



HARM REDUCTION GUIDELINES

for

Needle and syringe programs

Opioid substitution therapy

Prevention and management of opioid overdose with naloxone

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1.1 Introduction

Harm reduction refers to approaches, policies, programs, interventions and practices that aim to reduce the adverse physical and mental health, social and economic consequences of injecting drug use. Harm reduction is underpinned by a human rights and public health framework with the goal of reducing the risks of transmitting preventable diseases and mortality.

These guidelines are intended to be used by practitioners implementing HIV and harm reduction programs to people who inject drugs (PWID), such as clinical and non-clinical program staff and management; community and civil-society organizations, service users and health workers.

This document is informed by international research literature, previously published guidelines, clinical and consumer experience globally and experience of the authors. Literature reviews were conducted focusing on systematic reviews and clinical trials published since 2000 relating to harm reduction interventions and substance misuse treatment. The resultant document was circulated to the HAI technical advisor for comment before being finalized for publication by Heartland Alliance International (HAI).

The aim of these guidelines is to support the implementation of harm reduction services in accordance with the World Health Organization (WHO), United Nations Office on Drug Control (UNODC) and the Joint United Nations Programme on AIDS (UNAIDS) (WHO 2012) endorsed comprehensive package of gender-sensitive HIV prevention, treatment and care (Table 1) approach based on evidence and human rights to protect the health and well-being of people who inject drugs and the general public.

Table 1. Comprehensive harm-reduction service package for people who inject drugs

- 1. Needle and syringe programs (NSP)
- 2. Opioid substitution therapy (OST)
- 3. HIV testing services (HTS)
- 4. Antiretroviral therapy (ART)
- 5. Prevention and treatment of sexually transmitted infections
- 6. Condom programs for people who inject drugs and their sexual partners
- 7. Targeted information, education and communication
- 8. Prevention, vaccination, diagnosis and treatment of viral hepatitis B (HBV) and C (HCV)
- 9. Prevention, diagnosis and treatment of tuberculosis (TB)
- 10. Community distribution of naloxone

WHO (2016) 'Consolidated Guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update', Geneva: Author; 'WHO, UNODC, UNAIDS (2012) 'Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users-2012 revision', Geneva.

Many programs that already implement harm reduction services under the essential and recommended core package of health services according to the WHO, UNODC and UNAIDS standards of care have been thoroughly evaluated. Each component of the core package is proven to prevent HIV transmission to people who inject drugs. Supported by scientific evidence, much of it is summarized by the WHO/UNODC Evidence for Action technical papers and policy briefs. These guidelines provide best practice around harm reduction specific interventions, chiefly NSP, OST and opioid overdose management specifically using the antidote naloxone.

Several strategies and approaches can improve the accessibility, acceptability, availability and uptake of interventions for key populations that are most at risk of HIV infection and transmission, including people who inject drugs. According to WHO (2016), these have been identified as 'critical enablers' (Table 2). These guidelines assume that existing HIV services are already working to ensure these critical enablers are in place as far as possible to maximize accessibility for people who inject drugs and other key populations.

Table 2. Critical enablers for access services for key populations

- 1. Review of the legal and policy environment and revisions where necessary which promote human rights based and public health-centered interventions for KPs.
- 2. Country level legislative reform to pass laws which enforce antidiscrimination and protection which eliminate stigma, discrimination and violence against key populations.
- 3. Accessible, available and quality health services for people living with HIV.
- 4. Enhanced community empowerment and participation through comprehensive and community inclusive programming.
- 5. Preventing violence against key population by establishing formal mechanisms and processes which protect the rights of individuals access to justice.

UNODC et al (2017) 'Implementing comprehensive HIV and HCV programs with people who inject drugs: practical guidance for collaborative interventions', Vienna:

1.2 Gender, a key dimension to the success of harm reduction strategies

A systematic review of studies from 14 countries (Des Jarlais, 2012) found a significantly higher prevalence of HIV among women who inject drugs than among their male counterparts in settings with high HIV prevalence. Studies in nine EU countries found that the average HIV prevalence was more than 50% higher among women who injected drugs than among their male counterparts (European Monitoring Centre for Drugs and Drug Addiction, 2006).

 Compared to their male counterparts, women who inject drugs experience significantly higher mortality rates; an increased likelihood of injectingrelated problems; faster progression from first drug use to dependence; higher rates of HIV; and higher levels of risky injecting and/or sexual risk behaviors.

- For women who inject drugs, there is greater overlap between sexual and injecting social networks than there is for men who inject drugs. This may increase women's risk of acquiring HIV through sexual transmission as well as through unsafe injecting (Roberts, 2010).
- Women who inject drugs are more likely than their male counterparts to have a sexual partner who injects drugs, and to be dependent on them for help acquiring drugs and injecting (Pinkham, 2012).
- Relationship dynamics can make it difficult for women to access harm reduction services, enter and complete drug treatment (if desired) or practice safer drug use and safer sex (Pinkham, 2012).
- Intimate partner violence (IPV) is more commonly reported among women who inject drugs than among women in the general population. Violence has an immediate effect on a woman's ability to practice safer sex and safer drug injecting, and can contribute to continued drug use (Pinkham, 2012; (Gilbert, 2015).

Table 3: Recommendations for effective health and social services for women who inject drugs

- 1. Whenever feasible, collect gender-disaggregated data on the epidemiology of drug use and HIV; coverage and uptake of essential HIV and harm reduction services such as NSP, OST and ART; and other relevant subjects.
- 2. Continuously and meaningfully engage women who use drugs in policy and program design, implementation, monitoring and evaluation.
- 3. Consider unequal gender relationships as a risk factor and address gender based violence as a harm reduction issue.
- 4. Establish stronger protections for patient confidentiality.
- 5. Establish a system that guarantees free or low-cost, non-judgmental sexual and reproductive health services, including PMTCT, for vulnerable women, including women who use drugs.
- 6. Eliminate punitive approaches toward pregnant women who use drugs. Establish clinical protocols on OST and other care for pregnant women who use drugs and provide OST in maternity hospitals when possible.
- 7. Eliminate laws that make drug use, a history of drug use or participation in an OST program (as opposed to negligence or abuse) grounds for the removal of parental rights, as this is a strong deterrent to mothers in need of care.
- 8. Support links between harm reduction programs and primary healthcare and women's healthcare systems. (Pinkham, 2012)

1.3 Scaling up harm reduction interventions

Establishing new interventions may meet resistance or unwillingness from certain stakeholders such as politicians, law enforcement officials, health care staff, civil society organizations and community members.

Table 4: Results for harm reduction

Harm Reduction International's 2014 report on the global state of harm reduction provides an account of the levels of harm reduction programming globally, stating:

The numbers present a clear public health and human rights challenge. They demonstrate results where harm reduction is scaled up, serious harms where it is not, and identify where major investments are needed. Behind those numbers are the civil society frontline workers and activists driving change; and a funding crisis in harm reduction setting the agenda for advocacy in the coming years.

p. 10

To facilitate the implementation of a new intervention, a recommended course of action could include:

- Increasing motivation and buy-in across key stakeholders through harm reduction sensitization and training
- Lead community consultations on plans for harm reduction scale up, delivering awareness and sensitization and considering views of local residents and businesses
- Provision of technical assistance in the development of internal protocols and procedures relating to NSP, OST, naloxone and regulations on the control of narcotic medications
- Plans to integrate new harm reduction interventions into existing services as far as possible
- Plan (and deliver) training for staff
- Develop job descriptions for new staff
- Secure mechanisms for funding for new harm reduction interventions
- Develop gender specific monitoring and evaluation framework

The comprehensive package for the prevention, treatment and care of HIV among people who use drugs, produced by the World Health Organization (WHO), United Nations Office on Drugs and Crime (UNODC) and the Joint United Nations Programme on HIV/AIDS (UNAIDS), does not include contraceptive methods other than condoms; pregnancy tests; pre-and post-natal care; or links between harm reduction, drug treatment and prevention of vertical transmission of HIV.

Adding these services to the comprehensive package could help women who inject drugs to better manage their sexual and reproductive health, thus preventing unplanned pregnancies and improving pregnancy outcomes, including through improved access to prevention of vertical transmission of HIV.

Ideally, services should be targeted according to the documented needs of women in a given context. Women who use drugs should always be involved in the design and implementation of these programs, to ensure that programs are effective, appropriate, and respectful of the human rights of women who use drugs.

1.4 Local level mapping

In order to inform future harm reduction programming effectively and sustainably, a careful assessment and mapping exercise across localities is recommended to generate data to determine the specific requirements of people who inject drugs. A gender sensitive assessment can provide a foundation to determine the viability of a pilot for establishing NSP, OST and overdose management / prevention with naloxone. It will generate critical local level data relating to drug use, high-risk behaviors and specific needs of people who inject drugs and their communities. Data can be further used to inform human resources, financial requirements and the acquisition of commodities (naloxone kits, needles and syringes, wound care, methadone etc.).

Results from an assessment, in line with WHO/UNAIDS rapid assessment and response methodologies (RAR 2006) should aim to describe the following:

- 1. Local nature of the drug problem, structural factors and availability drugs
- 2. Types of illicit narcotics and licit pharmaceuticals used
- 3. Levels of opioids used, illicit and licit strength of opioids
- 4. Size estimation of PWID disaggregated by age and gender
- 5. Identified PWID locations, hotpots and times for each gender to determine the future locations for services as well as service structure and frequency of interventions (e.g. outreach, fixed or mobile)
- 6. Understanding of the demographics of the community (e.g. age, gender, ethnicity, language, family context, hierarchy)
- 7. Information around high-risk behaviors and risk perceptions,
- 8. Gender dynamics and their impact on safety and health behaviors,
- 9. Prevalence and forms of gender-based violence, sex work / sexual exploitation,
- 10.Information relating to existing access to sterile needles and syringes and kinds / sizes / brands of injecting equipment used by drug users, access to and use of illicit methadone / buprenorphine (if any), overdose management practices (in the absence of naloxone)
- 11. Existing systemic and structural barriers and any other factors which may hinder access to future harm reduction services and interventions

Effective harm reduction services will engage people who inject drugs, including women, girls and gender minorities, from the earliest opportunity during the mapping and assessment process to ensure the information collected is complete and accurate and can validate other forms of data. Advisory committees or steering groups, broadly representative of community members and their gender, can be formed to guide the planning phase and ongoing implementation of services to ensure programs provide acceptable, accessible and responsive harm reduction interventions to the greatest possible number of community members. Such committees should meet regularly to discuss on going service delivery and consider any significant changes in the needs and risk behaviors of all gender, local drug use patterns, high-risk behaviors and other factors which might require for interventions to be modified and adapted over time.

Consultation at the wider level is further recommended for the security and protection of people who inject drugs and for those staff and volunteers tasked to

deliver harm reduction services. Local authorities can be invited to join committees following close negotiation, advocacy and consultation with the most concerned. Contact persons can be identified within each authority (child care and social services, health, police, justice) during the various stages of program planning and implementation. Joint multidisciplinary training and sensitization sessions can be developed and delivered and policies and protocols agreed on how harm reduction programs will work in respect of confidentiality and safety of people who use drugs.

1.5 Providing quality harm reduction interventions

The quality of all harm reduction services is essential to their effectiveness for people who inject drugs and to improving health outcomes. An ineffective harm reduction service can compromise the entire spectrum of services offered by a comprehensive HIV prevention, treatment and care program not to mention damage agency credibility in the eyes of the program's partners, the local community and among the people who inject drugs themselves. To ensure the delivery of a quality harm reduction program, the following measures should be in place:

- Ensure the availability of and adherence to international and national guidelines by making these easily available in all possible ways
- Develop internal standard operating procedures which promote physical and mental health and safety for staff, participants and local communities
- Establish gender-balanced advisory steering committees which meet regularly to review program activities, issues, performance and complaints
- Encourage a multidisciplinary approach reliant on care-coordination and case management to ensure participants of all gender receive a seamless and coordinated range of services which meet their respective needs
- Develop clear referral systems to external health, social and legal services putting in place robust information sharing protocols, coordinating care and carrying out joint care planning where possible and relevant
- Establish service user feedback and complaint mechanisms which give participants, and notably women and girls, full opportunity to provide feedback on services received as well as shape future service provision
- Accommodate regular independent and gender sensitive inspections, evaluations and audits which evaluate premises, services, medical records to ensure compliance with legal requirements and procedures

2 Needle and syringe programs

Needle and syringe programs (NSP) aim to reduce the transmission of HIV and other infectious diseases as well as minimize other harms associated with unsafe injecting practices. NSPs achieve this aim through the provision of three different kinds of interventions: first, provision of sterile needles, syringes and other injecting equipment; second, information, education and communications (IEC) relevant to their target audience, and third, a gateway and onward referral system by engaging and referring participants onto other services such as HTS, OST, ART, legal advice and so on. NSPs are cost-effective, are not associated with increased drug use and can provide an essential access point into HTS and HIV treatment

for people who inject drugs as well as entry into other necessary services (Wodak and Mather, 2010).

2.1 Service delivery models

There are two basic models for NSP delivery: fixed sites and mobile services with the most effective NSPs providing both.

Fixed site: a fixed site NSP is a low-threshold service location where people who inject drugs collect new injecting equipment, dispose of used equipment and make use of other health and support services. The site should be accessible, service user- friendly, safe for participants and staff, have sufficient space and security for the storage of commodities, be well staffed, have responsive opening hours and offer additional services specific to the needs of people who inject drugs. The location of an NSP will be informed by mapping assessments (see section 1.3) carried out prior to implementation. The NSP should be within easy reach of local drug users.

Fixed site NSPs can be formed adjunct to existing services specifically for people who inject drugs e.g. in drop-in centers, one stop shops or open access drug treatment settings. Secondary outlets can also serve as NSPs such as in pharmacies or women's support centers. An NSP requires an office where sensitive service user level information is held securely, staff meetings and reviews take place and reports and monitoring information is recorded. The storeroom for commodities should be lockable. A separate entry and exit for NSP participants should be provided to provide people who inject drugs to access NSP services discreetly and quickly.

Table 5: Evidence

There is compelling evidence to suggest that a comprehensive package of HIV prevention strategies should be offered in a synergistic and integrated way (Beyrer et al., 2010; Lert & Kazatchkine 2007; Strathdee et al., 2012; Wood et al., 2002).

A review by Aspinall et al. (2014) reporting data on HIV outcomes, at low risk of bias and performing meta-analysis, reported a 34% risk reduction of HIV transmission in individuals exposed to NSP compared to individuals who had not accessed NSP services and those exposed to NSP much less frequently:

NSP should be scaled up, but should be considered as just one component of a comprehensive program of interventions to reduce both injecting risk and other types of HIV risk behavior. p. 244

Mobile programs: mobile NSP services operate from a vehicle or through outreach by health workers or peer educators in the local communities. Outreach staff have a pre-determined schedule of community visits to carry out in order to provide sterile injecting equipment, safer injecting leaflets and other IEC to hard-to-reach people who would otherwise face difficulties in accessing fixed site services. Workers also collect full sharps containers exchanging them for new containers. Mobile programs can begin quickly and are cost-effective (Jones et al. 2008,

UNAIDS 2007, UNODC et al 2017). However, the opportunities for providing a spectrum of health services are limited. Therefore, outreach workers have a critical role in contacting 'service naïve' people and ultimately motivating and engaging them for access into more comprehensive program services for physical and mental health, HIV prevention, treatment and care and wrap-around services.

Service providers must establish protocols for the transportation and disposal of contaminated injecting equipment to minimize any risks to staff, the public and other service users. NSPs are responsible for all steps in the disposal process and must establish clear procedures relating to the collection of used equipment and destruction or waste disposal according to local regulations. While people who inject drugs can be strongly encouraged to return contaminated injecting equipment when necessary, the provision of sterile equipment should not be contingent on an exchange policy. Many individuals will not carry used equipment and are unable to do so safely at the risk of various legal implications. Sharps containers can be located in hotspots for a given length of time and collected and replaced with a new container by outreach workers during a routine visits.

2.2 Hours of operation

Fixed-site, mobile and secondary NSPs should operate at times when people who inject drugs are most likely to need access to needles and syringes, which could vary according to gender. Ideally, this means operating seven days a week and being open during hours corresponding to need. Hours of operation can be reviewed regularly and modified as appropriate to determine the most suitable times and outreach locations and schedules for mobile services.

Outreach NSPs should maintain regular routines with fixed times and places in order to maximize contacts with people who use drugs and provide a consistent and regular service.

2.3 Inclusion criteria

Initial assessment: To ensure they receive appropriate and quality services, any individual receiving NSP services should be formally registered. An initial eligibility assessment is carried out at the first contact of a potential service user on outreach or at the fixed site service. Standard eligibility criteria require individuals to be current injectors (last 30 days). A brief initial assessment lasting no more than five minutes should be carried out to determine the forms of drugs used, frequency, routes of administration, length of time used and quantities of substances used. If the client is found eligible for participation, the staff member conducting the assessment can inform them they meet eligibility criteria, promote the importance of safer injecting practices, emphasize the importance of returning used equipment, and inform other people in need of the NSP services available as well as other services available via onward referral and contact details. Participants should be issued identification cards bearing their unique identifier code which is verification that they are registered with an authorized NSP.

Risk vulnerability assessment: a more detailed assessment should be conducted with the client at a later stage once the client has built up trust in the program

and the staff member(s). This more in-depth assessment provides information on injecting frequency, choice of needles and syringes, types of drugs used and specific risk factors around sharing and reuse. It can be carried out at quarterly intervals to monitor risk reduction and to inform responsive support in the event of any changing needs.

2.4 Commodities: types and purpose of injecting equipment

The provision of sterile needles, syringes and other drug preparation equipment and disposal services is highly effective in reducing transmission of HIV, HCV and HBV by reducing the number of injections with unsterile and used equipment (Aspinall et al. 2014). NSPs should be implemented within the framework of the comprehensive package and committed to a multidisciplinary approach (Wodak and Mather, 2010).

NSPs should provide sterile needles and syringes as a minimum requirement in accordance with internationally recognized standards (UNODC 2007 and 2017). In addition, established NSPs provide a multitude of other injecting commodities such as filters, spoons, alcohol swabs, sterile water ampoules, safe tourniquets, acid sachets, filters, puncture-proof sharps containers, safer injecting literature, male and female condoms and lubricant. For outreach-based NSPs, safer injecting packs / kits containing essential equipment will be prepared in advance. These can include a range of the following:

- Needles/syringes (1ml, 2ml, 5ml 10ml, 20ml)
- Sharps container of the appropriate size
- 2x alcohol swabs for each syringe dispensed
- Tourniquet
- Water ampoule
- Acidifier
- Filters
- Educational material on safer injecting
- Condoms

Depending on people's needs, NSPs may need to prepare two model kits with variations on some of the content such as 'starter kits' as and 'continue kits'. Data from the local needs assessment and mapping exercise should be used to inform which commodities are provided and in what quantities in consideration of the following:

Needles and syringes: the types of needles and syringes supplied by NSPs should be procured and provided according to the needs of users and their needle gauge and syringe volume requirements. The best practice is single-unit needle and syringes (such as the 1ml diabetic disposable) over two-piece units since there is a reduced risk of HIV surviving in dried blood within the attached units. (WHO, UNODC, UNAIDS (2007). Furthermore, NSPs should prioritize the use of low-dead space syringes (LDSS). These are designed to reduce the amount of blood remaining in the syringe once the syringe plunger is fully pushed down. Studies show that a reduction in dead space reduces the survival of HCV and HIV in blood remaining in the syringe thus where procurement and financial resources allow,

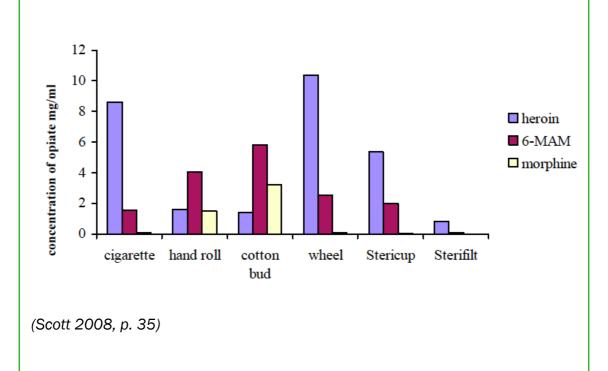
NSPs should provide LDSS in addition to other types of syringes (WHO, 2012). Retractable syringes are not recommended. A choice of syringes should be provided and NSPs normally stock between 1ml, 3ml, 5ml, 10ml and 20ml syringes and needles with a 24" and 26" gauge.

Filters: filters are placed between the needle tip and drug solution to prevent insoluble particles from entering the syringe and bloodstream. The optimum recommendation by WHO, UNAIDS and UNODC is to provide filters with a pore width of 0.22 μ m and those which promote single use. The Sterifilt[®] is one form of filter which retains less drug than a cigarette or makeshift filter, loses its strength when wet and breaks if multiple use is attempted. It also functions with crushed tablets as well as powdered drugs.

Furthermore, filters of lower porosity enable a lower level of drug retention which discourages filter reuse and sharing preventing the risk of HIV transmission and other viral and microbial infections. Eliminating less than half of all particles above 10 μm , cigarette filters are discouraged and also for the reason that fibers may break off once damp. In the absence of custom filters, plain filters and cotton wool are preferable to using no filter.



A number of scientific studies have proven how the use of different filters (both commercially produced and home-made) may reduce or increase the risks of HIV and HCV transmission due to the various filters' absorption capacities and thus, risks for future reuse and sharing. Scott (2008) reports that the Sterifilt filter retained significantly less opiates compared to homemade filters such as cigarette filters, hand rolling filters and cotton buds, as shown by the results in figure 1:



Scott's study demonstrates how a commercially produced and single-use filter, such as the Sterifilt, retains significantly less opioids than other forms thus decreasing the risk of future re-use by other users. Studies by Keijzer & Imbert (2011) and an EMCDDA-APOTHICOM pilot (2003) of injection materials for HIV and HCV risk reduction reveal both a high uptake of micro-, commercially produced filters when readily available and free of charge. The former study reported positive feedback from people who inject drugs using the Sterifilt filters.

Sterile water: water is often used in drug preparation and contaminated water can be a source of bacterial and skin infections. When water is shared between more than one person, small amounts of blood from another individual may enter the communal water source thus increasing the risk of transmission of HIV and other viruses. The optimum recommendation is for a single-use vial or ampoule of water for single use to be used per injection (WHO, 2004; WHO, 2007; Wodak & Cooney, 2005). These are often available in 5ml plastic or glass ampoules, which is normally a sufficient quantity for preparing drugs into an injectable form for single use. The ampoule cannot be recapped thus discourage re-use and reduce the risk of contamination. In the absence of single use ampoules, water boiled for several minutes or bottled water are secondary options (WHO 2004). Tap water, waste water and toilet water can be contaminated and while tap water can be potable, when injected intravenously it may still cause infections.

Spoons: spoons are used to mix drugs into an injectable solution and can serve as a cooker for the solution when applied over heat. Steel spoons should be distributed for the mixing and cooking processes, which provide stability in handling: a longer handle than commonly used bottle tops and soda cans and straight sides to contain the drug solution to contain the liquid and facilitate improved filtering. Cooking is often required with street heroin along with the addition of water and an acidifier (explained below) to dissolve the drug. The sharing of spoons promotes the transmission of HIV and other viruses thus individuals should be provided with spoons for their sole use only.

Acidifiers: acids may be required to dissolve drugs into a salt to create a solution appropriate for injection, as in the cases of heroin and crack cocaine. Citric, ascorbic (vitamin c) or acetic acid are safer forms than vinegar or lemon juice and can be provided in single use sachets, limiting the risks of overuse and sharing. Vinegar and lemon juice are rarely found in single-use form and can become breeding grounds for bacteria and fungi, leading to infections. Sterile, pharmaceutical quality and single use sachets of around 100-300mg ascorbic or acetic acid are available to distribute to people who inject drugs. Often, only a small amount of an acidifier from a sachet (around 20mg citric acid for around 130mg brown heroin) is sufficient to dissolve heroin or crack cocaine (Scott, 2008) yet People may be tempted to use an entire sachet unnecessarily, especially if their drug solution remains cloudy. Cloudiness is often attributed to impure drug solutions, i.e. those mixed with other materials and bulking agents, and does not necessarily suggest the heroin or crack cocaine is undissolved. Acidifier overuse can be a major cause of vein damage and caution should be exercised in using the correct amount for drug preparation.

Heat source: many drugs may require heat for preparation. A candle, tea light or lighter may be distributed and may also act as a light source to support users in preparing and injecting their drugs more clearly. A tea light is an ideal form of heat and light.

Alcohol swabs: single-use swabs containing a minimum 70% isopropyl alcohol (WHO, 2016) are used to clean the skin prior to and following injection, protecting individuals against abscesses and other bacterial infections. The swab should be placed just above the intended injection site then drawn once across the site with the skin being allowed to dry naturally prior to injection. Post injection, any spilled blood can be cleaned up using a swab. Swabs should be discarded properly following use.

Tourniquets: A tourniquet acts to assist vein access and should be elastic or rubber-based for quick release. Many drug users use bandanas, rope, belts or other fabric-based tourniquets yet these have limited elasticity and may cause damage to the skin and veins. They may be difficult to clean from blood spills. NSPs are encouraged to provide pliable, elastic tourniquets.

Bleach and other disinfectants: UNAIDS, UNODC and WHO guidelines indicate that there remains some controversy around the use of bleach and other disinfecting agents for injecting equipment (WHO, 20107). Bleach is found to be moderately effective for disinfection of needles and syringes containing the HIV virus. Best results were found with cleaning using the 2x2x2 method: flushing twice with clean water, twice with pure bleach, twice with clean water. This method reduced the HIV virus by 95% and rinsing a contaminated syringe with clean water reduced the virus by 70%. Should individuals ask about bleach as a harm reduction measure, it is important for staff to explain the limited effectiveness of bleach at reducing the risk of getting HIV or HCV. WHO and UNODC (2017) emphasize that bleach be used only in the absence of NSP where the availability of sterile needles and syringes are limited and only if they follow the correct steps for bleach-based disinfection.

Sharps containers: NSPs are responsible the collection of used injecting equipment and their subsequent destruction as well as at all phases in between. Puncture proof containers should be provided to staff and service users for disposal up to ³/₄ full and then to transport and store used needles and syringes for NSPs to collect at a later date.

Safer injecting information: safer injecting kits should contain vital information around safer injecting practices. Information should be developed according to the literacy and language needs of the beneficiary groups so they are responsive and relevant.

Women-specific items: women's hygiene materials and female condoms along with syringes, male condoms, wipes, and lubricant.

2.5 Commodities: stock management

In order to procure and manage stock, NSPs will need to generate a target number of people in need. A size estimation of people who inject drugs will have

been generated by a recent assessment and mapping exercise or service level data. To be effective in changing high-risk behaviors, WHO recommends that NSPs provide clean needles and syringes regularly (at least three needles and syringes weekly) to at least 10% of people who inject drugs locally by the end of the 12th month.

Based on a size estimation of 10,000 people who inject drugs, the estimation process for stocking an NSP is projected as described in Table 6:

Table 6: Sample estimation calculator for NSP commodities

Months 1-3 (set-up phase):

O per week:

Months 4-6 (initiation phase):

500 per week average 13 weeks: 6,500

Months 7-9:

1,500 weekly average x 13 weeks: 19,500

Months 10-12:

2,500 per week average x 13 weeks: 32,500

Annual estimate during first 12 months: 58,500

Adapted from WHO (2007) 'Guide to starting and managing needle and syringe programs', p. 11

Authorized NSP staff, responsible for procurement, stock control and inventory, must ensure that NSPs are stocked and restocked as required to ensure that the demands of participants are being met. Fluctuations in demand should be closely monitored to determine peak-times / peak-days with the NSP re-stocked and practices planned accordingly.

NSP procurement leads are further required to check that injecting equipment is stored safely and securely and within acceptable date limits for use. Adequate levels of stock must be maintained at all times through rigorous inventory verification at fixed site services and for those supplied to outreach workers. A minimum of a three months' supply onsite is recommended.

2.6 Clinical waste management and collection

The storage, collection and disposal of full sharps containers should be managed in line with national and local waste disposal procedures. Sharps containers must be correctly assembled prior to distribution and information should be provided to ensure they are not overfilled onsite or on outreach or returned by participants overfull. Sharps containers are for the disposal of needles, syringes and other injecting equipment used by NSP participants and other users within their networks. Given the health risks posed by hazardous waste, an NSP should consider itself responsible for all steps in the disposal process. NSPs require

protocols to ensure sharps containers are transported and disposed of appropriately.

2.7 Monitoring, evaluation and research

The purpose of monitoring NSP activities is to ensure that the project aims and objectives are being met. NSPs typically aim to reduce the transmission of HIV and other viruses as well as minimize other harms associated with unsafe injecting practices. NSPs seek to achieve this aim through the provision of three different kinds of interventions: first, the provision of sterile injecting equipment; second, by providing IECs; third, by engaging and referring participants into other services.

NSPs are responsible for ensuring monitoring systems capture relevant data to report across all three intervention areas and that this data also enables reporting against national level indicators relating to harm reduction and HIV prevention, treatment and care¹. Further, it is anticipated that NSP reports will also be used for service monitoring and planning for the benefit of people who inject drugs and for the wider population.

Monitoring should be carried out to record the following:

- Outreach worker logs and diaries
- Outreach based needle pack distribution levels and collection of sharps containers
- Fixed site logs and diaries
- Fixed site loose commodity distribution levels and collection of sharps containers
- Client retention and drop-out data (disaggregated by age and gender, anonymized, using unique identifier codes issued to all participants at the point of entry into NSP)
- Client overdose (nature of drug [e.g. opioid], outcome (e.g. naloxone provided, fatal, non-fatal)
- Pregnancy and related medical attention
- Stock register
- Incident register
- Needle stick injury register
- Condom distribution register
- Events such as police raids, gender-based violence, incarceration, expulsion, homelessness, etc.
- Group education sessions
- Behavior change counselling sessions
- Advice, education and information provided around safer injecting
- Incidents of overdose and other serious drug related incidents
- Onward referral
- Inward referral

¹ E.g. Joint United Nations Programme on HIV/AIDS (UNAIDS) Global AIDS Response Progress Reporting (GARPR) framework, national HIV and national hepatitis strategies

A bi-annual or annual evaluation of the NSP can be conducted to help ensure that program objectives are being met and that the program design is effective at achieving the desired outcomes. The process provides critical information to support the expansion or modification of programs for policy development. A range of qualitative and quantitative evaluation techniques can be used such as service user feedback surveys or specific operational research projects. In addition, outcomes can also be evaluated such as HIV incidence, needle sharing behavior, client satisfaction, etc.

2.8 Staffing a NSP

The backbone of an effective NSP is the team of outreach workers and peer educators working under the leadership of a project manager. All staff should possess core knowledge and skills in the following areas and should receive training in:

- Evidence-based harm reduction principles and approaches
- Gender issues (screening of gender-based violence and gender dynamics around needle sharing, counselling techniques for women, needs of women who use drugs etc.
- Purpose of injecting equipment commodities and according to drugs used
- Safer injecting and safer sex practices specifically for PWID
- Managing safe collection and disposal of used injecting equipment
- Behavior change strategies, motivation and engagement
- Basic counselling abilities, empathy, listening skills and a non-judgmental attitude
- Carrying out a screening assessment and developing a brief care plan
- Provide advice on other services and make onward referrals when necessary
- Conduct health education programs in the community with PWID
- Carry out reporting, basic data collection and documentation
- Knowledge on HIV, HCV, HBV and TB
- Basic abscess management

NSP management is responsible for the supervision of NSP staff, capacity building and program delivery and financial management of harm reduction activities. They should ensure NSP work plans are developed in close coordination with other staff and should conduct regular team meetings to review progress, project performance and review challenges and difficulties faced by the NSP and the staff, developing corrective measures and further action plans for follow-up. They are further required to oversee stock procurement, management, control and quality as well as ensure waste disposal is carried out in line with protocol and statutory regulations. They are also responsible for inter-agency coordination with partner health services, community-based organizations and service user networks and groups. It is the responsibility of the management to ensure timely reports are prepared and provided to stakeholders as and when necessary.

Outreach workers are primarily responsible for the mapping of sites for delivering NSP and regularly updating site related information. They are tasked to visit the sites regularly and, on a schedule, to ensure the regular distribution of safer

injecting packs to people who inject drugs and engage new participants into the program. They are responsible for ensuring they and peer-educators carry adequate supplies of safer injecting packs and other necessary commodities according to need. The composition of a team of peer educators and outreach workers should reflect the gender of the population that these agents will reach, in order to avoid power imbalance and other harmful gender dynamics. Outreach workers should supervise and support peer educators, providing back up support when a peer educator is unable to access a site. They may conduct sessions with participants on a one-to-one or group basis and can motivate participants to access further services. They are required to maintain their daily / weekly monitoring requirements and submit data and participate in staff meetings. On NSP outreach visits, workers and recommended to pack the minimum for effective distribution and exchange:

- Puncture proof sharps container(s), serially numbered and marked with biohazard symbol
- Puncture proof rubber gloves
- Tongs or forceps
- Disinfectant solution (bleach or hospital grade)
- Safer injecting packs / kits (see section 2.1 for contents; quantity will be determined by the pre-implementation mapping and local assessment)
- Basic first aid and dressing materials for wound and abscess management
- IEC materials on HIV prevention and safer injecting
- Women's hygiene materials and female condoms
- Forms for monitoring, log, diary, referral etc.
- Mobile phone for check-in and check-out with management

Peer educators are current or former drug users who express a willingness to volunteer for a given project for the benefit of his or her peers. Normally they are resident of the local area and have a good understanding of the local drug use context as well as having the goodwill of his / her community. Their key responsibilities are to build a rapport with participants and maintain contact, share agreed information within and between networks, facilitate linkages between peers and NSP staff, teach peers to practice safe injecting and safer sex practices, distribute safer injecting materials and commodities and information.

3 Opioid Substitution Therapy

Opioid Substitution Therapy (OST) is proven to be an effective harm reduction intervention and treatment approach which can reduce the frequency of injecting opioid use and risk of HIV transmission as well as reduce incidents of overdose and criminal activity. OST is seen to increase client adherence to antiretroviral therapy treatment (ART) for HIV as well as adherence to treatment for tuberculosis (TB) and is both safe and cost effective (WHO, 2009).²

OST is defined as the administration of pharmacological opioid agonist treatment, such as methadone and buprenorphine, and psychosocial support with the aims of reducing the use of opioids generally and via injection. Substitute prescribing replaces the opioid used with an agonist or antagonist of a different pharmacological group which has its action at the same receptors or in the same neuro-chemical pathways. The substitute drug can significantly reduce craving or limit the degree of withdrawal symptoms. Continued prescribing of substitute drugs is contingent on regularly monitored behavioral change (WHO 2009). Methadone and buprenorphine are the preferred forms of opioid agonist treatment and have undergone rigorous clinical trials for effectiveness and safety (WHO 2009, Dennis et al. 2014). Both medications provide good treatment outcomes and are on the WHO List of Essential Medicines for the treatment of drug dependence (WHO 2015). To cover participants' needs, WHO recommends for both medications to be available.

Substitution maintenance therapy is one of the most effective types of pharmacological therapy of opioid dependence. There is consistence evidence from numerous controlled trials, large longitudinal studies and program evaluations, that substitution maintenance treatment for opioid dependence is associated with generally substantial reductions in illicit opioid use, criminal activity, deaths due to overdose, and behaviors with a high risk of HIV transmission.

WHO/UNODC/UNAIDS position paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention 2004 p. 13

These guidelines should be reviewed and applied in conjunction with the relevant national legislation, guidelines and in line with statutory clinical regulations around pharmacology, clinical governance and medical practice. They include procedures and advice on current best practice in OST and intend to establish the essential minimum steps an OST service should carry out when providing substitute pharmacological treatment as well as key-working and psychosocial treatment for opioid dependence (WHO 2009, ACMD 2015). Key-working describes the process whereby a therapeutic relationship can be established and in the context of the individual having a tailored and individual care plan with goals (NICE 2007).

Clinical guidelines in OST will normally be put in place at the national level to represent the accepted treatment standards for the treatment of opioid dependence. Reliant on the relevant evidence-base for opioid agonist treatment and in consideration of local laws, policies and regulations, they should inform OST program-level guidelines. OST providers and OB-GYNs should be trained on drug use and drug treatment in pregnancy.

3.1 Service delivery model

An OST service should be a low-threshold program which is highly accessible, easy for participants to register, harm reduction and public health-focused, gender sensitive, friendly and reliant on an open-access model where a multitude of other

services are available for people who inject drugs. Such a program is more likely to demonstrate positive treatment outcomes among drug users (Amato et al. 2008, WHO 2009). An OST service will require a multidisciplinary team of medical and dispensing professionals, management team, key workers and administrative staff. OST can be delivered in specialized outpatient clinics, drop-in centers or one stop shops which have a clinical space adhering to medical and clinical protocols which adhere to statutory regulations for the safe storage and dispensing of controlled medicines such as methadone and buprenorphine. Due to the strict controls on dispensing and storage of controlled medicines such as methadone, and in order to prevent its diversion and risk of overdose, implementing agencies may require additional security personnel and added security measures.

An OST facility requires the following to receive participants, carry out assessments (including medical examinations and needs / risk assessments), appropriate spaces for dispensing and where medication can be safely and securely stored and consultation rooms for key-working and psychosocial services:

- A separate entrance / exit for OST participants
- Waiting room / reception area for participants which provides opportunity for access to other health and wrap-around services and IEC materials
- Clinical room(s) fully equipped for physical medical examinations, client opioid testing and primary care
- Consultation room(s) for key-working and care-planning
- Secure laboratory for safe storage of medications
- Private area for supervised dispensing
- Office for confidential client records and staff meetings

3.2 Inclusion criteria and screening processes

Maintenance prescribing may be helpful for participants with a diagnosis of opioid dependence and who are also:

- Regularly injecting
- Living with HIV and / or HCV and are not receiving ART or HCV treatment
- On ART
- Polydrug users motivated to reduce alcohol, pharmaceutical, stimulant and cocaine use once stable on OST

Needs assessment

A comprehensive assessment process should be completed to determine the physical, psychological and social needs prior to commencing treatment. At the assessment, the service user will be provided with information about methadone and buprenorphine treatment under the OST program and informed about issues relating to information sharing, conduct, consent and other relevant information.

In most cases, a clinician conducts a detailed substance use history with the support of a psychosocial professional based on self-reported information provided by the client. There are several assessment tools available and informed

by WHO ICD-10 diagnostic criteria for drug dependence (WHO 2016). An assessment should include:

- Drug use history and which drugs or illicit pharmaceuticals and psychoactive substance have been used recently
- Pattern of use, frequency and quantity
- Route of administration for drugs used
- Risk behaviors associated with drug use and other lifestyle factors
- Gender dynamics around drug provision, use and health seeking patterns
- Current level of neuroadaptation to each drug used
- Drug induced health problems (physical, psychological, social and economic)
- Previous responses to drug dependence treatment and other interventions for PWID
- How the client views their drug dependency and motivation to reduce it
- Status of HIV, hepatitis, TB and other infections and in the event the participant is infected, treatment received and health provider details
- Risk assessment (to self, to others, to staff)
- Short, medium and long-term goals of the participant and what has motivated him/her to access OST

Clinical examination

It is advised that clinicians carry out a physical examination to observe the following and document within clinical notes. A number of clinical resources and scales are available to evaluate levels of opioid intoxication and withdrawal³:

- Level of neuroadaptation
- Physical signs of opioid withdrawal
- Review of injecting sites
- Signs of injecting related health issues such as abscesses, vein damage or collapse
- Baseline observations: blood pressure and pulse

Toxicology screening

Urine, saliva or other biological samples can be tested by OST programs onsite and results used to indicate recent opioid use. Many OST programs require positive samples in addition to the assessment and physical examination processes to confirm opioid dependence and eligibility for enrolment in the program. However, it should be noted that biological drug testing can be costly and time consuming (UNODC 2016b). WHO recommends that biological drug testing is carried out in combination with other assessments and that entry into OST should not be delayed because of waiting times for test results (WHO, 2009). Processes for the collection, storage, disposal and results management of biological toxicology samples requires written clinical procedures

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³ For a review of validated screening instruments for the diagnosis of opioid dependence, see WHO (2009) and Wickersham et al (2015) 'Validation of a brief measure of opioid dependence: the rapid opioid dependence screen (RODS)'

Diagnosis

Opioid dependence can be diagnosed by trained practitioners following comprehensive assessment, physical examination and drug screening results however any diagnosis should be confirmed by the OST clinician before the participant commences substitute prescribing. Participants must be made fully aware of the treatment process and attendance requirements and once all other entry criteria has been fulfilled, they should be provided with a titration sheet, identification card and appointment time to commence titration.

3.3 Titration process

The comprehensive assessment process can inform the participant's level of opioid neuroadaptation and inform the initial dose of methadone or buprenorphine. The first few weeks within an OST program can be critical with the client at high risk of overdose given the difficulties in determining exact levels of neuroadaptation.

The initial dosing phase of methadone or buprenorphine is known as titration and the aim of this phase is establish a well-tolerated dose which can be increased gradually over time until the client is stabilized and no longer in opioid withdrawal or having to use opioids 'on top' of OST.

Day one: Due to risk of overdose, the participant should be titrated at a low dose: ideally between 10 and 30mg of methadone. This dose must be given under supervised consumption during a morning clinic with at least one clinical staff and one non-clinical staff in attendance. The participant should be observed for 90 minutes after this initial dose. Blood pressure and pulse should be taken and recorded prior to each increase of methadone up to 40mg on day one. Participants should be monitored for a further 60-90 minutes by a clinician. Blood pressure and pulse should be recorded again and if within acceptable limits, they can leave with an appointment to return the following morning to see whether a further incremental increase is required.

Day two: On arrival at the service, clinical staff should repeat the titration record sheet. If on day one of titration, the service user tolerated 40mg methadone and providing their blood pressure and pulse are within normal range, they are still feeling uncomfortable / in withdrawal, and have not used heroin in the previous 8 hours, they can be prescribed an increased dose up to 50mg. They will be required to remain for 90 minutes of observation. They can be increased up to 10mg each week until the optimal therapeutic level of methadone is established. If the participant feels comfortable on 50mg for example, no further increases are required. Participants who present to the OST program under the influence of drugs or alcohol will be considered unsafe for titration and rebooked.

Participants are normally required to take their medication by supervised consumption by an OST member of staff onsite. Methadone dosing involves dispensing the prescribed volume of liquid methadone into a cup which is then consumed under direct observation of a clinician. Talking to a participant post-

consumption is normally an effective measure to ensure the dose has been ingested and they should be encouraged to drink water following their dose.

Once a participant stabilizes and is testing negative to opioids they will leave the titration phase and enter maintenance phase. All participants should be reviewed one to two times weekly by a clinician and other member of keyworking psychosocial staff. If a participant fails to attend for their medication for a period of three consecutive days, normally they will be suspended from the OST program and required to register again and undertake a new assessment. All results should be clearly documented within clinical notes.

Clinicians should further consider the need to tailor dosage according to pharmokinetic factors such as metabolism and absorption which may affect titration doses.

3.4 Maintenance process

Maintenance prescribing describes the continued dosing of daily methadone (or buprenorphine) once the optimal dose has been reached, the participant is no longer using nor injecting additional opioids and can be seen to be stabilizing their substance use. Maintenance prescribing may lead to negotiated and agreed reduction or detoxification yet these are not the main aims of a harm reduction OST program. Continued prescribing of medication should be associated with strategies to monitor and affect behavioral change.

OST services should prescribe an effective and sufficient dosage of methadone (or buprenorphine) to ensure stabilization and be prepared to increase the dose if participants are continuing to use illicit opioids on top of prescribed opioids. Doses in the range of 60-109mg can be more effective than lower doses according to WHO guidelines and other studies.

3.5 OST for specific groups

There are a number of differences between men's and women's motivations to enter and complete opioid substitution therapy (OST) and other drug treatment modalities, Many women cite pregnancy as a central reason for entering treatment, although punitive policies that separate women who use drugs from their children can deter pregnant women and mothers from entering drug treatment (Pinkham, 2012).

OST and certain other types of drug treatment have been found to be especially effective in helping women to reduce their drug use, while detoxification alone is significantly less successful for women who inject drugs than for men.

Pregnant and breastfeeding women are generally eligible for OST and respond well to methadone (and buprenorphine) especially given the risks of withdrawal on the unborn baby and associated risks of miscarriage (UNODC 2016b). Both medications have minimal long-term developmental impacts on children compared to the risk of maternal opioid use and injecting drug use related health infections (WHO 2009 and UNODC 2016b). A relapse to opioid use can result in

poor obstetric outcomes. Once maintained on a stable dose, clinicians should review pregnant female participants closely, particularly between the second and third semester. During this period, changes such as increased metabolism, weight gain and increased circulating blood volume can result in a need for an increase in methadone dosage. The dose may be adjusted back to lower levels post-natally as some of these changes are reversed. Breastfeeding is safe during OST and the benefits of breastfeeding should be promoted. Women who are living with HIV should be advised on the risk of HIV transmission during pregnancy, during partum and breastfeeding and be actively referred to ART services for her own health and to prevent HIV transmission to the infant in accordance with national clinical guidelines.

Studies have shown that drug users living with HIV, AIDS, hepatitis, tuberculosis will adhere better to antiretroviral therapy and other treatment when maintained on OST. People living with HIV who are not receiving ART will likely adhere better to ART treatment regimen once stabilized on methadone (or buprenorphine). Participants with TB should have TB treatment prioritized over OST although OST should be provided where possible and providing other OST participants are not at risk of this highly contagious bacterial infection. OST services should ensure they have protocols in place to both accommodate participants with TB while protecting other participants and staff from contracting the infection.

3.6 Additional services/material assistance for women at harm reduction sites:

- Special time for women only ('Ladies' Night')
- Pregnancy tests; diapers and other supplies for children
- Informational materials specific to women
- Women-only support groups, women-specific counselling programs (including structured HIV prevention counselling interventions)
- Relationships with trusted gynecologists, obstetricians and other specialists for client referrals
- Training OST providers and OB-GYNs on drug use and drug treatment in pregnancy
- Take-home doses, flexible clinic hours.

3.7 Legal requirements on the control of opioid medications

Both methadone and buprenorphine are controlled medicines and are at risk of diversion into the black market for illicit sale and trade (INCB 2006, Wright et al. 2015, Alho et al. 2015). Countries operate within an international regulatory framework and both methadone and buprenorphine are medicines under international control and regulated under the United Nations conventions on drug control. These conventions ⁴ ensure that narcotic drugs and psychotropic substances, including opioids, are available exclusively for scientific and medical purposes. The conventions include the requirement to make treatment available for people dependent on narcotics or psychotropic substances. There are

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⁴ Single Convention on Narcotic Drugs of 1960 as amended by the 1972 Protocol, Convention on Psychotropic Substances of 1971 and United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988

international and legal regulations dictating how opioids should be procured, distributed, transported, stored and prescribed. All necessary measures should be put in place to prevent diversion of controlled medicines at the program level as well as the national level. At the program level, OST providers are responsible to ensure the following measures are implemented:

- Develop internal agency procedures on acquisition, turnover, dispensing and reporting of methadone (and/or buprenorphine) in adherence with the regulatory framework
- Appoint a professional team of staff members, responsible for the control of opioid medication within the agency and licensed for practice
- Ensure adherence to regulations around administration of medications, storage, transportation, dosing and supervised consumption
- Ensure there is procedure in place with sufficient budget in place contingency
 planning in place in the event a breach of protocol involving a diversion
 incident takes place. Added security measures may be required which could
 require additional resources

When administering methadone (or buprenorphine), as well as adhering to national regulations, the following should be adhered to by the OST implementing agency:

- Confirmation of the identity of the participant, name, date of birth against treatment chart / records
- To ensure the participant receives the full benefit of their medication they should be well informed of the nature of the medication as well as any side effects and made aware of the risks of using opioids and other drugs 'on top' of methadone (and buprenorphine)
- Participants must be supervised whilst their dose is administered
- Participants must be provided with, and encouraged to drink water following their dose not only to prevent diversion but also to improve dental care
- A record of methadone administration is to be documented on the client's medical chart / records and in a controlled drug register by recognized medical personnel and in line with local and national regulations
- Agencies should ensure they have an overdose prevention and management protocol in place (see section 4) since there is a risk of overdose during substitute prescribing, heightened during the first two weeks during the early titration phase. During this period, increased overdose prevention information and strategies should be exercised including making naloxone available onsite as well as the provision of naloxone to new OST participants accompanied by clear guidance around how it should be administered

3.8 Staffing an OST

A multidisciplinary team of clinicians, psychosocial staff, administration and management normally staff an OST service. Medical staff is primarily responsible for clinical assessment, pharmacotherapy, prescribing, dispensing and primary care. Psychosocial staff is responsible for delivering psychosocial interventions, care planning and all non-clinical aspects of care coordination and referral. The

staff should be gender balanced, and all staff should possess core knowledge and skills in the following areas and should receive training in:

- Gender and its relation to harm reduction.
- Evidence-based harm reduction principles and approaches
- Pharmacological treatments for opioid dependence
- Safer injecting and safer sex practices specifically for PWID
- Behavior change strategies, motivation and engagement
- Psychosocial treatment for opioid dependence
- Counselling abilities, empathy, listening skills and a non-judgmental attitude
- Carrying out a needs assessments and opioid dependence diagnostic criteria
- Developing a SMART based care plan based on goals and supporting a client on their care plans
- Provide advice on other services and make onward referrals when necessary
- Carry out reporting, basic data collection and documentation
- Knowledge on HIV, HCV, HBV and TB
- Basics of sexual and reproductive health and rights
- Basic abscess management
- Prevention and management of overdose with naloxone
- Management of drug and alcohol intoxication
- Dealing with difficult, aggressive or non-treatment compliant participants

OST management will be responsible for all aspects of the OST service including the supervision of non-clinical staff and clinical supervision for doctors, nurses and pharmacists. They are responsible for capacity building in OST and other harm reduction approaches. They should ensure OST work plans are developed in close coordination with other staff and should conduct regular team meetings to review progress, project performance and review challenges and difficulties faced by the OST and the staff. They are further required that prescribing practices, procurement, storage, dispensing and dosing conform to regulation. Management are also responsible for inter-agency coordination with partner health services, community based organizations and service user networks and groups. It is the responsibility of the management to ensure timely reports are prepared and provided to stakeholders as and when necessary.

Clinical staff: the various roles of clinical staff will normally be directed by national regulations on clinical governance. They are responsible for all clinical aspects relating to assessment, drug screening, prescribing, dispensing and primary care. A clinical team may consist of two doctors, two nurses and one pharmacist. Doctors may delegate some clinical responsibilities to nurses once a client is stabilized on treatment and have entered the maintenance phase. All clinical staff require regular access to clinical supervision as a safeguard against inappropriate prescribing and to guarantee professional clinical conduct. Dispensing staff are normally pharmacists. Pharmacists and nurses can supervise consumption.

Psychosocial staff is primarily responsible for the delivery of non-pharmacological interventions for participants in the OST service. They may provide individual or group sessions to participants and can address emotional, cognitive and behavioral barriers to participants accessing further services and to adhering to

treatment and services. They are responsible for developing care plans and coordinating care. They may provide case management and psychosocial interventions psychological services to support participants in reducing the harms associated with their drug use or working towards reducing or stopping their drug use altogether. (See section 5 for more detail).

3.9 Monitoring, evaluation and research

Like all harm reduction interventions, OST requires on going and intermittent monitoring and evaluation for both the OST process and additionally to monitor treatment outcomes. OST services typically aim to reduce the transmission of HIV and other viruses through the reduction of opioid use, other drugs and associated risk behaviors.

OSTs are responsible for ensuring monitoring systems capture relevant data to report across all three intervention areas and that this data also enables reporting against national level indicators relating to harm reduction and HIV prevention, treatment and care⁵. Further, it is anticipated that OST reports will also be used for service monitoring and planning for the benefit of people who inject drugs and the wider population.

Monitoring should be carried out to record the following (disaggregated by age and gender, anonymized, using unique identifier codes issued to all participants at the point of entry into OST)

- Number of participants informed about OST and referred
- Participants commencing OST (pharmacological and psychosocial)
- Participants retained on OST at intervals: 1 month, 3 months, 6 months, 12 months etc.
- Participants completing care plans
- Client treatment drop-out data
- Changes in client drug use levels
- Changes in risk behaviors among PWID
- Other changes in social functioning, physical and mental health
- Client overdose (nature of drug [e.g. opioid], outcome (e.g. naloxone provided, fatal, non-fatal)
- Stock register
- Incident register
- Needle stick injury register
- Condom distribution register
- Events
- Group education sessions
- Advice, education and information provided around safer injecting
- Incidents of overdose and other serious drug related incidents
- Onward referral

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⁵ E.g. Joint United Nations Program on HIV/AIDS (UNAIDS) Global AIDS Response Progress Reporting (GARPR) framework, national HIV and national hepatitis strategies

- Inward referral
- Organizational capacity and human resources

A bi-annual or annual evaluation of the OST can be conducted to help ensure that the program objectives are being met. The process provides critical information to support the expansion or modification of programs for policy development. A range of qualitative and quantitative evaluation techniques can be used such as service user feedback surveys or specific operational research projects.

4 Overdose prevention and management (with naloxone)

Opioid overdose is a life-threatening condition which can lead to coma, cerebral hypoxia, prolonged hospitalization, brain damage and death. Opioids activate receptors in the brain and when these drugs are used in excess, fatal respiratory depression can occur. A victim's breathing can slow to a point that there is an insufficient oxygen level in the blood. If oxygen saturation falls below 86% (normal range >97%) the brain will struggle to function. As a result, blood pressure drops, the victim becomes unresponsive and the heart rate slows resulting in cardiac arrest (WHO, 2014).

Opioid overdose is the main cause of drug-related mortality: contributing to roughly a third to a half of all deaths, attributable in most cases to opioids (UNODC, 2016a). Further research suggests that HIV seropositivity is associated with an increased risk of overdose and that overdose is the leading cause of death among PWID (Degenhardt, 2011).

Overdose can be both prevented and treated, thus staff in services working with people who inject drugs have an essential role in overdose prevention and management. Drop-in centers, one stop shops, NSPs and OST services should develop clear protocols and IEC materials which promote evidence-based overdose prevention and management practices (WHO, 2014).

Naloxone (N-allylnoroxymorphone) Hydrochloride (HCI) is an opiate antagonist that reverses the effects of an opioid overdose and by controlling the harm caused by injecting drugs, the risks of HIV transmission are reduced (UNODC 2013, UNODC 2016b). It has been used in opioid overdose management for over 40 years and is included in the WHO Model List of Essential Medicines (WHO 2016) and causes no harm if used by a non-opioid user having no effect. Many countries consider naloxone as one form of life saving emergency treatment under national first aid response yet there is increased advocacy to be done in other countries where naloxone remains unavailable. There is a greater need to strengthen overdose responses in the form of the low-threshold provision of naloxone to communities of PWID as well as through emergency health services. This low-cost approach can empower health care workers and people who use drugs to save lives. These guidelines are designed to guide all users of naloxone on its administration for reversal of coma and respiratory depression caused by opioid overdose. Due to the serious nature of overdose, it is appropriate to administer naloxone to any victim exhibiting significant symptoms suggestive of opioid overdose rather than risking the victim's life.

4.1 Risk factors for opioid overdose

Harm reduction services can sensitize people who inject drugs and other opioid users on the vulnerabilities to overdose and certain factors and situations which place people who opioid at an increased risk of overdose which include:

- Increase in opioid availability (illicit and prescribed)
- Increase / decrease in purity of narcotics such as heroin
- Increases in prescribing of pharmaceutical / prescription opioids
- Polydrug use particularly where opioids and other psychoactive substances are used in combination (alcohol, sedatives, benzodiazepines)
- Smoking crack cocaine while under the influence of a strong opioid leading to impaired breathing and acute hypertension
- Poly injecting heroin and cocaine (snowballing)
- No access to OST (OST reduces the risk of overdose substantially)
- Circumstances where tolerance to opioids is greatly reduced such as following prison release, hospital discharge, relapse post drug-detoxification (King, 2014; WHO, 2014)

4.2 Identification of opioid overdose

In order to effectively diagnose opioid overdose, the following opioid overdose triad should be observed as normally the victim will be unresponsive thus unable to communicate if and how much opioids were used:

- Pinpoint pupils
- Unconsciousness
- Respiratory depression (bradypnoea)
- <10 breaths per minute or 1 breath every 5 seconds

They might also have the following symptoms:

- Blue lips of fingernails
- Snoring / gasping
- Pale / clammy skin (WHO, 2014)

4.3 Responding to opioid overdose

SCARE ME is an acronym setting out the sequential steps which can be implemented in the event of suspected opioid overdose. Standard resuscitation procedures should be carried out accordingly and then considered for naloxone injection:

S= stimulation (wakening)
C= call for medical help
A=airway
R= rescue breathing
E= evaluate breathing and response

M=muscular injection of naloxone

4.4 Reversal of opioid overdose: naloxone

Naloxone is the most effective treatment for overdose. It is an opioid antagonist, which binds to opioid receptors reversing and blocking the effects of other opioids. Liquid naloxone for intramuscular injection is the most commonly distributed form and is also available as auto-injectable or as a nasal spray.

Important features of naloxone:

- It can very quickly and effectively restore normal respiratory function within 1 to 5 minutes for a victim whose breathing has slowed down or stopped
- The effects last between 60 and 90 minutes.
- As a precaution, participants who have consumed high levels of opioids or those highly dependent on opioids long term may suffer an acute withdrawal following naloxone administration therefore other resuscitation measures should be readily available. Naloxone can bring on a rapid state of withdrawal thus participants may require prolonged monitoring. Additional support can be provided to manage the symptoms relating to their withdrawal from opioids as well as psychological support following the trauma experienced as a result of the incident. Abrupt reversal of narcotic depression may result in nausea, vomiting, sweating, tachycardia, hyperventilation, increased blood pressure, tremulousness, ventricular tachycardia and fibrillation, pulmonary edema, seizures and cardiac arrest
- Participants may remain at risk of further overdose immediately after the initial dose of naltrexone is administered (see next section for repeated naltrexone administration)
- Opioid overdose is life threatening and as such there are no contraindications to naloxone administration
- Naloxone carries no potential for abuse
- The following groups require caution when Naloxone is administered. However, the conditions covered may not be known prior to its administration:
 - Participants with pre-existing cardiovascular disease or in those receiving potentially cardiotoxic drugs, since serious adverse cardiovascular effects may occur
 - o Participants with renal insufficiency/failure or liver disease
 - Pregnant women who are known or suspected to be opioid-dependent.
 Risk benefit must be considered before administration of naloxone since maternal dependence may be accompanied by fetal dependence. The neonate should be monitored for respiratory rate and signs of opioid withdrawal
 - Lactating women, it is not known whether naloxone is distributed into breast milk thus must be used with caution
- Participants excluded from services should duly receive naloxone given the severity of opioid overdose and risk to the client's life

- Participants who do not wish to receive naloxone treatment should be advised
 of the life-threatening risks of not receiving naloxone and should always be
 referred to a doctor
- Participants on concurrent medication should receive naloxone regardless of the form of medication or non-opioid drugs taken: opioid overdose is life threatening. Naloxone should not be mixed with preparations containing bisulphite, metabisulphite, long-chain or high molecular weight anions or any solution having an alkaline pH
- Non-proprietary naloxone injection is often available in 1ml ampoules or vials containing 400mcg/ml (0.4ml) of naloxone HCl or 2ml pre-filled syringe containing 1mg/ml of naloxone hydrochloride (WHO, 2014)

4.5 Protocol for the administration of naloxone

Once opioid overdose has been established, presuming naloxone is available, it should be administered without delay and in accordance with the other standard resuscitation procedures under the SCARE ME protocol (section 4.3).

WHO (2014) recommends that individuals administering naloxone should select a route of administration based on the formulation available, their skills in administration and the local context. Naloxone injection is available for subcutaneous (SC), intramuscular (IM) or intravenous (IV) injection or for intravenous infusion. For the purposes of this protocol, naloxone injection may be given by SC or IM injection. WHO (2014) reports that IM naloxone may result in a more rapid clinical response.

- 1. Ideally, consent in principle, verbal or written, should be obtained prior to administration; however, the majority of participants requiring naloxone will be unable to provide consent. If the client is incapable of giving informed consent, naloxone should be administered as lifesaving treatment. All people who inject drugs registered at an agency providing harm reduction intervention should be made aware of overdose management procedures with naloxone with informed consent requested in writing at the earliest opportunity. This consent should remain valid unless the individual withdraws it for any reason. If consent for naloxone is either refused or withdrawn, this decision must be documented clearly
- 2. Gloves should be worn by the individual administering the naloxone injection with the desired injection site cleaned with an alcohol swab
- 3. Ensure the victim is still in recovery position
- 4. Remove the outer cap or seal from the ampoule or vial carefully leaving the rubber plug intact
- 5. Inset a sterile (>3cm) needle / syringe through the plug from the upside-down vial, pulling back on the plunger taking up to 1ml

Inject a 1ml dose of naloxone at a 90-degree angle by SC or IM injection. IM injection should be into a large muscle preferably upper arm or thigh muscle. Injection into outer buttocks is possible although effect of naloxone may be more delayed due to fatty tissue. WHO guidelines state that in most cases 0.4-0.8mg is an effective dose (WHO, 2014). Recent UNODC (2016b) guidelines state that 0.4-2mg is recommended for an initial dose.

- 6. Wait 3 minutes and if there is still no respiratory function to the naloxone, repeat 1ml and observe for 2 to 5 minutes. If no response, re-repeat 1ml naloxone at same intervals, administering up to a total of 10mg (UNODC 2016b)
- 7. If the victim has not responded after 10ml, the situation is unlikely to be an opioid overdose and emergency medical services must respond
- 8. Since naloxone has a shorter duration of action than many opioids, close monitoring and repeated injections are necessarily according to the respiratory rate and depth of coma
- 9. Medical advice must be sought following naloxone administration
- 10. With their consent, any client treated with naloxone injection under this protocol should be referred to emergency medical services. Participants should not be transferred to emergency medical services unwillingly: drug users are subject to stigma and discrimination and may be incredibly resistant to attending post-resuscitation care. Thus, it is critical to have PWID-friendly, PWID-competent post-care emergency medical services trained and identified.
- 11.All overdose management incidents must be recorded in incident report according to agency procedures and used sharps equipment disposed of in accordance with protocol
- 12. Dispose of used injecting equipment in accordance with agency procedures for safe disposal

4.6 Service delivery model

In the majority of cases, overdoses are witnessed by a family member or peer thus increased access naloxone in line with WHO guidelines (2014) could significantly reduce the high numbers of opioid overdose related mortality if more people are enabled to carry the naloxone antidote. WHO, UNODC and UNAIDS promote enhanced and adequate access to naloxone which promote the provision of naloxone across the community and to a broad range of users partners and networks including peers, community members, HIV treatment services and outreach workers, family members, civil society organizations, healthcare providers, emergency health services, hospitals and others (WHO 2013).

Legal and policy level barriers will often restrict access and use of naloxone by lay 'first responders' and beyond basic hospital and emergency medical services. Harm reduction services should collect data on the prevalence and nature of overdose among participants to include both participants experiencing and witnessing overdose to support efforts for naloxone to be provided more widely within the community.

5.0 Integrating evidence-based psychosocial interventions into harm-reduction programs for PWID

Global guidelines recommend the delivery of psychosocial interventions as part of routine care in PWID programs (WHO 2009). OST and NSP are found to be more effective when coupled with psychosocial assistance to encourage behavioral and emotional change (Gowing et al. 2001). Psychosocial interventions can be provided in conjunction with OST, NSP and Naloxone and can help individuals identify and address the reasons for substance misuse, the associated negative

consequences as well as the benefits associated with reducing high-risk behaviors. Such interventions can help to identify and develop skills to prevent relapse into opioid use once individuals are stabilized on OST.

Syndemics of mental health and psychosocial issues, substance abuse and infectious diseases, often resulting from trauma as well as further trauma present in the lives of many PWID due to criminalization, marginalization and discrimination, HAI utilizes a trauma-informed approach to psychosocial interventions. A trauma informed approach includes knowledge and awareness about trauma in general and the ways in which traumatic experiences shape people's perceptions, behaviors and beliefs. It considers the impact of traumatic events on not only the individual but also the family and community and recognizes that interventions should be developed for and implemented at each level. It recognizes that the response to a traumatic event is mediated by individual, family and community factors and avoids assuming that trauma results in a mental health disorder or in severe emotional distress. It does not focus only on pathology but recognizes that individuals, families and communities have assets and resources and seeks to understand and utilize factors that contribute to resilience and recovery. Lastly, it focuses on empowering the affected individuals and community (SAMHSA, 2014).

Psychosocial interventions include brief interventions and counselling, motivational interviewing, cognitive behavioral therapy, group therapy, a family therapy and relapse prevention. Interventions often integrate case management to address the broader basic needs of participants and can be delivered in either a one-to-one and / or group format. According to UNODC Guidelines and International Standards for the Treatment of Drug Use Disorders (2016), these interventions can assist participants by providing support as they attempt to manage the consequences of drug use, factors impacting drug use, and high-risk drug related behavior and should form the basis of a care-plan based on SMART objectives.

- 5.1 Brief interventions: these aim to help individuals understand how their substance misuse and associated high-risk behaviors are putting themselves and others at risk and associated approaches can help them reduce or address these issues. They can be an effective first intervention to motivate individuals to access services for the first time and provide a medium to build trust and a therapeutic relationship with a service provider or practitioner. Brief interventions usually involve 45-60 minutes of counselling over a short period of time. Due to the brief nature of delivering such interventions, they can be delivered flexibly on outreach or during visits to low-threshold services such as One Stop Shops.
- 5.2 Motivational Interviewing: Motivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion. Techniques employed by a practitioner include reflective listening, developing discrepancy between patient goals and values and

current behaviors, avoiding conflict and argument, practicing empathy, adjusting resistance and supporting self-belief and non-judgment (Miller & Rollnick, 2002). They aim to help individuals explore their ambivalence around their substance misuse and high-risk behaviors and in course can bring about positive behavioral and psychological changes. Motivational interviewing can be delivered as a structured, semi-structured or brief intervention and tailored to the individual.

Motivational interviewing (MI) is a method well adapted to harm reduction that consists of several (often four) sessions that focus on the ambivalence to change and addressing this ambivalence and strengthening a person's own motivation and commitment to change.

The method of MI includes:

- Engaging (process by which both parties establish a helpful connection and a working relationship)
- Focusing (process by which therapist develops and maintains a specific direction in the conversation about change)
- Evoking (eliciting the participant's own motivations for change; harnessing the participant's won feelings about why and how they might change)
- Planning (an ongoing process that involves helping someone develop a sense of commitment and formulating a specific plan on action)

The participants and therapist will move in and out of the four processes and at times engaging in a conversation that involves more than one process at a time (SAMHSA, 2001)

- 5.3 Cognitive Behavioral Therapy (CBT): CBT is a time-sensitive, structured, present-oriented psychotherapy directed toward solving current problems and teaching participants skills to modify dysfunctional thinking and behavior. Typically, CBT interventions include recognizing and addressing faulty or unhelpful ways of thinking as well as learned patterns of unhelpful behaviors. In the context of substance use, cognitive strategies may address maladaptive thoughts that relate to substance use and relapse. Behavioral strategies include coping with cravings, cue and trigger exposure, promotion of non-drug / harm related activities, relaxation techniques and developing coping strategies as part of a plan. Further, CBT develops social skills learning in assertive behavior and refusal skills and problem solving. Due to CBT being delivered as a time-limited and structured intervention, it is better suited to individuals already stabilized in treatment such as OST (Magill & Ray 2009).
- 5.4 Other psychosocial models supporting behavior change: further behavioral approaches such as contingency management, 12 step approaches and cue exposure treatment show promising results and could be explored further and delivered as an adjunct to pharmacological OST in tandem with evidence-based psychosocial interventions.

5.5 Individuals with 'co-occuring disorders' (formally named, 'dual diagnosis' (mental health and substance misuse comorbidity): People with mental health disorders are more likely than people without mental health disorders to experience an alcohol or substance use disorders. Cooccurring disorders can be difficult to diagnose due to the complexity of symptoms, as both may vary in severity. In many cases, people receive treatment for one disorder while the other disorder remains untreated. This may occur because both mental and substance use disorders can have biological, psychological, and social components. Other reasons may be inadequate provider training or screening, an overlap of symptoms, or that other health issues need to be addressed first. People with cooccurring disorders are best served through integrated treatment. With integrated treatment, practitioners can address mental and substance use disorders at the same time, often lowering costs and creating better outcomes. Research indicates that individuals with trauma-related mental health issues have higher rates of comorbid substance misuse problems (Ouimette & Brown 2014). High-risk behaviors may arise as a result of substance use which may result in traumatic experiences or alternatively, trauma survivors may use substances as a form of self-medication to manage those traumatic experiences (Brady & Sinha 2005), On the other hand, some research challenges the self-mediation theory in favor of increased biological susceptibility to substance addiction co-occurring with certain mental health issues (Meuser, 1998). Regardless, harmreduction services should provide a trauma informed model of treatment reliant on evidence-based psychosocial interventions to support individuals with such a pervasive co-occurring disorder. Trauma-informed treatment can support individuals to develop strategies to increase safety in their current lives as well as develop skills to manage difficult situations or traumatic triggers (Drake, 2001; SAMSHA, 2016).

Several key-principles of trauma-informed practice have distinctive parallels with evidence-based treatment for problem substance misuse and drug related high-risk behaviors (Finkelstein et al. 2004) and can thus be integrated with psychosocial interventions for people who inject drugs such as OST programs. According to Finkelstein (2004), there is a growing evidence-base for several treatment models for individuals with co-occurring substance misuse and trauma histories and symptoms. The Substance Abuse and Mental Health Services Administration (SAMHSA) has created a database of evidence-based trauma-informed programs and practices (NREPP) for review and possible integration with harm reduction and substance misuse programs (SAMHSA NREPP).

5.6 Building a good therapeutic relationship with individuals in harm reduction programs: One significant driving factor contributing to positive outcomes is for an effective therapeutic relationship (or alliance) between the practitioner and the individual (Kelly et al. 2010). In a harm reduction or substance misuse treatment setting a therapeutic relationship should aim to support the practitioner and individual when working together to achieve common tasks and goals in reducing substance misuse and associated harmful behaviors. Krause et al. (2011) define this alliance as '...an emergent quality of working together productively within an

asymmetrical relationship.'(p. 279). A study by Meir, et al. (2006) found that individuals who had built a sub-optimal therapeutic alliance with their practitioner remained in treatment for substance misuse for a significantly shorter period of time compared to others who had reported having a strong therapeutic relationship. Duncan and Miller (2008) further suggest that a strong therapeutic relationship contributes to a 6 to 9 per cent increase in favorable behavior change among individuals accessing treatment for substance misuse. Variables that are conducive to a positive provider-participant relationship include a non-judgmental attitude, warmth, mutual respect, empathy, safety, confidentiality, trust and authenticity (SAMHSA, 2014).

6 Other key protocols and standard operating procedures

To safeguard the safety of staff and service users as well as to adhere to maintaining an optimal level of occupational health and safety, all services are advised to develop further procedures and protocols.

Universal precautions: universal precautions are a set of procedures designed to prevent transmission of HIV, Hepatitis B and C and other blood borne pathogens when providing first aid or health care. Universal precautions should be followed regardless of the client's infection status. These precautions include:

- Wearing of disposable gloves
- Washing contaminated hands / body parts with soap and water followed by drying
- Disinfection of contaminated surfaced with a solution of 1 part bleach-10 parts water or hospital grade disinfectant. Allow area to remain saturated for a minimum of 3 minutes before drying.
- Using disposable cleaning materials
- Disposal of cleaning and waste products according to local regulations and agency protocol

(WHO, 2008)

Needle stick injury: in the event of an accident needle prick with a contaminated needle, there may be a risk of being infected with HIV, hepatitis, tetanus or other pathogens. All staff regularly working around contaminated needles and syringes should be vaccinated against HBV and tetanus. If a staff member of client is accidentally pricked with a used needle, service providers should follow certain procedures to reduce the risk of contracting blood-borne infections. Protocols should include:

- Retain the offending needle / syringe in a safe container for examination later
- Cleaning of the area of the prick
- Washing of the wound with soap and water as soon as possible
- Encouraging the wound to bleed by squeezing the puncture site
- Second phase of cleaning the area with soap and water
- Application of antiseptic and a bandage

 Report to management and undertake evaluation and assessment for infection testing, Post Exposure Prophylaxis (PEP) and counselling as per agency protocol (WHO, 2008)

Management of sharps and other used injection equipment: service providers, particularly NSPs, require procedures for the handling of both sterile and used sharps by staff members and should also be trained to advise all participants around safer handling of used equipment. For staff, recommendations should include:

- Staff should not handle returned needles: participants should place their own needles in sharps containers
- Staff should be aware that participants may be carrying needles loose in their pockets and clothes or in non-secure containers such as plastic / paper bags
- Counting of returned / used needles should always be estimated by visual examination or asking the client rather than staff touching the needle
- Staff should always wear puncture proof gloves and use tongs / forceps to collect a discarded needle in the community and not from a client and should always have a sharps contained on them for immediate disposal (WHO, 2008)

Offsite communications protocol: Outreach workers and peer educators are required to keep in close contact while on field visits. Specific procedures around access, identification, communication, safety-in-numbers, lone working, dealing with aggressive behavior etc. are necessary to ensure that workers are not in any danger of physical risks when on outreach nor when in an inhospitable environment or dealing with a difficult client situation.

Code of conduct for participants: at the point of entry into a service for PWID, staff should explain confidential sharing, informed consent and information sharing and conduct.

Gender based violence management: Problematic drug use among women is often associated with a history of sexual abuse and women who inject drugs experience elevated rates of IPV. Violence has an immediate effect on a woman's ability to practice safer sex and safer drug use and contributes to continued drug use (Gilbert, 2015). A history of violence can make women feel uncomfortable in certain situations – for example, in a support group where the majority of participants are men, or when receiving pelvic examinations. Where a history of trauma contributes to problem drug use or risky behaviors, it is important that harm reduction and drug treatment programs take this into account and that staff are aware of how to deal appropriately with these issues.

7 Conclusion

Effective harm reduction program for PWID are proven effective in preventing HIV and other blood borne viruses. It can provide an entry point for staff to engage with otherwise 'treatment naïve' participants who are in urgent need of specialist health treatment and other services. NSPs, OST services and the administration

of naloxone do not lead to an increase in drug use or injecting drug use and in fact can result in an increased uptake of other drug treatment and health services among drug users.

Irrespective of the compelling evidence for harm reduction interventions, NSPs, OST services and naloxone distribution programs may face barriers during implementation and are advised to carry out advocacy programs with law enforcement agencies and communities locally, delivering sensitization on the issues of drug use and HIV as well as principles and wide evidence base for harm reduction. Management must ensure they are collecting pertinent data routinely and reporting on the numerous positive treatment outcomes and require all the necessary local and policy level permissions to implement activities. Any incidents occurring in harm reduction services, including community objections or concerns, law enforcement incidents and legal ramifications must be reported, addressed and documented to the service provider steering committee and other relevant officials.

References and recommended reading

Advisory Council on the Misuse of Drugs, United Kingdom (2015) 'How can opioid substitution therapy (and drug treatment and recovery systems) be optimized to maximize recovery outcomes for service users?' ACMD Recovery Committee Optimizing OST Report to the Inter-Ministerial Group on Drugs (UK), November 2014.

Alho H, D'Agnone OD, Krajci P (2015) 'The extent of misuse and diversion of medication for opioid substitution treatment: a review and expert opinions', *Heroin Addiction Related Clinical Problems*, 2015; 17, p. 25-34.

Amato L, Minozzi S, Davoli M, Vecchi S, Ferri MMF, Mayet S. (2008) 'Psychosocial and pharmacological treatments versus pharmacological treatments for opioid detoxification', Cochrane Database of Systematic Reviews 2008, Issue 4.

Aspinall, EJ, Nambiar, D, Goldberg DJ, Hickman M, Weir A, Van Velzen E, Palmateer N, Doyle JS, Hellard ME, Hutchnison SJ (2014) 'Are needle and syringe programmes associated with a reduction in HIV transmission among people who inject drugs: a systematic review and meta-analysis', *International Journal of Epidemiology*, 2014, February; 43 (1) p. 235-248.

Behrer C et al. (2010) 'Time to act: a call for comprehensive responses to HIV in people who use drugs', *Lancet*, 376(9740), p. 551-563.

Brady KT & Sinha T (2005) 'Co-occurring mental and substance use disorders: the neurobiological effects of chronic stress', *American Journal of Psychiatry*, 162, p. 1483-1493.

Degenhardt L et al. (2011) 'Mortality among regular or dependent users of heroin and other opioids: a systematic review and meta-analysis of cohort studies', *Addiction*, 2011; 106(1):32-51.

Degenhardt L & Hall W (2012) 'Extent of illicit drug use and dependence, and

Harm reduction guidelines

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their contribution to the global burden of disease', *Lancet*, Jan 7; 379(9810):p. 55-70.

Dennis BB, Naki L, Bawor M, Bonner A, Verenbut M, Daiter J, Plater C, Pare G, Marsh DC, Worster A, Desai D, Samaan Z, Thabane L (2014) 'The effectiveness of opioid substitution treatments for patients with opioid dependence: a systematic review and multiple treatment comparison protocol', Systematic Reviews, 2014, 3: 105.

Des Jarlais DC et al. (2012). Are females who inject drugs at higher risk for HIV infection than males who inject drugs? An international systematic review of high seroprevalence areas, *Drug and Alcohol Dependence*, doi: 10.1016/j. drugalcdep.2011.12.020.

Drake, R. E., Essock, S. M., Shaner, A., Carey, K. B., Minkoff, K., Kola, L., et al. (2001). Implementing dual diagnosis services for clients with severe mental illness. Psychiatric Services, 52(4), 469-476.

Duncan B & Miller S (2008) 'When I'm good, I'm very good, but when I'm bad I'm better: A new mantra for psychotherapists', *Psychotherapy in Australia*, p. 60-69.

Duncan B, Miller S, Reynolds L, Sparks J, Claud D, Brown J & Johnson LD (2004) 'The session rating scale: Psychometric properties of a 'working' alliance scale', *Journal of Brief Therapy*, 3, p. 3-11.

EMCDDA and APOTHICOM (2003) 'Pilot of injection material exchange programme (IMEP) in Ivry-sur-Seine pharmacies circulating the new single-use and sterile filter, Steriflit, for HIV and HCV risk reduction'. Lisbon, Portugal.

EMCDDA (2011a) The State of the Drugs Problem in Europe. Annual Report 2011, European Monitoring Centre for Drugs and Drug Addiction, Lisbon, Portugal.

EMCDDA (2011b) Guidelines for the Treatment of Drug Dependence. A European Perspective: Selected issue, Author: Lisbon, Portugal. European Monitoring Centre for Drugs and Drug Addiction (2006) Annual report 2006: the state of the drugs problem in Europe. Lisbon: European Monitoring Centre for Drugs and Drug Addiction. Lisbon, Portugal.

Finkelstein N, VandeMark N, Fallot R, Brown V, Cadiz S, Heckman J (2004) 'Enhancing substance abuse recovery through integrated trauma treatment', National Training Consortium, United States.

Gilbert, L., et al. (2015). Targeting the SAVA (Substance Abuse, Violence, and AIDS) Syndemic Among Women and Girls: A Global Review of Epidemiology and Integrated Interventions. J Acquir Immune Defic Syndr 69 Suppl 1: S118-127.

Gowing L, Farrell M, Bornemann R, Sullivan LE, Ali R (2008) 'Substitution treatment of injecting opioid users for prevention of HIV infection', *Cochrane Database of Systematic Reviews* 2008, Issue 2.

Harm Reduction International (2014) 'The Global State of Harm Reduction 2014'. London, England.

International Narcotics Control Board (2006) 'International Narcotics Control Board (INCB) Report 2006'. Vienna, Austria.

Jones L, Pickering L, Sumnall H, McVeigh, J & Bellis, A (2008) 'A review of the effectiveness and cost-effectiveness of needle and syringe programmes for injecting drug users', Centre for Public Health, Liverpool John Moores University.

Keijzer, L and Imbert, E (2011) 'The filter of choice: filtration method preference among injecting drug users', Harm Reduction Journal v8; 2011.

Kelly S, O'Grady K, Brown B, Mitchell S & Schwartz R (2010) 'The role of patient satisfaction in methadone treatment', *The American Journal of Drug and Alcohol Abuse*, 36, p. 150-154.

King, N., Fraser, V., Boikos, C. et al. (2014). Determinants of increased opioid-related mortality in the United States and Canada, 1990-2013: A systematic review. AJPH 104: e32-e42).

Krause M, Altimir C & Horvath A (2011) 'Deconstructing the therapeutic alliance: reflections on the underlying dimension of the concept', *Clinical and Health* 22(3) p. 267-283.

Lawrinson P, Ali R, Buavirat A et al. (2008) 'Key findings from WHO collaborative study on substitution therapy for opioid dependence and HIV/AIDS', *Addiction*, 103, p. 1484-1492.

Lert F & Kazatchkine MD (2007) 'Antiretroviral HIV treatment and care for injecting drug users: An evidence-based overview, *International Journal of Drug Policy*, 18(4), p. 255-261.

Magill, M & Ray, LA (2009) 'Cognitive-behavioural treatment with adult alcohol and illicit drug users: a meta-analysis of randomized controlled trials', *Journal of Studies on Alcohol and Drugs*, 70, p. 516-527.

Mattick RP, Kimber J, Breen C, Davoli M (2008) 'Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence', *Cochrane Database of Systematic Reviews* 2008, Issue 2.

Meier P, Barrowclough C & Donmall MC (2005) 'The role of the therapeutic alliance in the treatment of substance misuse: a critical review of the literature', Addiction, 100, p. 304-316.

McLellan AT et al., (2000) 'Drug Addiction, a chronic medical illness: Implications for treatment, insurance and outcome evaluation', *Journal of American Medical Association*, 284:13.

Miller WR & Rollnick S (2002) *Motivational Interviewing: Preparing People for Change*, 2nd Edition. New York: Guildford Press.

Mueser, K. T., Drake, R. E., & Wallach, M. A. (1998). Dual diagnosis: A review of etiological theories. *Addictive Behaviors*, 23(6), 717-734.

National Institute for Clinical Excellence, UK (2007) 'NICE Clinical guideline 51: Drug misuse – psychosocial interventions'. London: NICE.

Ouimette P & Read JP (2014) *Trauma and substance misuse: causes, consequences and treatment of comorbid disorders*, 2nd Edition, American Psychological Association.

Pinkham Sophie, Myers Bronwyn, Stoicescu Claudia. (2012) Developing effective harm reduction services for women who inject drugs. Adv Prev Med. 2069123.

Prochaska J & DiClemente C (1982) 'Trans-theoretical therapy – towards a more integrative model of change', *Psychotherapy: Theory, Research and Practice* 19(3) p. 276-288.

Prochaska J, DiClemente C & Norcross JC (1992) 'In search of how people change: applications to addictive behavior', *American Psychologist*, 47, p. 1102-1114.

Roberts A, Mathers B & Degenhardt L on behalf of the Reference Group to the United Nations on HIV and Injecting Drug Use (2010) Women who inject drugs: A review of their risks, experiences and needs. Sydney, Australia: National Drug and Alcohol Research Centre (NDARC), University of New South Wales.

Substance Abuse and Mental Health Services Administration (SAMHSA) National Registry of Evidence-based programs and practices (NREPP). SAMHSA NREPP website accessed April 11, 2018 at https://nrepp.samhsa.gov/landing.aspx.

Substance Abuse and Mental Health Services Administration (SAMHSA). (2001). TIP 35. Enhancing Motivation for Change in Substance Abuse Treatment DHHS Publication #. (SMA) 01-3602.

Substance Abuse and Mental Health Services Administration (SAMHSA) Trauma and Justice Strategic Initiative. (2014). SAMSHSA's concept of trauma and guidance for a trauma-informed approach. US Department of Health and Human Services, SAMHSA, Office of Policy, Planning and Innovation. HHS Publication No. 14-4884. Rockville, MD, USA.

Substance Abuse and Mental Health Services Administration (SAMHSA). (2016). Website on co-occurring disorders. https://www.samhsa.gov/disorders/co-occurring. Accessed April 11, 2018.

Scott J (2008) 'Safety, Risks and Outcomes from the Use of Injecting Paraphernalia', Scottish Government Social Research, The Scottish Government: Edinburgh.

Scott J (2002) 'Investigation into the effectiveness of filters used to prepare injections made with Subutex tablets', Department of Pharmacy and Pharmacology, University of Bath.

Strathdee SA et al. (2012) 'Towards combination HIV prevention for injection drug users: addressing addictophobia, apathy and inattention', *Current Opinion in HIV and AIDS*, 7(4), p. 320-325.

Strike C et al. (2006) Needle exchange programs: best practice recommendations, Toronto (ON): Ontario Needle Exchange Coordinating Committee.

United Nations Office on Drugs and Crime (2008) *Drug Dependence Treatment: Treatnet Training Package*. Vienna, Austria.

United Nations Office on Drugs and Crime (2009) *Principles of drug dependence treatment*. Vienna, Austria.

United Nations Office on Drugs and Crime (2016a) World Drug Report. Vienna, Austria.

United Nations Office on Drugs and Crime (2016b) *Manual for the training of policymakers on the nature, prevention and treatment of drug use disorders*. New York, New York.

United Nations Office on Drugs and Crime et al (2017) Implementing comprehensive HIV and HCV programs with people who inject drugs: practical guidance for collaborative interventions. Vienna, Austria.

Wickersham JA, Marwan MA, Cannon CM, Altice FL, Springer SA (2015) 'Validation of a brief measure of opioid dependence: the rapid opioid dependence screen (RODS)'. *Journal of Correct Health Care* 2015 January: 21(1) p. 12-26.

Wodak A & Maher L (2010) 'The effectiveness of harm reduction in preventing HIV among injecting drug users', NSW Public Health Bulletin (304) (2010).

Wood E et al. (2002) 'Factors associated with persistent high-risk syringe sharing in the presence of a established needle exchange programme', AIDS, 16(6), p. 941-943.

World Health Organization (1992) The ICD-10 classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines. Geneva, Switzerland.

World Health Organization (1998) *Principles for preventing HIV infection among drug users*, WHO Regional Office for Europe. Copenhagen, Denmark.

World Health Organization (2004) *Neuroscience of psychoactive substance use and dependence*, Summary. Geneva, Switzerland.

World Health Organization (2004b) 'Effectiveness of sterile needles and syringe programming in reducing HIV/AIDS among injecting drug users: Evidence for Action Technical Papers'. Geneva, Switzerland.

World Health Organization (2005a) Effectiveness of Drug Dependence Treatment in Preventing HIV among Injecting Drug Users: Evidence for Action Technical Papers. Geneva, Switzerland.

World Health Organization (2005b) XIV Edition of the Model List of Essential Medicines. Geneva, Switzerland.

World Health Organization (2005c) Effectiveness of Drug Dependence Treatment in Preventing HIV among Injecting Drug Users. Geneva, Switzerland.

World Health Organization (2007) Guide to starting and managing needle and syringe programs. Geneva, Switzerland.

World Health Organization. (2008). Core components for infection prevention and control programmes. Report of the second meeting of the informal network on infection prevention and control in health care. June 26-27. Geneva, Switzerland.

World Health Organization (2009) Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence. Geneva, Switzerland.

World Health Organization (2012) Guidance on prevention of viral hepatitis B and C among people who inject drugs. Geneva, Switzerland.

World Health Organization (2014) *Community management of opioid overdose*. Geneva, Switzerland.

World Health Organization (2016) mhGAP intervention guide for mental, neurological and substance use disorders in nonspecialized health settingsversion 2.0. Geneva, Switzerland.

World Health Organization (2016) WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings. Geneva, Switzerland.

WHO, UNODC, UNAIDS (2004) Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper. Geneva, Switzerland.

WHO, UNAIDS, UNODC (2007) Guide to starting and managing needle and syringe programmes. Geneva, Switzerland.

WHO, UNODC and UNAIDS (2009) Technical Guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users, Geneva, Switzerland.

Wright N, D'Agnone OD, Krajci P, Littlewoood R, Alho H, Reimer J, Roncero C, Somaini L, Maremmani I (2015) 'Addressing misuse and diversion of opioid

Harm reduction guidelines

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substitution medication: guidance based on systematic evidence review and real-world experience', *Journal of Public Health 2015*, p. 1-7.