drug interactions can complicate the treatment. Therefore, before recommending an HIV treatment regimen, opioid substitution therapy, and any other co-infection management, health care providers should carefully consider potential drug-drug interactions. They should also ask about other medications a person may be taking in order to reduce the risk of potentially toxic drug interactions.

Drug Interactions of Clinical Significance in Substance Use Disorders

HIV infection

It is important to be aware of clinically significant drug interactions that may occur between opioids, treatments used to manage opioid dependence and medications used to treat HIV given the high prevalence of HIV in opioid dependent patients.

There are several medical treatments used to treat opioid dependence. These include the medical withdrawal from opioids and maintenance treatment with methadone or buprenorphine.

Medical withdrawal from opioids has been shown to have a high relapse rate. The lifestyle instability often associated with such relapse to illicit injection drug use may increase associated injecting and sexual risk practices, with implications for individuals' own health as well as others they are in contact with. Instability resulting from relapse to drug use may also reduce adherence to ART which is crucial to ensure its longer-term effectiveness. Non-adherence to ART also potentially increases HIV transmission to others. For these reasons opioid substitution therapy is recommended over opioid withdrawal treatment for opioid dependence among opioid-dependent people with HIV infection.

Interactions between methadone and several HIV therapies demonstrate the potential for adverse drug effects that can occur when absorption of a drug is altered. Methadone is a full μ opioid receptor agonist. A general effect of such drugs is to slow gastrointestinal mobility. Methadone has been associated with significant decreases in the absorption of HIV medications that are sensitive to the acidic environment of the stomach. Adverse events related to inhibition of the clearance of opioid medications have the potential to produce opioid toxicity including altered cognition and decreased respiration.

Of equal concern are the drug interactions that result in diminished concentrations of opioid therapies. Co-administration of a medication that induces methadone metabolism could result in a reduction of plasma methadone concentrations in a methadone- maintained patient leading to the potential development of opioid withdrawal symptoms.

Opioid withdrawal may lead to resumption of illicit opioid use or the use of other illicit substances and associated high-risk behaviors risk.

The NNRTIs, as well as the protease inhibitor combination drugs have been linked to opioid withdrawal in methadone-maintained patients. Notably, these medications were not associated with the onset of opioid withdrawal among buprenorphine-maintained individuals despite marked reductions in buprenorphine plasma concentrations.

Description of the interactions

Potential clinically significant interaction - likely to require additional monitoring, alteration of drug dosage or timing of administration

Lopinavir/ritonavir (LPV/r) + methadone

Coadministration of methadone (5 mg single dose) and lopinavir/ritonavir (400/100 mg twice daily) decreased methadone Cmax and AUC by 45% and 53% (n=11). Increase dose of methadone according to patients' withdrawal symptoms. In addition, caution should be exercised as both drugs have risks of QT prolongation. ECG monitoring is recommended.

Efavirenz (EFV) + methadone

Coadministration of efavirenz (600 mg daily) to subjects stable on methadone maintenance (35-100 mg daily) decreased methadone Cmax (45%) and AUC (52%) (n=11) so the methadone dose needs to be increased by~22% to alleviate withdrawal symptoms. Patients should be monitored for signs of withdrawal and their methadone dose increased as required.

Efavirenz (EFV) + buprenorphine

Coadministration of efavirenz (600 mg once daily) significantly decreased buprenorphine AUC by 50% in HIV subjects; however, no subject developed an opioid withdrawal syndrome. Efavirenz concentrations remained in the therapeutic range. Dose adjustments are unlikely to be required but consider monitoring for withdrawal symptoms.

Atazanavir + ritonavir (ATV/r) + buprenorphine

Coadministration of atazanavir/ritonavir (300/100 mg once daily) and buprenorphine (stable maintenance dose, once daily) increased buprenorphine AUC, Cmax and Cmin by 67%, 37% and 69%, respectively; norbuprenorphine increased by ~2-fold. If co-administered, monitor for sedation and cognitive effects and consider a dose reduction of buprenorphine.

Atazanavir + ritonavir (ATV/r) + methadone

Coadministration with atazanavir/ritonavir has not been studied. No significant effect on methadone concentrations was observed when co-administered with atazanavir alone. There are no data for coadministration with atazanavir/ritonavir 300/100 mg, but low dose ritonavir has been shown to have no significant effect on methadone concentrations. No dosage adjustment is necessary but consider monitoring for withdrawal symptoms. However, the product label for atazanavir advises caution when prescribing atazanavir with medicinal products which have the potential to increase the QT interval; methadone has a known risk of QT prolongation. ECG monitoring is recommended.

Lopinavir/ritonavir (LPV/r) + naloxone

Coadministration has not been studied. Naloxone is mainly glucuronidated by UGT2B7. Naloxone concentrations may decrease due to induction of UGT2B7 by lopinavir/ritonavir. Naloxone dosage might need to be increased in case of incomplete opioid intoxication reversal.

Atazanavir + ritonavir (ATV/r) + naloxone

Coadministration has not been studied. Naloxone is mainly glucuronidated by UGT2B7. Naloxone concentrations may decrease due to induction of UGT2B7 by atazanavir/ritonavir. Naloxone dosage might need to be increased in case of incomplete opioid intoxication reversal.

Potential weak interaction - additional action/monitoring or dosage adjustment is unlikely to be required

Zidovudine (AZT, ZDV) + methadone

Coadministration of zidovudine (200 mg every 4 hours) and methadone (30-90 mg daily) had no effect on methadone pharmacokinetics, but increased zidovudine AUC (29-43%). Clinical monitoring for potential toxicity of zidovudine may be required.

No clinically significant interaction expected

- Lopinavir/ritonavir (LPV/r) + Buprenorphine
- Tenofovir-DF (TDF) + Methadone
- Zidovudine (AZT, ZDV) + Buprenorphine
- Emtricitabine (FTC) + Buprenorphine
- Tenofovir-DF (TDF) + Buprenorphine
- Emtricitabine (FTC) + Methadone
- Dolutegravir (DTG) + Buprenorphine
- Dolutegravir (DTG) + Methadone
- Emtricitabine/Tenofovir alafenamide (FTC/TAF) + Buprenorphine
- Emtricitabine/Tenofovir alafenamide (FTC/TAF) + Methadone
- Emtricitabine/Tenofovir-DF (FTC/TDF) + Buprenorphine
- Emtricitabine/Tenofovir-DF (FTC/TDF) + Methadone
- Efavirenz (EFV) + Naloxone
- Emtricitabine (FTC) + Naloxone
- Tenofovir-DF (TDF) + Naloxone
- Dolutegravir (DTG) + Naloxone
- Emtricitabine/Tenofovir alafenamide (FTC/TAF) + Naloxone
- Emtricitabine/Tenofovir-DF (FTC/TDF) + Naloxone
- Zidovudine (AZT, ZDV) + Naloxone
- Abacavir (ABC) + Naltrexone
- Efavirenz (EFV) + Naltrexone
- Lamivudine (3TC) + Naltrexone
- Lopinavir/ritonavir (LPV/r) + Naltrexone
- Nevirapine (NVP) + Naltrexone
- Tenofovir-DF (TDF) + Naltrexone
- Zidovudine (AZT, ZDV) + Naltrexone
- Emtricitabine (FTC) + Naltrexone
- Atazanavir + ritonavir (ATV/r) + Naltrexone
- Dolutegravir/Lamivudine (DTG/3TC) + Naltrexone
- Dolutegravir/Abacavir/ Lamivudine (DTG/ABC/3TC) + Naltrexone

Summary of interactions

Tuberculosis– Tuberculosis is a common opportunistic infection often seen in those with immunosuppressed states such as HIV/AIDS. Tuberculosis can also occur independently and is seen more frequently in heroin-dependent individuals. Medications used to treat tuberculosis can have significant interactions with methadone. The best known of these interactions is that of rifampin (a first-line agent used in combination with isoniazid for the treatment of tuberculosis infection) which induces methadone metabolism. Rifampin has been associated with significant opioid withdrawal symptoms in methadone-maintained patients. Some patients receiving buprenorphine also develop opioid withdrawal symptoms when treated with rifampin.

Rifabutin can be substituted for rifampicin in those requiring tuberculosis treatment who are also receiving methadone treatment. While rifabutin can also induce CYP 3A4, it appears not to produce the withdrawal symptoms rifampin does.

Rifampin is also used as a treatment for methicillin-resistant staphylococcus aureus (MRSA). This increasingly common infection also occurs in methadone-treated patients who will similarly require substitution of rifampicin with rifabutin in this clinical circumstance.

Hepatitis C– Hepatitis C virus (HCV) is a frequent infection in opioid-dependent patients with the reported rate of HCV in injection drug users in Bangladesh to be estimated at approximately 40%. Injection drug use remains the most common cause of HCV in Bangladesh. The standard of care for HCV is a combined regimen consisting of sofosbuvir and velpatasvir. These medications have a high rate of adverse symptoms and side effects associated with their use, experienced as opioid withdrawal among opioid-dependent patients on methadone and ART.

Description of the interactions

Emtricitabine / Tenofovir + Sofosbuvir / Velpatasvir

Coadministration of tenofovir disoproxil fumarate with velpatasvir may increase the plasma concentrations of tenofovir. The proposed mechanism is inhibition of the P-glycoprotein (P-gp) transporter-mediated efflux of tenofovir DF by velpatasvir. In pharmacokinetic studies, administration of various tenofovir DF-containing products or antiretroviral regimens in combination with sofosbuvir-velpatasvir 400 mg-100 mg once daily to healthy volunteers resulted in approximately 1.3- to 1.8-fold increases in tenofovir systemic exposure (AUC). In contrast, no significant interaction was observed with tenofovir alafenamide. Caution is advised when tenofovir disoproxil fumarate is prescribed with sofosbuvir-velpatasvir. Renal function should be closely monitored.

Efavirenz / Emtricitabine / Tenofovir + Sofosbuvir / Velpatasvir

Coadministration with potent or moderate inducers of CYP450 isoenzymes may decrease the plasma concentrations of velpatasvir, which has been shown in vitro to be metabolized by CYP450 2B6, 2C8, and 3A4. The interaction has been studied with efavirenz, a moderate CYP450 2B6 and 3A4 inducer. In 14 healthy volunteers, administration

of sofosbuvir-velpatasvir 400 mg -100 mg once daily with efavirenz/emtricitabine/ tenofovir disoproxil fumarate 600 mg/200 mg/300 mg once daily decreased mean velpatasvir peak plasma concentration (Cmax), systemic exposure (AUC) and trough plasma concentration (Cmin) by 47%, 53% and 57%, respectively, compared to administration of sofosbuvir- velpatasvir alone. No clinically relevant pharmacokinetic changes were observed for sofosbuvir or its predominant circulating metabolite, GS-331007. Given the risk of reduced viral susceptibility and resistance development associated with subtherapeutic antiviral drug levels, concomitant use of sofosbuvir-velpatasvir with potent or moderate CYP450 inducers is not recommended.

Other Infections– There are four antibiotic treatments, specifically antifungal and antibacterial therapies that cause potentially clinically significant drug interactions with methadone as a result of inhibition of CYP 450 3A4 which can increase methadone concentrations. Both the antifungal medications fluconazole[i] and voriconizole are inhibitors of this enzyme and might increase methadone plasma concentrations when administered concomitantly. Similarly, ciprofloxacin inhibits CYP450 3A4. Because buprenorphine is a substrate of CYP450 3A4, its plasma concentrations would likely be increased in the presence of any of these antibiotics as well. However, the ceiling effect for opioid agonist effects of buprenorphine could diminish any potential opioid toxicity.

Anxiolytics– The use of anxiolytic medications, benzodiazepines and sedative hypnotics by those with opioid dependence and those being treated with buprenorphine or methadone is common.

The anxiolytics share common pharmacological properties of sedation and altered cognition. In combination with methadone or buprenorphine, these drugs have potential for significant harm. Opioids such as methadone and, to a lesser extent, buprenorphine with its partial agonist effect, can decrease respiration through agonist action at mu receptors in the medullary respiratory center. Benzodiazepines (and alcohol) act synergistically in that these drugs facilitate inhibition at gamma-aminobutyric acid (GABA) receptors and alcohol decreases the excitatory effect of glutamate at N-methyl-D-aspartic acid (NMDA) receptors. These mechanisms may help to explain fatal overdose in the presence of opioids and/or benzodiazepines and alcohol.

Anticonvulsants- Anticonvulsant medications are commonly prescribed to patients being treated with methadone or buprenorphine to treat either seizure disorders or mental illnesses including bipolar disorder and schizoaffective disorder. Several anticonvulsants have clinically significant drug interactions with methadone. Carbamazepine, phenytoin, and phenobarbital are all inducers of CYP450 3A4 and have been associated with opioid withdrawal when administered to methadone-maintained patients. For this reason larger doses of methadone have been required in patients treated with anticonvulsants that induce methadone metabolism.

Interactions between Opioids and Other Abused Substances

Psychostimulants: Cocaine and Methamphetamine

Recently, it has been found that cocaine can significantly diminish buprenorphine concentrations. This may be the result of cocaine having an effect on inducing buprenorphine metabolism through induction of CYP450 3A477 or through induction of Pglycoprotein.

Stimulants used to treat attention deficit hyperactivity disorder (ADHD) include methylphenidate, amphetamine, and pemoline. To date, no clinically important drug interactions have been reported between methadone or buprenorphine and these medications.

References

In press. Karan, L.; McCance-Katz, EF. Pharmacokinetics. In: Kosten, TR.; Gorelick, D.; Fiellin, D., editors. Principles of Addiction Medicine.

The American Journal on Addictions. (2003). Pharmacologic treatments for heroin and cocaine dependence. Kleber HD. 12(Suppl): S1–4.

Harvard Review of Psychiatry. (2004). Office based treatment of opioid dependence with buprenorphine. McCance-Katz EF. 12:321–338. [PubMed: 15764468]

Annex 1: The Injecting Risk Questionnaire (IRQ)

INJECTING RISK QUESTIONNAIRE (IRQ)

Assessment date :
Assessed by :
Client ID :
Client Name :
Gender : ☐ Male ☐ Female ☐ Transgender
Age (Yrs) :
Primary drug(s) : ☐ Non-crack cocaine ☐ Alcohol
[Please tick (√) in : ☐ Crack ☐ Poly Drug
appropriate box] : ☐ Opiates ☐ Marijuana
☐ Other

Proceed with interview only if respondent has injected a drug in the last 4 weeks.

The first two questions are about sharing injecting equipment in general.

Sharing mean using someone else's equipment, which has already been used, or someone using yours, regardless of whether you were both present at the time. Injecting equipment includes needles, syringes, filters, spoons and cookers, and washouts.

	Frequently	Sometimes	Hardly ever	Never
1. During the last 4 weeks, how often have you shared injecting equipment?				
2. During the last 4 weeks, with how many different people have you shared injecting equipment?	..... Number of people			

The next questions are about using other people's equipment or them using yours. I will also ask you with how many different people you have done any of these things. Finally, I will ask your age and type of drug you mainly inject. During the last 4 weeks, how often have you done any of the following things

	Frequently	Sometimes	Hardly ever	Never
3. Given or lent used needles/syringes to a sexual partner?				
4. Given or lent used needles/syringes to a friend or acquaintance?				
5. Given or lent used needles/syringes to a stranger?				
6. Injected with needles/syringes that had already been used by a sexual partner?				
7. Injected with needles/syringes that had already been used by a friend or acquaintance?				

	Frequently	Sometimes	Hardly ever	Never
8. Injected with needles/syringes that had already been used by a stranger?				
9. Filled your syringe from one that had already been used by someone else?				
10. Let someone else fill their syringe with a syringe you had already used?				
11. Drawn up from a container or spoon into which someone else had put a used syringe?				
12. Put a used needle into a container or spoon that was then used by someone else?				
13. Used a filter into which someone else had put a used syringe?				
14. Let someone else use a filter into which you had put a used syringe?				
15. Used the same water or bleach as someone else for flushing out or cleaning?				
16. Used old syringes that had been kept in the same container or 'sin bin' as someone else's old syringes?				
17. During the last 4 weeks, with how many different people have you done any of the things on this page?	..... Number of people			

Annex 2: The Intoxication Scale

Intoxication Scale

To be completed for all persons who are refused methadone dosing due to drug or alcohol intoxication

Date: ...../...../..... Name: .....

What drugs has person used in last 24 hours? (tick all that apply)

☐ Heroin ☐ Cocaine ☐ Methamphetamines (including speed, crystal meth)
☐ Benzodiazepines ☐ Methadone ☐ Other opioid
☐ Buprenorphine ☐ Alcohol ☐ Won't answer ☐ Other, specify:.....

Time: **Tick one response for the following**	Time: **Tick one response for the following**	Time: **Tick one response for the following**
Speech o Slurred o Normal o Agitated or pressured	Speech o Slurred o Normal o Agitatedor pressured	Speech o Slurred o Normal o Agitated or pressured
Best verbal response o Clear, oriented response o Confused response o Inappropriate words o Incomprehensible sounds o No verbal response	Best verbal response o Clear, oriented response o Confused response o Inappropriate words o Incomprehensible sounds o No verbal response	Best verbal response o Clear, oriented response o Confused response o Inappropriate words o Incomprehensible sounds o No verbal response
Alertness o Alert, responsive o Slightly drowsy o Very drowsy, butresponds to voice o Very drowsy, only responds to painful stimuli	Alertness o Alert, responsive o Slightly drowsy o Very drowsy, but responds to voice o Very drowsy, only responds to painful stimuli	Alertness o Alert, responsive o Slightly drowsy o Very drowsy, butresponds to voice o Very drowsy, only responds to painful stimuli
Best eye response o Eyes open spontaneously o Eyes open to verbal command o Eyes open to pain o No eye opening	Best eye response o Eyes open spontaneously o Eyes open to verbal command o Eyes open topain o No eye opening	Best eye response o Eyes open spontaneously o Eyes open to verbal command o Eyes open to pain o No eye opening
Pupil size o Pin-point o normal in room light o dilated	Pupil size o pin-point o normal in room light o dilated	Pupil size o pin-point o normal inroom light o dilated
Gait o Impaired o normal	Gait o Impaired o normal	Gait o Impaired o normal
Orientation to time/place o Knows where they are and day/date o Shows some confusion o Unable to determine/refuses to answer	Orientation to time/place o Knows where they are and day/date o Shows some confusion o Unable to determine/refuses to answer	Orientation to time/place o Knows where they are and day/date o Shows some confusion o Unable to determine/refuses to answer
Breathalyser result: (if applicable)	Breathalyser result: (if applicable)	Breathalyser result: (if applicable)

Staff assessment as to all drug types implicated in intoxication:

NOTE: Tick all that apply, which may include drugs not disclosed as having been used by person.

Central nervous system *depressants*:	**Central nervous system *stimulants*:**
☐Opioids (including buprenorphine/other opioid	☐Methamphetamines (including yaba)
☐Benzodiazepines	☐Alcohol
☐Other ***please specify:***	☐Other, ***please specify***
☐Other, ***please specify***	

Where possible/ appropriate, consider performing a routine set of observations on client.

Other clinical notes:

.....

.....

.....

.....

Outcome – please tick one for each question.

Did person remain on site for further monitoring?

☐Yes ☐No

Was safer drug using advice provided?

☐Yes ☐Unable to do so before client left ☐ Other:

Were you able to contact nominated person (eg friend or family member)?

☐Yes ☐No, declined ☐No, unable to offer before client left ☐ Other:

Was any transport arranged, either to safe place/other location?

☐Yes ☐No, declined ☐No, unable to offer before client left ☐ Other:

Staff name & designation..... Date: .....

Signature.....

Annex 3: The Clinical Opiate Withdrawal Scale (COWS)

CLINICAL OPIATE WITHDRAWAL SCALE (COWS)

Flowsheet for measuring symptoms over a period of time during methadone induction

Assessment date :
Assessed by :
Client ID :
Client Name :
Gender : ☐ Male ☐ Female ☐ Transgender
Age (Yrs) :
Primary drug(s) : ☐ Non-crack cocaine ☐ Alcohol
[Please tick (√) in : ☐ Crack ☐ Poly Drug
appropriate box] : ☐ Opiates ☐ Marijuana
☐ Other

Enter scores at time zero, 30 minutes after first dose, 2 hours after first dose, etc.				
Times:				
Resting Pulse Rate (record beats per minute) Measured after patient is sitting or lying for one minute 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120				
Sweating over past ½ hour not accounted for by room temperature or patient activity. 0 no reportof chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face				
Restlessness Observation during assessment 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds				
Pupil size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible				
Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort				

Runny nose or tearing Not accounted for by cold symptoms or allergies 0 not present 1 nasalstuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks				
GI Upset over last ½ hour 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhoea 5 Multiple episodes of diarrhoea or vomiting				
Tremor observation of outstretched hands 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching				
Yawning Observation during assessment 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute				
Anxiety or Irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult				
Gooseflesh skin 0 skin is smooth 3 pilo-erection of skin can be felt or hairs standing up on arms 5 prominent pilo-erection				
Total scores				
Observer's initials				

Score:

5-12 = mild;

13-24 = moderate;

25-36 = moderately severe;

more than 36 = severe withdrawal

Use of COWS in methadone induction

		Methadone dose
Initial Dose	Mild (COWS score 5-12)	No Methadone
	Moderate (COWS score 13-24)	10 mg
	Moderately severe (COWS score 25-36)	10-20 mg
	Severe withdrawal (COWS score >36)	20-30 mg
	Heavily dependentusers	25-40 mg
2nd dose+4Hours (minimum)	Depending on COWS	5-30

Annex 4: The Essential Medicines List for OST Clinics in Bangladesh

Essential Medicines List for OST Clinics, Bangladesh	
SL No.	**Generic**
1.	Cap. Cefixime 200mg
2.	Tab. Azithromycin 500mg
3.	Cap. Ciprofloxacin 500mg
4.	Cap. Flucloxacillin 500mg
5.	Tab. Metronidazole 400mg
6.	Tab. Ibuprofen 200mg
7.	Cap. Omeprazole 20mg
8.	Tab. Amitriptyline HCL 25mg
9.	Tab. Loratidine 10mg
10.	Salbutamol HFA inhaler (MDI) 100mcg/puff
11.	Beclomethasone HFA inhaler 250mcg/puff
12.	Tab.Prednisolone 20mg
13.	Cream Betamethasone 0.1% + Neomycin 0.5%
14.	Tab. Vit B1,6,12
15.	Tab. Ascorbic Acid 250mg
16.	Cream Permethrine 15gm
17.	Cream Clotrimazole 1%
18.	Tab. Paracetamol 500mg
19.	Glucose ORS Saline
20.	Miconazole base oral gel 2%
21.	Povidone Iodine Solution 100ml
22.	Chlorhexidine Hand Rub 0.5% (250ml)
23.	Tab. Ondansetron 4mg
24.	Tab. Warfarin 5mg
25.	Tab. Docuset Sodium 120mg
26.	Syp. Lactulose 100ml
27.	Tab. Hydrochlorothiazide 25mg
28.	Tab. Diazepam 5mg
29.	Cream Gentamycin 0.3%
30.	Tab. Mirtazapine 15 mg
31.	Tab. Quetiapine 25 mg
32.	Tab Olanzepine 5 mg
33.	Tab. Dapoxetine 30 mg
34.	Tab. Sodium Valproate 500 mg
35.	Inj. Naloxone

C: Psychosocial Management standard operating guidelines

Psycho-Social Interventions in OST

Preamble

Psychosocial management is a key ingredient for success of any intervention targeting behaviour change. This is especially true for working with people who are marginalised due to widespread misconception, stigma, and discrimination. This is also the case for the drug users in general and specifically people who inject drugs (PWID). Due to the complex interplay of the nature of drug, health consequences, and behaviour patterns, these individuals live in a resource constrained setting where they often lack shelter, housing, educational opportunities, access to health and stable occupation. Their complexities in life increase manifolds when they have physical and psychological disorders coupled with drug use, which is often the case.

Psychosocial support for PWID has been well regarded in improving their adherence to treatment and contributing to their enhanced well-being. This psychosocial guideline will present strategies, approaches and recommendations for ensuring psychosocial support for the PWIDs in OST service delivery setting.

The content of this guideline has been selected based on thorough review of the internationally available guidelines, in-depth interview with counsellors working in the OST care context, and stakeholder consultation with professionals working with PWID. It presents evidence-based strategies for improving the psychosocial state of OST clients.

Who this guideline is for?

This guideline is specifically designed to support the counsellors working in the OST care context. This will be useful firstly, in orienting the newly recruited counsellors and secondly as a handy reference guide for the more experienced counsellors working in OST. Additionally, this guideline will be useful for other health professionals and case managers in gaining an overview of the psychosocial support strategies relevant to OST clients.

Key terms in understanding opioid dependence and psychosocial support

Drug dependence and addiction

The difference between drug dependence and addiction can be difficult to understand. Some organisations have different definitions, use the words interchangeably or even abandon both terms altogether, “substance use disorder” often being the preferred term in the scientific community. (Also see earlier sections on Assessment of Opioid Dependence which includes the sets of criteria used in the DSM-5 and ICD-10).

When people use the term “dependence,” they are usually referring to a physical dependence on a substance. Dependence is characterised by the physical symptoms of tolerance and withdrawal. While it is possible to have a physical “dependence” without having an “addiction”, substance dependence can be its precursor.

“Addiction” is sometimes delineated as being when substance use becomes the main priority of the person, regardless of the harm this may cause to themselves or others. Using these definitions, drug addiction is a more severe level of dependence.

Tolerance

A condition, resulting from persistent use of a drug, characterised by a markedly diminished effect with regular use of the same dose of the drug or by a need to increase the dose markedly

over time to achieve the same desired effect. Tolerance is one of the two prime indications of physical dependence on a drug, the other being a characteristic withdrawal syndrome (see substance withdrawal). Development of drug tolerance involves several mechanisms, including pharmacological ones i.e. metabolic tolerance and pharmacodynamic tolerance, and a behavioural one i.e. a behavioural conditioning process).(American Psychological Association, 2020).

Withdrawal

A group of symptoms of variable clustering and degree of severity which occurs on cessation or reduction of use of a psychoactive substance that has been taken repeatedly, usually for a prolonged period and/or in high doses. The syndrome may be accompanied by signs of physiological disturbance. A withdrawal syndrome is one of the indicators of a dependence syndrome (World Health Organization, 2008).

Relapse

The recurrence of a disorder or disease after a period of improvement or apparent 'cure'. The term also refers to recurrence of substance use after a period of abstinence (American Psychological Association, 2020).

Assessment

A systematic process of obtaining information from a person and using it to make inferences or clinical judgments about them. In a clinical context, this process is known as a psychological assessment (American Psychological Association, 2020). Assessment process may range from observation, in-depth clinical interview, structured interview or administration of psychological scale and tests.

Treatment plan

The recommended steps of intervention that the therapist or counsellor devises after an assessment of the client has been completed (American Psychological Association, 2020).

Social integration

The process by which separate groups are combined into a unified society, especially when this is pursued as a deliberate policy. It implies a coming together based on individual acceptance of the members of other groups(American Psychological Association, 2020).

Rehabilitation

The process of bringing an individual to a condition of health or useful and constructive activity, restoring to the fullest possible degree his or her independence, well-being, and level of functioning following injury, disability, or disorder. It involves providing appropriate resources, such as treatment or training, to enable such a person (e.g., one who has had a stroke) to redevelop skills and abilities he or she had acquired previously or to compensate for their loss(American Psychological Association, 2020).

Psychotropic medication

Any medication that has the capacity to affecting the mind, emotions, and behaviour. These are usually prescribed to treat psychological disorders, however, some of these may be misused due to their psychoactive and addictive properties.

References

American Psychological Association. (2020). APA Online Dictionary of Psychology. Retrieved November, 26, 2020, 2020, from https://dictionary.apa.org/

World Health Organization. (2008). Operational guidelines for the management of opioid dependence in the South-East Asia Region: WHO Regional Office for South-East Asia.

Case Management in the OST context

Case management in the context of OST is defined as a process that involves the designation of a primary worker whose responsibilities include the ongoing assessment of the client and his/her problems, ongoing adjustment of the treatment plan, linking to and coordination of required clinical and psychosocial services, monitoring and support, developing and implementing a discharge plan when a treatment goals have been reached, and advocating for the client (Ontario Addiction Services Advisory Council, 2000).

OST clients often have a range of diverse needs arising from their medical, psychological, social, interpersonal, occupational, and legal aspects of their lives. The complex interplay of issues arising in all these and other domains can make it difficult to address these in a singular fashion. When an individual service provider knows about and treats only a single aspect of the complex problem, it can be less than optimal.

Additionally, access to services is often limited for individuals with complex needs and referral is often ineffective without intensive follow up. A more coordinated, integrated and holistic approach tailored to the client's particular needs is often necessary. A case management approach is therefore crucial where a designated care provider has a more holistic understanding of the individual's situation, is able to articulate the client's range of support needs, challenges and resources, linking the individual with resources and interventions best suited for him/her, and tracking progress and outcomes of interventions, adjusting them as needed over time.

Key Functions of Case Management

- ✓ Assessment
- ✓ Planning
- ✓ Linkage
- ✓ Monitoring
- ✓ Advocacy

Which clients should be case managed?

Case management is especially useful in the treatment of clients with severe and complex problems that may involve multiple different types of care givers and service agencies. In the context of limited manpower, it is important to identify the sub-group of OST clients who will benefit the most from the case management approach most.

Generally, clients with significant physical, psychological and social needs who are at the greatest risk of destabilisation and relapse to risky drug use should be identified and prioritised for case management. Key case management domains in the OST clinic context may include the following.

- Drug & alcohol use and dependence
- HIV risk behaviours
- Medical conditions (including HIV, HCV, TB)
- Serious mental health conditions
- Accommodation
- Employment

Case management can also be required even where the OST Clinic provides integrated primary health care i.e. where the range of clients' needs from the key domains are provided under a single roof.

Effectiveness of Case Management

OST programs that include some form of case management and counselling show better results to those that provide methadone as a stand-alone intervention. Case management contributes to enhanced motivation, enhanced treatment retention, improved treatment outcomes, decreased use of illegal opioids and other substances and improved overall functioning in the areas of criminality, homelessness, mental health and vocational and educational involvement.

The Case Management Process

Case management involves the coordination of services for people with complex needs. Co-ordinating the continuity of care and support to ensure that the multiple immediate and longer-term needs of the client are addressed. It is individually tailored and longitudinal work - moving in steps and adapting to the client's changing health and situation as he or she makes progress over time.

With a major focus on the removal of barriers and obstacles, case management needs to be individualised, comprehensive, flexible and personal. Success of case management depends on the positive therapeutic relationship between the client and the case manager, who can also be a care provider for some aspects of the client's issues and needs. The case manager may be expected either to link their client to services or to actually provide most of the services, depending on the resources and availability of services, within the OST Clinic and the community.

The case management process starts with assignment of a case manager to a client. Once a new client is assigned, the case manager moves across the key functions of case management with the client.

Assessment: Ongoing assessment is the heart of individualised and comprehensive case management. Careful assessment of pressing immediate concerns, long term needs and goals as well as available resources of the clients themselves is necessary. Assessment may include the history and present state of drug use, legal, medical, psychological, occupational, residential and relational aspects of the client's life. Baseline assessment serves as the basis, but case managers should be mindful that assessment is never complete and ongoing data and other information about the specific client should be continuously accumulated in the case management file of the client.

Planning: The second step it to prioritise and plan for the needs identified in the assessment phase. Although, immediate goals and dealing with unforeseen crises may be prioritised by case managed clients, the overall longer-term goals should be identified and kept in clear focus for successful planning. Identifying and deciding suitable intervention options and linking them with existing resources needs to be done continuously over time.

Linkage: One of the most visible roles of the case manager is the linkage and referral where he/she directly connects the client to a desired service. Referral can be within centre (in case of integrated service delivery clinics) or to an outside centre (in case of stand-alone clinics). Careful consideration of needs should occur before making or pursuing a referral. Regular communication between the organisations may serve well in ensuring consistency in coordinating treatment referral. This should occur with the client's full knowledge, and their consent should be sought for information-sharing of a personal, confidential nature between agencies. Developing and keeping a contextualised referral directory is essential and may prove extremely useful for case managers.

Monitoring: It is essential to monitor if services are being provided as planned and whether the progress is being made as expected. In cases where the progress is not being achieved, a though analysis may be required to find out what is not working and why. Monitoring also provides useful information for case mangers regarding strengths and barriers of the referral service/s and contributes in future service planning.

Advocacy: The clients who benefit most from case management are usually those with the most complex needs and should generally only be a small proportion of the overall OST population at any one time. But ignored, they can have a disproportionate impact on Clinics' overall effectiveness, which relies on attracting and retaining such high risk PWID.

Additionally, it should be noted that the more complex OST clients often face challenges in accessing appropriate care, experiencing stigmatisation and discrimination by mainstream services and authorities related to their histories of illicit drug-related behaviours. Advocacy, is therefore a crucial component in case management for ensuring access to service and overall wellbeing of these OST clients.

Becoming an Effective Case Manager

Case managers should be assigned on the basis of what the key issues are for a particular client. Those with mainly physical issues might be assigned to a nurse or doctor, whereas those with psychosocial issues might be assigned to a counsellor or peer worker. Effective case managers have several characteristics which are necessary for the task including the following list. Attitude, intention and effort to serve the client group

- Awareness of personal beliefs and biases
- Knowledge and skills as well as the awareness about the limits of knowledge and expertise
- Well informed about local resources and sources of support
- Knowledge about available services
- Understanding of the challenges and their impacts on both clients and providers
- Openness to access support
- Cultural sensitivity

Regular Case Management meetings

Case managers should aim to meet with clients assigned to them on a fortnightly basis to monitor their progress in reaching their treatment goals, and other aspects of their treatment plans, making adjustments to these as necessary.

It is also recommended that OST Clinics hold on-site multi-disciplinary Client Case Management meetings involving all staff at least monthly where newly enrolled complex clients can be allocated to an appropriate case manager, depending on which issues (clinical or psychosocial) prevail.

Existing clients presenting new challenges can also be assessed for the need for case management at these meetings. The progress of OST clients currently being case managed can also be shared with other members of the multidisciplinary team at these meetings – such meetings also providing an important opportunity for knowledge and skills sharing among members of the OST Clinic team.

Social Support for OST clients including peer counselling and advocacy

When professionals discuss psychosocial service delivery, the psycho-part often receives much attention and effort that the social-part, which is often left only minimally addressed. It is also sometimes assumed that if the psychological part is addressed, the client will be able to automatically manage the social part themselves. Psychosocial guidelines rarely talk about social intervention beyond family and peer support. Professionals working in OST settings should advocate for the social welfare as well as the social support of their clients.

Priority Social Welfare Support Area for OST clients

Accommodation

Securing stable accommodation for the OST clients is essential for regaining their normal life and functioning. It is preferred that such accommodation is away from drug hot-spots and other cues that increase the risk of relapse and destabilisation of clients' social situation. In the case of street-based clients, who have lost contact with their families, group housing may be arranged if feasible.

Apart from clients' wellbeing, stable accommodation is crucial from program perspective as well. A number of OST clients are lost to follow-up; ensuring a stable accommodation may reduce the rate of such client loss. It is also essential for reducing potential risks associated with takeaway methadone dosing.

Educational and skills- training

Identifying educational and skills-training opportunities for the OST client can increase their hope and employability. Engagement into such programs can contribute to breaking drug-related risk behaviour patterns by placing the client away from the risk context, and by re-integrating him/her closer to a regular functional life.

Identification of skills training areas should fit well with the individual clients and his/her preferences. Peer support workers and counsellors can provide useful information in this regard.

Employment

Opioid dependent PWID are often engaged full time in different drug-related activities before their enrolment in the OST program. They can then suddenly find a large amount of free time which they previously used for acquiring drugs and the money needed to buy drugs (often through illegal means). Engagement in employment may help them not only use their time in more productive way, but also help them gain confidence and greater purpose in life.

Identifying employment opportunities to secure a legal income for the OST clients is a major challenge. Professionals working with OST clients repeatedly reported the usefulness of such opportunities in sustaining stability of the clients.

Advocacy with the prospective employers can be useful for the clients. Additionally, ongoing advocacy may be required regarding their need to visit OST centre regularly in office times, which the employer may not accept otherwise.

Social Support for OST clients

Spouses, family members, peers, and neighbourhood factors have been shown to play key roles in both an individual's drug dependence and gaining stability on OST. Social factors have been found to be important in influencing retention in treatment and ultimate recovery.

Impact of Social Support

- Creates a sense of belongingness and inclusion
- Creates a sense of safety and security
- Reduced stress, isolation and loneliness
- Enhanced sense of meaning and purpose
- Hope and optimism about the future
- Provides an opportunity to escape the narrow world of one's own concerns
- Counteracts shame, isolation and secrecy

Different forms Social Supports Required to OST Clients

Family Support

Support from partners and family members has been reported as a critical component in medication adherence among PWID (Moran, Knudsen, & Snyder, 2019). Improved family relationships is important for ensuring support and encouraging change for individuals dealing with drug dependence (Moran et al., 2019).

Engagement of the family and caregivers can serve as additional support or as an extension to the service delivery team in stabilising the OST client. The following activities can be considered for acquiring family support.

Family meetings: Family members often have unanswered queries and concerns regarding the clients, drug use, OST services. Meeting with them can be useful in clarifying those which in turn improve their communication and relationship with the client. But the client needs to agree to such meetings in advance.

Feedback: A two-way feedback can enhance communication, confidence, and trust between the family, client and the service provider. The issue of confidentiality should be carefully considered in providing feedback.

Family counselling: Involving the family members in counselling sessions with the OST clients can help in gaining a sense of ownership and responsibility in both parties. This is crucial for a healthy and supportive relationship between the client and the family.

Family support groups: Support groups for the family members can be a useful idea to help them share their emotions, unspoken words, concerns and to learn from other families regarding management of these concerns and challenges. In the context of stigma and secrecy, these groups can be the only opportunity for many families to share their thoughts to a non-professional community.

Community support

People in the community may be affected by drug-related activities in their local area (e.g. illegal activities including petty theft, unsafe disposal of needle-syringes). Drug users often become the scapegoat for other problems in the society as well. Changes in community perception, stigma and discrimination is essential for ensuring wellbeing and stability of the OST clients. Community participation is also required for smooth operation OST Clinics and its related services (e.g. NSP) in the community.

The public health benefits of OST for the community and individuals can be emphasised in sensitisation programs. The following sensitization activities can be useful to establish acceptance of OST clients and the services they need.

Meeting with community leaders: Community leaders, social activists, police personnel and other key influencing individuals can be invited to the advocacy meetings to orient

them about nature of the OST programs, its benefits and importance. When these key stakeholders in the local community become supportive to the OST program, other community members are also more likely to accept it.

Awareness program: Awareness in the community can be raised through public campaigns, open days, public seminars,and posters. These might focus on general issues such as illicit drug use and associated harms, harm reduction, OST, and treatment options.

Media: Electronic and print media can also play an important role in creating awareness and sensitising community on a wider scale. Health awareness programs, advertisements, documentaries, case studies and success stories can be published in the media including social media platforms.

Self Help Groups

Self-help groups can provide material assistance as well as emotional support to its members. These small voluntary groups enhance a greater sense of personal identity (Katz, 1986). Self-help groups are inexpensive options for providing important psychosocial support to the OST clients.

Peer support

Peers play an important role in the social sphere of the drug users as they often have limited social connection with others. The peers can exert considerable influence on maintaining or recovering from drug taking behaviours. Peer support is therefore, highly regarded as a valuable and vital component in promoting OST and is often the most suitable and sustainable way to encourage ongoing service delivery. Due to their similar experiential context, peers can often understand and communicate with other PWID more effectively and gain their trust.

Peer support has been found to be associated with increased satisfaction with treatment, increased treatment retention, improved relationship with providers, and reduced relapse in substance intervention (Sharon Reif et al., 2014)

Some OST Clinics intensively use peer support in the form of outreach work. Although outreach workers can also include non-peers, the use of peers is generally perceived as being more effective. However, the problems faced by peers themselves can occasionally hamper structured service delivery. For this reason, close monitoring, training, and support of peer outreach workers needs to be ensured.

Peer support can be used for many other purposes too including awareness-raising, motivational work. Experience-sharing, needle syringe program delivery, making contact with the most at-risk PWID for enrolment into OST, linkage and referral support, making contact with clients lost to follow up and advocacy on their behalf.

Peer Counselling

Peer counselling is a semi-formal form of support where an OST client shares concerns and experiences with the aim of receiving support from a peer. The peer counsellor serves as an independent living model for the client (peer). Both clients and peer-counsellors share similar perspectives but the latter usually have a wider perspective due to experience and training.

There are several differences between peer counselling and formal professional counselling which often get mixed up due to inappropriate understanding of the peer counselling concept. Some of these differences are presented below.

Peer Counselling	Professional Counselling
Learning from peer/examples (personal)	Learning from analysis (impersonal)
Mostly look for problem outside the client	Mostly look for problem inside the client
Lesser boundaries of work	Work boundaries are strictly mentioned
Semi-formal/informal in nature	Formal in nature
Personal sharing more common	Personal sharing generally not recommended

Advocacy for Social Support

OST clients often face many challenges including limited access to appropriate care, experiencing stigma and discrimination, criminalisation by mainstream society, and limited social support in many areas. Advocacy is therefore a crucial component in all OST Clinics. Effective advocacy can enhance the overall quality of services and contribute to significantly reducing public health concerns.

Advocacy for OST clients need to done at multiple levels and in parallel.

Government level: Advocacy with all levels of Government to reform unsupportive policy frameworks; develop more functional policies and laws; development of new services or increasing to the capacity of existing services; OST clients' inclusion in social safety nets and social protection.

Community level: Advocacy at community level is vital to increase public awareness, promote de-stigmatisation; increase access to social services; and maximise social integration.

Family level: Advocacy at family level may focus on reintegration and inclusion, access to support; access to shelter and ensuring other rights.

Especially considering the resource-constrained Bangladesh context, existing opportunities such as vocational, educational, shelter, and legal supports are often not accessible to socially marginalised groups such as PWID. Advocacy should also focus on promoting these forms of social welfare support for OST clients.

Brief interventions

Psychosocial support is a major component in successful OST implementation. However, in a resource constrained setting it is not always possible to provide intensive counselling or psychotherapy for every client. Moreover, many of the clients often do not show readiness for intensive psychological support and not all clients need it.

Brief interventions can be a useful option to increase access to psychosocial support in the OST context. Its utility has been proven for OST clients in India and other countries in reducing their drug using risk behaviour (Varshney et al., 2016).

Brief interventions aim to help clients reduce their drug use and risk behaviour through a brief form of advice or counselling. Usually brief interventions range from 5 minutes (for brief advice) to 15-30 minutes (for brief counselling). Occasionally, the length may extend further where motivational interviewing is also conducted.

Brief interventions involve several different but inter-related activities, namely screening, motivational interviewing, information, counselling, and skills training. The behaviour change process often takes a long time. Even with motivational interviewing, moving from one step to the next is not immediate. The client may come repeatedly with new concerns,

queries, and challenges, where brief intervention can be extremely useful in quickly addressing these though advice, information or counselling without needing to wait for the scheduled formal counselling session.

Brief Interventions can be deliverable by a wide range of professionals working in a range of settings (e.g. community care, OST Clinics, NSPs). It is useful for a range of drug-using clients and needs for example, overdose prevention, safer injecting techniques, controlled drug use, and treatment adherence.

Brief intervention

- ✓ Personalized
- ✓ 5-30 Minutes
- ✓ Short-term goal
- ✓ Cost-effective
- ✓ Can be delivered with limited training
- ✓ Suitable for a range of setting
- ✓ Referral for advanced need

Brief intervention is not suitable for intensive problems for which medical or psychological therapy may be required. Referral or formal counselling should be considered in such cases. However, brief intervention can support or motivate the clients for accessing those services.

Components of Brief Intervention

Research findings suggested at least six components contribute consistently to the effectiveness of Brief Intervention. These components, often summarised in the acronym FRAMES includes Feedback, Responsibility, Advice, Menu of options, Empathy and Self efficacy.

Feedback: Clients need personalised feedback relevant to their state and behaviour. Rapport, long-term observation and structured assessment are important for such feedback provision. Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) can be useful for assessment and personalised feedback. A translated and validated Bangla version of the tool (ASSIST V3.0 Bangla) is also available (Hossain et al., 2018).

Responsibility: Brief intervention values understood choice. The clients need to see and take responsibility of their own behaviour and relevant change.

Advice: Clients are often unaware of the impact of their actions, patterns of behaviour and their consequences. The service provider needs to provide clear advice regarding the risk and consideration for changing behaviour. Such advice needs to be delivered in a sensitive and non-confrontational manner.

Menu of options: Clients often have a narrowed understanding of what to do or what can be done. People around them on the other hand provide instructions on what they think the person should be doing. Brief intervention provided, in the form of advice, presents the client a menu of choices they can consider for themselves. Providing choices reinforces the sense of personal control and responsibility for making change and strengthen the clients' motivation for change.

Empathy: A warm, non-judgmental, non-confronting approach is necessary for effective brief interventions. Empathy allows the service provider to acquire the perspective of the client while the client can see the reflection of understating, concern and care in the provider.

Self-efficacy: Encouragement is necessary for the client to feel optimism to attain chosen goals. When people believe or feel that they 'can do', it increases the likelihood of making effort in that direction. This effort in turns raises possibility of success.

Motivational Interviewing

Motivational interviewing (MI) was developed by Mil ler and Rollnick (2002) and is a widely used interviewing and behaviour change technique in the context of OST. MI is a specialised interviewing strategy used to encourage clients to work toward their treatment goals and promote internally motivated behaviour change. Drug users can find themselves in

situations where their decision making and motivation to make changes is impaired due to the complex interplay of cognitive, behavioural, social and biological factors. Therefore, MI is especially valued among professionals working with current and recovering drug users in helping them move through stages of change (Prochaska & DiClemente, 1982).

Motivational interviewing can be used as a stand-alone therapeutic tool. However, it is widely used among other therapeutic procedures as part of an overall psychosocial intervention.

Use of Motivational Interview

- ✓ Increase Awareness
- ✓ Raise Concern
- ✓ Add Perspective
- ✓ Enhance Motivation
- ✓ Engage in Change Process
- ✓ Improve Adherence
- ✓ Sustain Change

MI respects the principle of informed choice and clients' ability change to make better choices. With respect to the client' autonomy, the counsellor works collaboratively to help the client realise what is best for him/her. MI assists a natural process of change and it utilises the relational context between the client and the therapist.

Behaviour Change Model

Having some understanding of the process of change is very useful for a counsellor. The 'Stages of Change model' from Prochaska and DiClemente (1982) is a widely used and valued model in understanding and working with high risk behaviour among PWID. This model helps the counsellor assess the client's readiness to change and decide the next step accordingly. The model suggests five stages in the process of change.

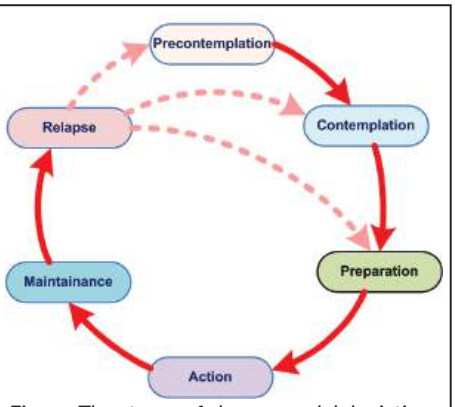


Figure: The stages of change model depicting deferent stages of changes and progression from one stage to the next one.

In the ***pre-contemplation phase*** the client may not see the usefulness of change or is not considering or unwilling to change.

In the ***contemplation phase*** the client may perceive and express some concerns as well as consider the possibility of change however, is still ambivalent about it.

In the ***preparation phase*** the client is interested in and plans for making changes in his/her behaviour in the near future but has not taken that step yet.

In the action phase the client actively take steps demonstrates some changes but may still be a bit unstable in consistency.

Finally, the client achieves and demonstrates consistency in sustaining changed behaviour in the **maintenance stage. Relapse** occurs when the client has ceased continuing and maintaining the changed behaviour and reverts back to previous undesired behaviour.

Although these stages are usually presented in the circular formation, many clients will not move through these in the same circular order. People may reverse several times in different stages before moving towards maintenance.

When in the process of assessment or intervention, the counsellor may find a client in a specific stage, he/she can then decide how to proceed and what information the client is in need of. There is no usefulness in having a lengthy discussion about the cost and benefits of stopping injecting practice when a client is already in the maintenance phase. The following table presents appropriate strategies to be adopted by a client's counsellor at specific stages[2].

[2] Adapted from HIV counselling handbook for the Asia-Pacific. (World Health Organization, 2009)

Clients' Stage of Change	Appropriate motivational strategies
Pre-contemplation The client is not yet considering change or is unwilling or unable to change	• Establish rapport, ask permission, and build trust • Raise doubts or concerns in the client about. substance-using patterns • Express concern about impact on health and lifestyle and keep the door open for discussion
Contemplation The client acknowledges concerns and is considering the possibility of change but is ambivalent and uncertain	• Normalise ambivalence about change • Help the client "tip the decisional balance scales" toward change using evidence from the client's life and health information • Elicit and summarise self-motivational statements of intent and commitment from the client • Elicit ideas regarding the client's perceived self-efficacy and expectations regarding behaviour change and treatment
Preparation The client is committed to and planning to make a change in the near future but is still considering what to do	• Explore behaviour change treatment expectations and the client's role • Clarify the client's own goals • Negotiate a change-or treatment plan and behaviour contract • Consider and address barriers to change • Help the client enlist social support
Action The client is actively taking steps to change but has not yet reached a stable state	• Engage the client in treatment and reinforce the importance of remaining in treatment • Acknowledge difficulties for the client in early stages of change • Help the client identify high-risk situations through a functional analysis and develop appropriate coping strategies to overcome these
Maintenance The client has achieved initial goals such as reduced intercurrent drug use and or injecting risk behaviours and is now working to maintain gains	• Support lifestyle changes • Affirm the client's resolve and self-efficacy • Help the client practice and use new coping strategies to avoid a return to risky injecting drug use • Develop a "fire escape" plan if the client resumes substance use • Review longer-term goals with the client

Principles of Motivational Interviewing

There are four principles of MI which are: express empathy, develop discrepancy, roll with resistance, and support self-efficacy. These four principles are used in an integrated fashion throughout the motivational interviewing process.

Express empathy

Understanding client's perspectives and concerns and being able to communicate this understanding is crucial for any therapeutic work. Empathic style is associated with improved

treatment outcomes. This empathy and its expression are even more important in motivational interviewing. Specifically, due to the fact that many people often disregard the ideas of OST clients, their feelings and perspectives, the counsellor needs to do the following to ensure expression of empathy.

- Demonstrate curiosity and interest in understanding the client
- Listen rather than tell
- Communicate acceptance and respect for the client as well as his/her thoughts and feelings
- Demonstrate an open, non-judgmental and collaborative approach
- Provide support throughout the process

Develop discrepancy

Dissonance is an important pre-requisite for change. In the MI, the therapist tries to identify and raise concern regarding any discrepancy the client have in their actions (behaviour) and intentions (goals). In this process clients can see (maybe for the first time) how his/her current or ongoing behaviour (risk practice, or drug use) interferes with what his/her dreams or goals in life are. A discrepancy between present behaviour and important goals motivates change. The counsellor needs to be aware of the following.

- Remain curious (trying to understand how discrepancy came into existence).
- Invite the client to examine their behaviour and help developing his/her awareness of consequences
- Refrain from taking positions regarding client's choice rather try to understand and explore how his/her choice is connected with his/her goals
- Initiate further curious questions to visualise the discrepancy

Roll with resistance (avoid argument)

Resistance and reluctance to change already established sets of behaviour is common among all of us. Similarly, for OST clients, they may find it difficult to think about or take action towards change. Not only verbalising concerns and worries associated with changes, clients may even resist the idea of changes and present arguments against it. This resistance is part of the process and the counsellor must refrain from providing counter-arguments or from showing flaws in his/her arguments. Such arguments between client and counsellor will only strengthen the client's resistance. The counsellor needs to be mindful of the following.

- Resistance is a signal to change
- Arguments are counter-productive
- Instead, invite new perspectives rather than imposing
- Offer additional and alternative view of what might work better

Support self-efficacy (confidence)

OST clients often present with long history of trying and failing to maintain abstinence or reduced levels of risk behaviour, which in turn reduces their hope for success of future attempts of behaviour change. Raising their self-efficacy belief is of crucial importance in ensuring clients actively engage in the change process. Counsellors need to do the following to boost the confidence in OST clients.

- Elicit self-motivational statements

- Explore examples in client's life where he/she was able to change some aspects
- Appreciate even small changes
- Foster optimism about client's ability to change

Interview techniques useful in MI

Counsellors use a set of verbal and non-verbal micro skills in the process of assessment and intervention irrespective of the therapeutic model he/she chooses to use. All those are useful in motivational interviewing. However, the following section presents a set of five interviewing techniques that are well regarded for their usefulness in MI.

Open-ended questioning

While close-ended questions provided quick answers, open-ended questions are more useful to understand clients' content and their thoughts and feelings as they provide more detailed information. Open-ended questions encourage the client to do most of the talking, help the counsellor to avoid making premature judgments, and keep communication moving forward.

Reflective listening

Reflective listening is a fundamental component of motivational interviewing as well as in many other therapeutic approaches including person-centred therapy, CBT, systemic and family therapy. It involves the therapist listening to the client and reflecting on the information provided by him/her. Reflective listening strengthens the empathic relationship and encourages further exploration of problems and feelings. Reflective listening helps the client by providing a synthesis of content and process, encourages the client to keep talking, strengthens the therapeutic alliance and clarifies what the client means.

Summaries

Summarising consists of grasping the essence of what a client has expressed and communicating it back. Summarisation provides a bridge between different themes from the interview and reconnects the client as well as the counsellor to the most salient ideas from the discussion.

Affirmations

When the counsellor affirms a decision or a behaviour made by the client, it helps boost his/her self-efficacy and confidence. The counsellor needs to provide appropriate and valid affirmation. Complimenting a negative behaviour or falsely appreciating a client's behaviour do more harm than the temporary benefit.

Change talk

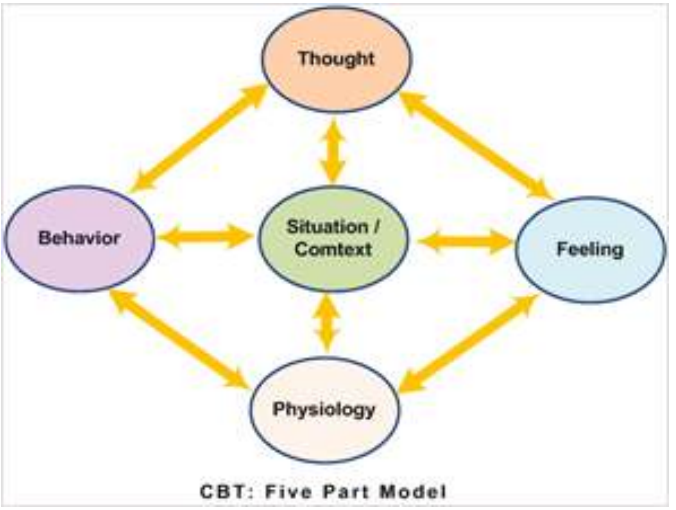
The fundamental task of motivational interviewing is engaging the client in the process of change. Change talk generally refers to client's self-statements that verbalise thoughts, desires and abilities about change and the benefits of these changes. The counsellor may encourage verbalisation of such statements by exploring with client, the perceived benefit of changes.

The Effectiveness of Motivational Interviewing

Counsellors working with OST clients and drug users more generally report the usefulness of motivational Interviewing in managing clients. Research data has also proven motivational Interviewing as more effective and superior to education intervention in reducing high risk injecting behaviours among PWIDs (Bertrand et al., 2015).

Cognitive Behaviour Therapy (CBT)

Cognitive Behaviour Therapy (CBT) is a structured time bound therapeutic process that emphasises on the role of person's belief system and its interaction with behaviour, emotion, physiology and environmental context in psychosocial problems. How we interpret or perceive our environmental context plays a major role in our emotions, physiology and behaviour. Our interpretation and perception of psychosocial context is largely determined by our thinking process. These cognitive processes are explored and amended in CBT. CBT has been proven effective in numerous cultural settings and with large varieties of problems including drug dependency in OST context (Dugosh et al., 2016; Pan et al., 2015).

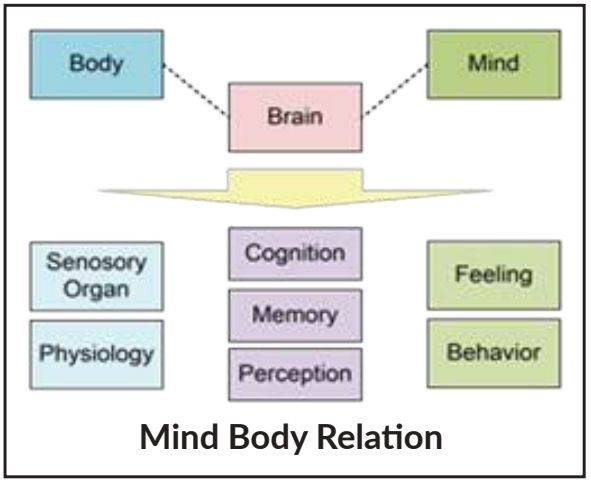


CBT for opioid dependence focuses on the notion that behaviours are function of beliefs. For example, substance use is a learned behaviour capable of being modified through correcting distorted belief patterns.

The "cognitive" component of CBT aims to change distorted, negative thinking styles and rationales for substance use. It follows that once a client has "reprogrammed" their thinking around drug use, they will make better decisions about their use, resulting in reduced use and harm. An example is being able to identify, and hence avoid, high-risk situations which might lead to relapse. The "behavioural" component of CBT aims to reinforce positive behaviour associated with good outcomes. Contingency management is an example.

Mind Body Relation

Understanding the mind body relationship is an important aspect in psychosocial service delivery and reception. If either the counsellor or the clients do not believe or is doubtful about the relationship, it is unlikely that psychological intervention will be bring any benefit for the client. Considering the cultural context of Bangladesh, the client group which is mostly coming from a resource constrained and less educated environment, it is generally observed that it will rely more on biological causation and have little understanding of the mind body relationship.



Mind Body Relation

The counsellor needs to explore what clients believe and, if necessary, communicate the idea of connection between mind and body with him/her before proceeding with psychological interventions. The five-part model (Greenberger & Padesky, 1995) can be useful in explaining the relationship to the client.

Useful CBT Techniques for OST Context

Psycho-education

Psycho-education is an important adjunct to many therapeutic approaches including CBT. It aims to socialise the client in the therapeutic process and to create awareness. Psychoeducation involves providing educative information to the clients regarding the nature of the problems, process and principles of therapy. It prepares the ground for implementing the therapy and engaging the clients in the process. However, the counsellor needs to refrain from long one-way lecturing in the name of psychoeducation, which often disengages the client.

Useful CBT Techniques

- ✓ Psycho-education
- ✓ Pros and cons analysis
- ✓ Problem solving
- ✓ Thought Challenge
- ✓ Behavioural Experiment
- ✓ Relaxation Exercise

Pros and cons analysis

We all use cost benefit analysis in our life in a more or less subtle and automatic way. Pros and cons techniques just do the same in a more purposeful and focused way. The client is instructed to think about and discuss with the counsellor:

I. the benefits of engaging into or continuing a specific behaviour (for e.g., enrolment in OST) and

II. the costs engaging into or continuing a specific behaviour.

It can be done in the other way round as well. It helps the client and the counsellor see the supporting details for changing a behaviour.

Problem solving

This involves making a decision and taking action on a real-life problem or crisis. As a human being all of us are equipped with problem-solving skills and we use it all the time. However, in case of a major problem, we often get stressed and lose some of our capacity to solve that problem.

In the OST context, chronic substance users and HIV positive clients (at the later stages) may have impaired cognitive functioning, making it difficult for them to initiate and adhere to an HIV prevention and treatment program. They may have limited planning and organisation skills, speed of information processing, verbal fluency, and memory functioning. Structured problem-solving approaches, preferably using a problem-solving matrix can be useful for them.

Steps in Problem Solving

1. Clarify the problem
2. Generate alternative options
3. Brainstorm costs and benefits of each option
   - Critically evaluate the costs and benefits
   - Identify the most important benefits and most troubling costs (put a * mark)
4. Choose the most suitable option
5. Develop an action plan for the chosen option
6. Develop skills and strategies necessary to act on that
7. Follow up the outcome

Thought Challenge

This is an effective cognitive technique of CBT for countering irrational and negative thoughts. Different versions of the thought challenge procedure slightly modified from the original one depicted by (Beck, 1995) are available. However, a counsellor can use a version most suitable for his or her client group or can modify the steps keeping the core essence intact. The following is an example of the six-step thought challenge procedure.

1. What is the worst that will happen?
2. What is the evidence supporting this idea?
3. What is the evidence against this idea?
4. What are the benefits of thinking in this way (the worst thing that will happen)?
5. What are the costs of thinking in this way?
6. What should I do about it?

Behavioural Experiment

Behavioural experiments are planned simple experiments to test the validity of a belief. This can be very powerful in modifying faulty beliefs and myths. In the OST context, one of the major barriers of enrolment is the myths regarding OST (methadone) among PWID. One such myth is: "if a person takes methadone, and then takes another drug this will cause instant death". In this case the counsellor may set a behavioural experiment with the client, where the client will interview a fixed number (e.g., 5) of current OST clients receiving methadone to check if they have ever used other substance and have died.

Relaxation Exercise

This behavioural technique is useful for dealing with many different problems and contexts. The process of progressive muscular relaxation along with its rationale is detailed in the self-care section of this guideline.

Contingency Management

Contingency management involves the contingent presentation and withdrawal of reward and punishment. When a desired object or outcome appears after a behaviour it increases the possibility of increasing that behaviour, in the same way as when an undesired object or outcome appears after a behaviour it decreases the possibility of that behaviour being repeated. Contingency management is a method used to change behaviour by rewarding desirable behaviour. In essence, it is a structured system of boundaries agreed upon a priory by the client and the service provider to increase desired behaviours and decrease risky or undesired behaviours of the client.

Due to the simplicity of the basic principle, contingency management can be administered by any staff with relatively little training. Once the system is designed and in place, the contingency management system should be followed precisely as per schedule. It has been associated with greater treatment retention and decreased substance use when used with OST case management. One of the key prerequisites for its effectiveness is inclination and engagement of the client (Rhodes et al., 2003; Sindelar et al., 2007; Bickel et al., 2008; Wood et al., 2006).

Basic Principles in Contingency Management

Learning theories serves as the core principles behind contingency management. Four concepts namely, association, reinforcement, punishment and spread of effect are of particular importance for understanding.

Association: If two different things are presented together or in close proximity, an association is formed. We form numerous associations (healthy and unhealthy) throughout our lives. Learning from association shapes our behaviour. For example, we tend to carry umbrella in a gloomy day because gloomy days are associated with rain.

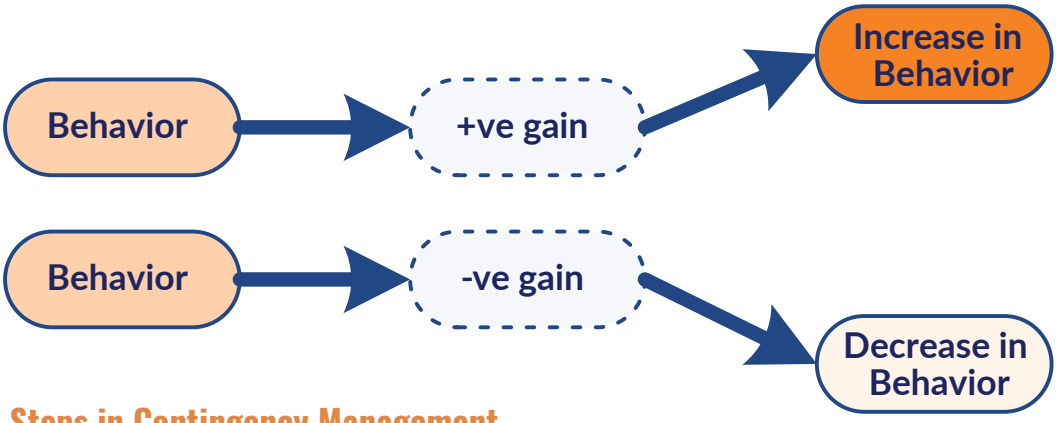
Reinforcement]: A behaviour increases when a desirable outcome occurs or when an undesirable outcome is removed. For example, when we are appreciated (a desirable outcome) for doing something we tend to like that and continue doing that more.

Punishment: Organisms tend to avoid painful conditions or negative consequences. If a behaviour is associated with painful outcome, it is likely that the behaviour will be reduced.

Spread of effect: The effect of reinforcement and punishment stay for a duration of time and the effect gets associated with the behaviours and activities caried out within that time period. Reinforcement and punishment have strongest effect on behaviours nearer (immediately before or after) to their initiation, however have a proportionally small additional effect as well on other behaviours in the vicinity.

Contingency Management Process

PWIDs and other drug users develop numerous unhealthy associations and risky behaviour patterns though the process of association. For example, an ex-drug user might get triggered by seeing injecting practice by current drug users because his memory and bodily reactions are associated with these contexts. When these individuals join the OST program, they may still have many associations and connected risky behaviour patterns, which they often find difficult to modify. Contingency management offers a great hope for these clients in OST. In this process, an individual behaviour is altered by changing its consequence (positive or not positive)



Basic Steps in Contingency Management

Step 1: Identify a target behaviour that needs to be modified or the client wishes to modify.

Step 2: Clearly define the behaviour so that it can be observed or measured. For example, if an OST client is concurrently using benzodiazepines (sleeping pills) which is problematic, the counsellor may want to advise the client e to "reduce his/her interest in benzodiazepines". However, "***interest*** in benzodiazepines" is difficult to observe or measure, so it would be better to revise the target as "reduce his/her ***use*** of benzodiazepines" which is easier to define (number of times, number of pills) and monitor.

The Counsellor also needs to identify the outcome indicators i.e. how to know that the behaviour has changed or reduced. – for example, reduced number of intoxicated presentations to the OST Clinic for methadone dosing.

Contingency Management

- ✓ Define target behaviour
- ✓ Identify reward
- ✓ Select outcome indicator
- ✓ Joint decision on schedule of contingeny
- ✓ Monitor progress
- ✓ Provide personal feedback
- ✓ Small is not trivial

Step 3: Identify a reward/reinforcement suitable for use with a specific client and the specific target behaviour. Punishment can also be used, however, due to the risk of unwanted spread to other behaviour and ethical concerns, punishment is usually not recommended. Identification of rewards should be based on discussion with the specific client, an object can be rewarding for one person but discouraging for another person. Individual assessment of client's preferences plays a vital role in selecting a reward.

Step 4: Discuss with the client (and colleagues as necessary), and then plan a schedule of reinforcement in association with the target behaviour. For example, if the client refrains from using sleeping pill for a day, he will get a priority pass for one day in the methadone queue.

This might be followed by the "reward" of allowing the client to receive one takeaway dose of methadone per week. Depending on their ongoing stability, which should be monitored this might be increased further.

Develop and implement a reward management system tailored to each client as needed.

Step 5: Use verbal appraisal and appreciation even for small change in the desired direction. Continuously monitor the progress, discuss the obstacles and problem-solve challenges. Personal feedback helps a lot.

Step 6: A good strategy at the beginning is to selectively reinforce the adaptive behaviour and ignore the maladaptive behaviours. This helps the client get more motivated to stay in the program and learn the system, which can later be used to decrease maladaptive behaviour.

Sexual Dysfunction and its Management

Understanding Human Sexual Response

Human sexual response cycle has four distinct phases namely, arousal (excitement), plateau, orgasm and resolution. Men and women experience these phases in similar pattern; however, the duration and specific response may vary.

The four phases of human sexual response cycle are discussed below along with characteristic bodily changes associated with these phases. Understanding of these phases and the associated responses is crucial for the counsellors and therapists working with sexual dysfunction.

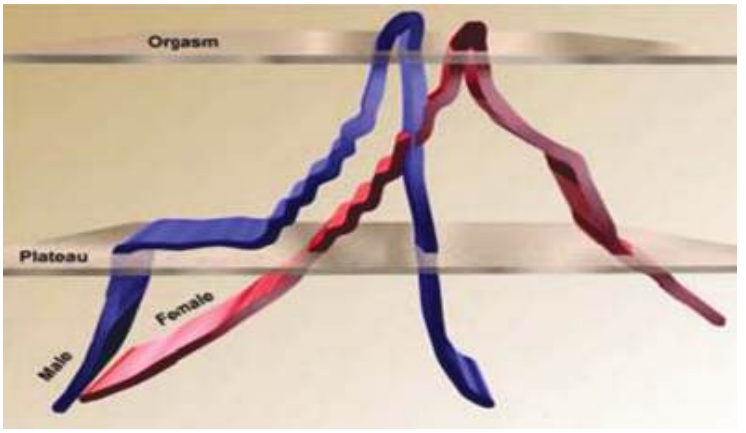


Figure 1. Human sexual response Cycle

Phase 1 – Arousal.

The arousal or excitement phase begins when people get stimulated with sexual thought, image, touch or other cues. It can last from a few minutes to several hours. The arousal response gradually increases and if sexual activities are not performed it dissipates gradually. The following features and bodily changes are generally observed in arousal phase

Both gender	Men	Women
• Heart rate and breathing accelerates • Localised skin flashes may appear • Nipples harden or become erect • Blood flow increase in the genitals	• Penis becomes erect • Couper's fluid (lubrication) flows to the tip of penis • Testicles swell and the scrotum tightens	• Swelling occurs at the clitoris and labia minora (inner lips) • Vaginal lubrication begins • Breasts become fuller and the vaginal walls begin to swell

Phase 2 – Plateau

In this phase the sexual pleasure remains relatively uniform and hence is the name 'plateau'. Generally, the plateau phase last for few minutes and it extends to the brink of orgasm. The changes started at the arousal phase continue and intensify in the plateau phase and some additional changes are observed. The following are some common response in plateau phase.

Both gender	Men	Women
• Breathing, heart rate, and blood pressure continue to increase • Muscle spasms may begin in the feet, face, and hands • Muscle tension increases	• Testicles withdraw up into the scrotum	• Vagina continues to swell • Clitoris becomes highly sensitive • Clitoris retracts under the clitoral hood to avoid direct stimulation

Phase 3 – Orgasm

The orgasm is the climax of the sexual response cycle. The sexual excitement or pleasure reaches the peak level in this phase. It is the shortest of the four phases and generally lasts only a few seconds. The following features are observed in the orgasm phase.

Both gender	Men	Women
• Involuntary muscle contractions • Blood pressure, heart rate, and breathing are at their highest rates, with a rapid intake of oxygen • Sudden, forceful release of sexual tension • Sex flush may appear over the entire body	• Rhythmic contractions of the muscles begin at the base of the penis • Ejaculation of semen occurs	• Vagina muscles contract • The uterus undergoes rhythmic contractions

Phase 4 – Resolution

This is the closure of sexual response cycle until the next one begins. During resolution, the body slowly returns to its normal level of functioning, and changes in the previous phases return to the normal state.

The characteristics of resolution phase may vary based on the presence of absence of orgasm before it. If preceded by orgasm, the resolution phase takes around a minute or so before returning to normal state. However, when orgasm is not achieved, the resolution phase may take much longer, even hours. Resolution generally followed by a sense of relief as well as occasional fatigue.

Although many women quicky return to the orgasm phase with further sexual stimulation, men need more recovery time after orgasm. This time period is called the refractory period. In this period men usually have only limited interest in sex and find it difficult to achieve penile erection. The length of the refractory period may vary among different individuals as well as at different ages. It varies from minutes in those of younger age to a few days or even longer in those of more advanced age.

Sexual Dysfunction

Sexual dysfunction is defined as the persistent impairment of the normal patterns of sexual interest or response (Hawton, et al., 1989). Based on different states of the sexual response cycle or aspects of sexual functioning, the dysfunctions have been categorised in four broad types. Manifestation of these dysfunctions may differ among men and women. The following sections discuss different types of sexual dysfunction. Please consult DSM-5 (American Psychiatric Association, 2013) for further reading on diagnostic criteria if necessary.

Table 1. Categories of sexual dysfunctions among men and women

Aspects of Functioning	Male Sexual Dysfunction	Female Sexual Dysfunction
1. Interest	Low sexual interest	Low sexual interest
2. Arousal	Erectile dysfunction	Impaired sexual arousal Vaginismus
3. Orgasm	Premature ejaculation Retarded ejaculation	Orgasmic dysfunction
4. Other	Dyspareunia Sexual aversion	Dyspareunia Sexual aversion

Definitions of Sexual Dysfunctions in Both Genders

Low sexual interest: persistent and recurrent deficiency or absence of sexual fantasies and desire for sexual activity.

Dyspareunia: recurrent or persistent genital pain associated with sexual intercourse. Dyspareunia is diagnosed only if no medical reasons for pain can be found.

Sexual aversion: persistent and recurrent extreme aversion to, and avoidance of all or almost all genital sexual contact with sexual partner.

Definitions of Male Sexual Dysfunctions

Erectile dysfunction: persistent and recurrent inability to attain or maintain an adequate erection until completion of sexual activity.

Premature ejaculation: persistent and recurrent ejaculation with minimal sexual stimulation that occurs before, upon, or shortly after penetration and before the person wishes it.

Retarded ejaculation: persistent and recurrent delay in, or absence of orgasm following a normal sexual excitement phase during sexual activity.

Definitions of Female Sexual Dysfunctions

Impaired sexual arousal: failure of physiological response related to arousal e.g. vaginal swelling, lubrication, sexual sensation.

Vaginismus: sexual intercourse is either impossible or extremely painful because of spasm of the muscles surrounding vagina occurs when Penetration is attempted.

Orgasmic dysfunction: this classification is questionable because sexual enjoyment without reaching orgasm is not considered as problem unless the person herself views it so.

Additional Problems Related to Sexual Functioning

Apprehension about sexual dysfunction: reporting of sexual problem in the absence of any regular sexual activity cannot be accepted as proof of really having the problem. (Nakra et al., 1977).

Misconceptions and myths: misconceptions and myths related to sexual development, functioning, and activity. Can be deep rooted and may be tough to remove it with factual information.

Dhat syndrome: Dhat syndrome is a culture-bound syndrome found among men in South-East Asia. Generally fuelled my myths and misconceptions, it is characterised by a spectrum of cognitive and somatic manifestations associated with anxiety and depression regarding loss of semen.

Causes of Sexual Dysfunctions and Problems

Sexual dysfunction may arise from a number of causes including social, relational, psychological and biological factors.

Table 2. Some of the common causes of sexual dysfunction

Learning & Experience ▪ Inadequate sexual information ▪ Restrictive upbringing ▪ Traumatic early sexual experience ▪ Impaired self-image **Performance** ▪ Unreasonable expectation ▪ Performance anxiety ▪ Random failure ▪ Anticipation of failure	**Relationship** ▪ Poor communication between partners ▪ Loss of attraction between partners ▪ Discord in the general relationship ▪ Infidelity in relationship ▪ Dysfunction in the partner/s ▪ Restricted foreplay	**Psychological State** ▪ Guilt, shame ▪ Psychiatric disorder: anxiety depression, drug dependency **Biological** ▪ ***Physical cause :*** pituitary tumours, diabetes, rectal surgery, ageing, torture ▪ ***Psychiatric medication*** : Benzodiazepines, tricyclic antidepressants, SSRIs ▪ ***Drug use :*** long term opioid use, methadone

Relationship Between Sex and Drugs

Sexual dysfunctions serve as a causal as well as maintaining factor for drug use (Hossain & Gaffar, 2014) and in the same way, drug dependence serves as a causal as well as maintaining factor for sexual dysfunction. Additionally, drugs can be closely linked with relationship and other psychosocial concerns leading to impairment in sexuality. Decreased arousal and impaired orgasm are most commonly observed impairments caused by long term drug use.

Substance	Sexual Impairment
Alcohol	Decreased arousal Erectile dysfunction Delayed orgasm
Cannabis	Erectile dysfunction
Opioids	Decreased desire Erectile dysfunction
Benzodiazepines	Erectile dysfunction
Stimulants	Decreased desire Erectile dysfunction Delayed orgasm

Methadone and Sexual Dysfunction

OST clients receiving methadone treatment commonly complain about their sexual functioning. There is some scientific ground behind this claim. Gonadotropin releasing hormone (GnRH) from hypothalamus stimulates the release of follicle-stimulating hormone (FSH) and lutenising hormone (LH) from the pituitary. These contribute to the release of testosterone in males and progesterone in females. Methadone can interferes with the release of GnRH from the hypothalamus which leads to decreased testosterone in males and progesterone in females causing sexual impairment (Seyfried & Hester, 2012).

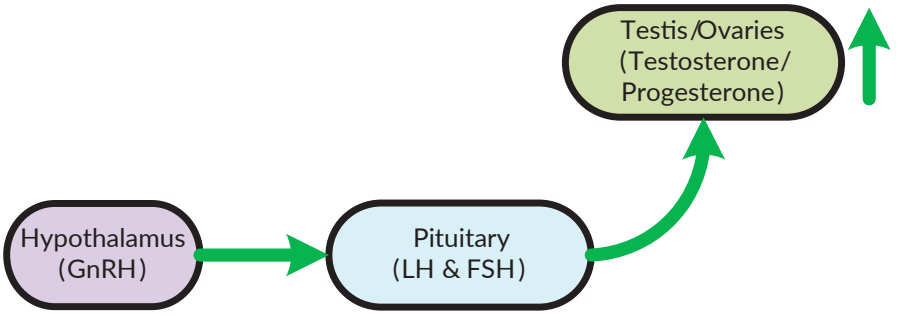


Figure 2 a. Hormonal process in increase of sexual arousal.

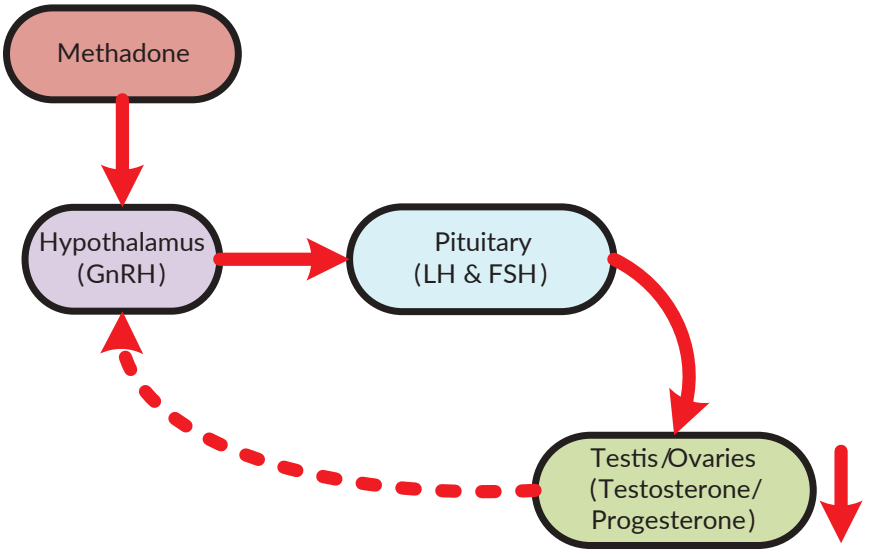


Figure 2 b. Hormonal process in the decrease of sexual arousal

However, this is often more psycho-social rather than related to the pharmacology of methadone. It should be noted that perceived functioning vs. actual functioning are often different. It is also generally observed that retrospective rating of sexual functioning before initiating methadone treatment is usually over-estimated by clients. Additional assessment data from partners may clarify a better picture of their actual state when it comes to sexual functioning.

Treatment for Sexual Dysfunction

Virtually all of the complaints about impairment of sexual functioning in OST settings are made by the male clients. Therefore, the following sections will focus discussion on interventions for male sexual dysfunction.

Treatment for Male Sexual Dysfunction	
Medical Approaches	**Psychological Approaches**
Medication (e.g.Viagra)	Sex education
Injection (e.g. Papaverine)	Conjoint sex therapy
MUSE (medical urethral system)	Kegelexercises
Vacuum constrictive device	Relationship-focused therapies
Surgery (penile prothesis)	Stress management, relaxation and anxiety reduction techniques
Anxiolytics for anxiety reduction	

Medical Interventions

There are several medical and psychiatric interventions for sexual dysfunctions which should be advised by a medical practitioner with specialist training and skills for treating sexual dysfunction. Therefore, these services should be provided through appropriate referral, and hence will not be discussed further here.

Psychological Interventions

There is a range of psychological interventions that can be provided by partially trained counsellors to highly skilled clinical psychologists. The following section provides a summary of the techniques.

Sex Education

Limited sexual knowledge is a major contributor of sexual dissatisfaction and sexual dysfunction. The service provider is therefore required to assess clients' knowledge and to provide detailed information on the following areas. It is preferable that delivery of this information is coupled with elaborate drawing and pictorial materials.

- Sexual anatomy of both genders
- Sexual physiology of both genders
- Sexual functioning of both genders
- Sexual response of both genders
- Foreplay and varied practices of foreplay
- Variations of size and shape of genitalia
- Semen and its production

Sex therapy

Sex therapy targets regaining appropriate sexual functioning though a more direct approach than sex education. Please note that detailed sex education should be provided before proceeding with sex therapy. Generally ***conjoint sex therapy*** is preferred over solitary therapy with clients who have regular sexual partners. In conjoint sex therapy, both the client and his partner participate together in the therapy session. There are several stages and techniques in sex therapy.

Sensate focus exercise: The client and his partner are asked to engaged in elaborate practice of foreplay as a homework assignment for a week or so until the next sex therapy session is conducted. The client and his partner are also instructed to invite each other for sensate focus exercises, and to communicate using the personal pronoun

'I' (e.g., I liked this one). The partner takes an active and passive role in turns. The rationale for sensate focus exercises is provided to the client and his partner (if present). As long as the sensate focus exercises are being practiced, sexual activities are prohibited until the next stage of therapy (i.e., containment).

The targets for sensate focus exercise are:

- Enjoyed physical contract
- Reduced sexual anxiety
- Enhanced confidence
- Improved sexual communication
- Focus on the sensation of physical touch
- improved sexual communication between the partners

Sensate focus exercises are done in two steps spanning across two weeks. The first step is ***non-genital sensate focus*** where the clients engage in foreplay without touching the genital organs and female breasts. This allows them to appreciate the pleasant value of physical contract without even touching the genital organs.

The second step, ***genital sensate focus,*** involves a similar task, however, here they can touch each other's genitals and the female partner's breasts. They are instructed that the focus is to explore, not to acquire orgasm. The ban on penetrative sex also continues. Some additional techniques are used in this genital sensate focus step.

- **Waxing and waning:** This is useful for clients with erectile dysfunction. In this technique, the partner is asked first to gently arouse the client's penis by touching and stroking. Once an erection is achieved, the partner then stops the stimulation until the erection subsides. The partner will again gently arouse the client's penis by touching and stroking. This will continue several times. This helps the client feel confident that erection can be achieved and even after it is subsided.
- **Start-stop:** This is useful for clients with premature ejaculation. Before proceeding with this the client is instructed to find his ***ejaculatory inevitability period which*** is the point of sexual arousal after which an ejaculation occurs. The partner's role will be to stimulate client's penis gradually towards that. However, the client has to ask the partner to stop before the ***ejaculatory inevitability period*** is reached. After the passage of some time, the ejaculatory urge is reduced and the partner should start again in the same way. The client will be told to try to tolerate the stimulation for longer in each trial.

Containment exercise: In containment exercise, the client is instructed to insert his penis in his partner's vagina (if it's a heterosexual partner). This is only done after the earlier stages are successfully passed. There two steps in containment exercise. The first is ***containment without movement,*** where the client inserts his penis but does not engage in thrashing; he may only move a little if he senses the penis is subsiding. The second step is ***containment without movement*** where the client is allowed to gently thrash. This is practically speaking when the client's sexual functioning is restored.

Kegel Exercise

This is another approach suitable for treating erectile dysfunction. In Kegel exercise, the client is given the following instructions.

- Make sure your bladder is empty
- Tighten your pelvic floor muscles and hold tight for 3 - 5 seconds.
- Relax the muscles for 3 - 5 seconds
- Practice this regularly

Relationship-focused therapies: Additional to directly enhancing sexual ability, improving the relationship with one's sex partner often plays an important role in increasing the quality of one's sexual life.

Anxiety Reduction Techniques: Anxiety and stress are also known to inhibit normal sexual response. General psychological strategies including CBT and other behavioural therapy can be useful in reducing anxiety and stress among clients. Relaxation exercises (discussed in self-care section) can be useful in this regard. In case of severe anxiety or depression, specialist referral options should be considered.

Conclusions

Impairment of sexual functioning is generally reported to improve over time as stabilisation on OST is achieved. Clients should be reoriented to focus on the pleasure rather than the sex act itself.

It should be noted that sexual function depends a lot on relationship with partners and other contextual factors.

Sexual dysfunction may also be affected by the concurrent use of benzodiazepines, which is not uncommon among OST clients, so this should also be discussed and discouraged. For the same reason the use of diazepines for anxiety should also be avoided, as this is likely to compound and not reduce sexual dysfunction issues. Alternative anxiolytics may be considered, or better still, non-medical approaches to manage anxiety as listed above.

Connecting clients with experiential evidence from OST peers can also be reassuring and useful in regaining confidence.

Self-care for OST Clinic Staff

The working contexts of the jobs we do are known to potentially create stress among the staff. Such stress and subsequent burnout are especially common among staff working in the sometimes challenging work context of providing OST. It is therefore crucial that the staff are engaged in self-care activities to ensure and protect their own well-being.

PMR can be useful for OST clients as well; it is especially effective for psychosomatic problems. Teaching clients the skills and practices of PMR can be valuable in the OST context.

Practising progressive muscle relaxation (PMR) is a proven strategy for reducing stress and preventing burnout. Regular practice of PMR is necessary to achieve it full benefit, however, sporadic use has also been reported to bring immediate relief. The following section presents the rationale, preparation and steps associated with PMR.

Progressive Muscle Relaxation

Rationale

Our bodies respond automatically to stressful situations and thoughts by becoming tense. The opposite relationship also works. A good way of relaxing the mind is to deliberately relax the body. In a progressive muscle relaxation, each muscle group is tensed in turn, and the tension is then released. This relaxes the muscles and allows you to notice the contrast between tension and relaxation. Through regular practice your body will learn to identify tensed muscle and then be able to relax it.

Preparation

Lie down flat on your back, on a firm bed, a couch, or on the floor. Support your head and neck with a pillow or cushion. Alternatively, you can sit in a comfortable chair with your head well-supported. Close your eyes if you are comfortable doing so.

Instructions

Focus your attention on different parts/muscle groups of your body in sequence. When you focus on a specific part of your body please do the following 4 tasks in sequence

a. Tighten the muscles of that part.

b. Hold the tightness, observe it and feel the tightness for 5 to 7 seconds.

c. Release the tension and observe the difference in these muscles.

d. Observe the difference and feel the relaxed muscles for 10 to 15 seconds.

Now practice the above mentioned 4 tasks on the following 13 muscle groups of your body. Relaxation should be enjoyable so if any part of the exercise is too difficult skip it for the moment. If you have any injuries you may wish to leave out that part of the exercise.

1. Your Arms: Extend your arms as if someone is pulling you by hands, feel the tightness on your arms. Focus your attention on the exact points on your arms where you are feeling the tightness. Tighten > Observe > Release > Observe.
2. Your Arms: Fold your arms so that you feel the tightness on your arms. Tight > Observe > Release > Observe.
3. Forehead: Tighten your forehead by trying to look up. Tighten > Observe > Release > Observe.
4. Nose: Tighten your nose. Tighten > Observe > Release > Observe.
5. Tongue and lips: Tighten your tongue and lips by pulling your lips inwards and turning the tongue upward to the palate. Tighten > Observe > Release > Observe.
6. Neck and shoulders: Tighten your neck and shoulders by trying to bend your neck downward and pulling your shoulders upward. Tighten > Observe > Release > Observe.
7. Chest and back muscles: Tighten your chest and back muscles by pulling your arms backward. Tighten > Observe > Release > Observe.
8. Belly: Tighten your belly. Tighten > Observe > Release > Observe.
9. Buttocks: Tighten your buttocks by pulling the muscle inward. Tighten > Observe > Release > Observe.
10. Thighs: Tighten your thighs by gently pressing the floor with your feet. Tighten > Observe > Release > Observe.
11. Tighten the upper side of your legs by extending your legs and at the same time bending your feet downwards. Tighten > Observe > Release > Observe.
12. Calf muscles: Tighten the calf muscles of your legs by extending your legs and at the same time bending the feet upward. Tighten > Observe > Release > Observe.
13. Toes: Tighten the muscles around toes. Keep your feet flat or on the ground extend your toes upward. Tighten > Observe > Release > Observe.

You have completed all 13 groups of muscles. Take a deep breath and scan your body to see if there is any remaining tightness in any part of your body. If there is any, try to follow the “Tighten > Observe > Release > Observe” on that part/muscle group.

Try to practice these regularly even at times when you do not feel stressed.

Annexure 5: Methadone Take home consent form

Prioritized HIV Prevention and Treatment Services for Key Populations in Bangladesh

Comprehensive prevention programs for people who inject drugs (PWID) and their partners

Implemented by: PR:

I ....., MMT no. ....., Service center name ....., for personal/familial/health/professional (tick the appropriate) reason, can not come to service centre every day. Hence, I am taking methadone doses of ..... days from ..... Service centre, ... ml/mg per day, in a total .....ml/mg with my own responsibility.

This service centre properly oriented and instructed me/my family member about how to take and preserve methadone with precaution. In a regular interval, I/my family member (who is present at the time receiving take home dose) will inform my status to service centre through phone call/physical presence/POW. CARE Bangladesh will not be responsible for any unwanted situation, such as police action, caused by misuse or overuse of methadone. CARE Bangladesh preserves the right to exclude me from this service if they find any misuse of methadone.

Signature of OST client:

Signature of family member/CBO representative/Peer:

Address:
Phone:

.....from service centre
Date:

i Physician's Desk Reference. 59th. Montvale, NJ; Thomson: 2005. Fluconazole; p. 2480

এইডস সম্পর্কে জানুন, সুস্থ থাকুন

জাতীয় এইডস/এসটিডি কন্ট্রোল
স্বাস্থ্য অধিদপ্তর, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়

DEPARTMENT OF NARCOTICS CONTROL BANGLADESH
মাদকদ্রব্য নিয়ন্ত্রণ

Save the Children