TRAINING MANUAL ON HIV AND HCV RAPID TESTING IN LOW THRESHOLD SETTINGS FOR PWUD
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This training manual was developed within the EU-funded programme, Joint Action on HIV, Viral Hepatitis and Tuberculosis among People Who Inject Drugs in Europe (HA-REACT). The manual is designed to be a complete tool to provide staff in low-threshold settings the knowledge, skills and techniques needed for testing people who use drugs for HIV and HCV and linking them to needed care.

The content of the manual was adopted from previously developed guidelines, manuals and handbooks and is based on international best practices. The curriculum includes eight modules with descriptions of content to be taught and tips for practical exercises. The modules can be used as a complete 3-day training or independently.
“The content of this training manual represents the views of the authors only and is their sole responsibility; it can not be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.”
1. IN PREPARATION FOR THE TRAINING, TRAINERS WILL FIND IT USEFUL TO:

- study country/region legal situation with rapid HIV/HCV testing;
- study legal situation of people who use drugs;
- study possible options for HIV and HCV treatment;
- study barriers for linking patients to care;
- consult your country knowledge with local experts/peers;
- make sure you know who the trainees are and what are their needs and interests;
- make sure the participants have information about training goals, content and schedule ahead.

2. PREPARE THE TRAINING SPACE. MAKE SURE THAT:

- the training room is big enough and possibly has windows;
- hand-outs and training program printed out;
- all necessary materials (flipchart, markers, paper etc.) are in the room;
- the electronic equipment is working properly;
- drinking water is available in the trainings room;
- for trainings that involve people who use drugs it is advisable to have sterile injection equipment and naloxone available (and to inform participants about where it is located.)
ENSURE THAT YOUR KNOWLEDGE IS UP TO DATE!
OBJECTIVE:
By the end of the session participants will understand:
- the biology of HIV and HCV; modes of transmission of HIV and HCV; screening and diagnosis methods for HIV and HCV; HIV and HCV treatment options.
- Basic information about tuberculesis.

TRAINING METHODS:
Lecture, working groups.

TRAINING MATERIALS:
Power-Point slides and projector.

INSTRUCTION TO THE FACILITATOR:
During preparation, study the HIV and HCV epidemiological situation and access to treatment in the country. Start the session by introducing the main objectives. Adjust the language of your presentation to ensure that it is understandable to the people you are training (e.g. use less technical medical terminology for a group of social workers and peers).

Even in a group of experienced social workers and peers, provide basic information about HIV, HCV and TB from this module. Practice makes perfect!
1.1 THE BIOLOGY OF HIV

HIV stands for ‘human immunodeficiency virus’. HIV is the virus that causes AIDS. Immunodeficiency means decrease or weakness in the body’s ability to fight off infections and illnesses. HIV infection leads to a weakened immune system which makes a person with HIV vulnerable to a group of illness, e.g., opportunistic infections, that would not as easily affect a person who does not have HIV infection. AIDS stands for ‘acquired immune deficiency syndrome’ is the final stage of the disease caused by HIV. AIDS results when HIV infection progresses to an advanced stage, damaging the immune system to a point at which the body can no longer fight illness. AIDS is called a syndrome because it is characterized by a group of illnesses.

HIV vs. AIDS

- HIV IS A VIRUS THAT CAUSES AIDS;
- NOT EVERYONE WHO IS INFECTED WITH HIV HAS AIDS;
- EVERYONE WITH AIDS IS INFECTED WITH HIV;
- AIDS IS A RESULT OF THE PROGRESSION OF HIV INFECTION;
- PEOPLE INFECTED WITH HIV AND WITH A DETECTABLE VIRAL LOAD CAN TRANSMIT THE VIRUS TO ANOTHER PERSON;
- PEOPLE WITH UNDETECTABLE VIRAL LOAD CANNOT TRANSMIT THE VIRUS.

There are two types of HIV viruses, HIV-1, and HIV-2. Both produce the same patterns of illness. HIV-2 causes a slower progress to AIDS than HIV-1. It is important for tests to detect both HIV subtypes, otherwise testing may lead to false negative results.

HIV infects a key group of cells called CD4 T-lymphocytes (later CD4) that coordinate the body’s immune defense system. CD4 T cells produce several proteins called cytokines which play an important part in immune response against pathogens. When HIV-infection destroys CD4 cells, it weakens the body’s ability to fight against pathogens. A healthy person has 800-1200 CD4 cells per one microliter of blood. When the amount of CD4 cells drops below 200 or-and specific diseases occur, a person living with HIV is diagnosed with AIDS. Figure 1 shows the virology and immunologic course of HIV disease.
After the virus enters the body, there is a period of rapid viral replication, leading to an abundance of virus in the peripheral blood. During primary infection (a stage of disease 2-6 weeks after infection), the level of HIV may reach several million virus particles per milliliter of blood. This causes a rapid decrease in CD4 cell count. CD4 count increases back to a normal level when body’s immune response to HIV turns on. However, even as the increased CD4 count decreases the virus load, the immune response cannot clear the infection because of the high mutation rate of HIV. The higher a person’s viral load is, the faster their CD4 cell count will fall, and their risk of getting AIDS will be higher.

Over time, more and more CD4 cells perish and ultimately, HIV causes AIDS by depleting too many CD4 T cells. This weakens the immune system and allows opportunistic infections to manifest. CD4 cells are essential to the immune response and, without them, the body cannot fight opportunistic infections. AIDS typically occurs about 10-12 years after the initial infection. With effective treatment with antiretroviral drugs (ARV) the viral load stays under 30 copies of the virus per milliliter of plasma and HIV viruses do not destroy CD4 cells anymore. As a result, the immune system function is restored and opportunistic infections are prevented. People living with HIV who start treatment early can reach the average of the life expectancy in connection with the dynamics described and shown in Figure 1.

Figure 1. Virologic and immunologic course of HIV disease
1.2 THE BIOLOGY OF THE HEPATITIS C VIRUS (HCV)

Viral hepatitis C is a liver disease caused by the hepatitis C virus (HCV) which attacks liver cells and replicates inside them leading to changes in liver cells and malfunctions. The virus can cause both acute and chronic hepatitis, ranging in severity from a mild illness lasting a few weeks to a serious, lifelong illness.

A significant number of those who are chronically infected will develop cirrhosis or liver cancer. Acute HCV infection is usually asymptomatic, and is only very rarely (if ever) associated with life-threatening disease. About 15–45% of people who get infected spontaneously clear the virus within 6 months of infection without any treatment; their immune system successfully clears from their bodies. The remaining 55–85% of people will develop chronic HCV infection. Of those with chronic HCV infection, the risk of cirrhosis of the liver is between 15–30% within 20 years.

Figure 2. Risk and time of progression to different liver disease states among people living with HCV
1.3 HIV TRANSMISSION

HIV is transmitted via blood during sexual intercourse (vaginal, anal, oral) with an infected partner (who has not achieved undetectable viral load through effective treatment with ARV drugs) or by contact with infected blood, most often by sharing of needles, syringes or other paraphernalia contaminated with the virus. It is also possible to get the infection by transfusion with HIV-infected blood. Children can get the infection from an HIV positive mother during pregnancy, birth or breastfeeding (Fig 3). The risk of transmission during unprotected anal sex is several times higher in than it is during vaginal sex. The transmission risk is greatest in the acute phase of the infection when the virus load is high.

Figure 3. How HIV is transmitted

HIV is not transmitted by air or water, mosquitoes, ticks or other insects, saliva, tears, or sweet that is not mixed with blood of an HIV infected person or by shaking hands, hugging, sharing drinking glasses and kissing (Fig 4).

Figure 4. How HIV is not transmitted
The hepatitis C virus is a blood borne virus. It is most commonly transmitted through exposure to small quantities of blood through:

- the sharing of injection equipment by people who inject drugs;
- the reuse or inadequate sterilization of medical equipment, especially syringes and needles in healthcare settings;
- the transfusion of unscreened blood and blood products;
- tattooing and piercing with inadequately sterilized equipment;
- household risks when living with persons with HCV – sharing razors, tooth brushes, nail clippers other things coming in contact with blood.

HCV can also be transmitted sexually and can be passed from a mother who is living with the virus to her baby however, these modes of transmission are much less common (Fig 5).
1.5 SCREENING AND DIAGNOSIS FOR HIV

There are number of good reasons why people should get tested for HIV. Access to testing for HIV helps those in need start antiretroviral treatment (ART). Even though HIV is still not a curable disease, ART helps people living with HIV live longer, healthier lives without AIDS. Another reason for people to get tested is that access to testing contributes to prevention of new infections. People who are aware that they are living with the virus tend to change their behavior to avoid transmitting the virus to others.

Also, access to ARV treatment reduces the risk of transmission. People living with HIV who have undetectable viral loads due to effective treatment cannot transmit the virus to others. In communities, the more people access ART, the fewer new infections there are. Another reason for HIV testing is that mother-to-child transmission can be prevented as mothers who know they are HIV positive can take ART. The probability that a mother living with HIV who is not on ART would transmit the virus to her child during pregnancy and/or delivery is approximately 20%. If a mother living with HIV takes ART, the probability of transmitting the virus to the child decreases to one percent. Finally, starting treatment early is more cost-effective than starting treatment later due to its benefits for the health of individuals taking treatment and to its impact on preventing transmission of the virus.

Acute primary HIV infection cannot be diagnosed from the symptoms which may start 2-6 weeks after transmission and last 1 to 4 weeks. Only 30-50% of infected persons show symptoms.

Symptoms can include fever, sore throat, fatigue, diarrhea, headache, joint and muscle aches and swollen lymph nodes. Once HIV enters the body, it infects CD4 cells and starts replicating. During this acute or primary phase of infection, the blood contains number of viral particles that spread throughout the body, seeding various organs, particularly the lymphoid organs. At the same time, the body starts to produce antibodies against HIV. If a person has HIV-RNA (the virus genome), HIV-antigens or antibodies to HIV in his or her body, this indicates that the person is infected with HIV.

HIV is usually diagnosed through the detection of antibodies against to HIV and/or the HIV p24 antigen rather than direct detection of the viral genome. Preliminary HIV-tests search for antibodies to HIV. They are enzyme immunoassays used in laboratories or rapid tests often used in low threshold services. All preliminary positive HIV-test results must be confirmed from a second sample with a confirmatory test done in a laboratory.
1.6 SCREENING AND DIAGNOSIS OF HCV

Because acute HCV infection is usually asymptomatic, few people are diagnosed during the acute phase. In those people who go on to develop chronic HCV infection, the infection often remains undiagnosed because it often remains asymptomatic until symptoms develop secondary to serious liver damage which often occurs decades after virus enters the body.

INCUBATION PERIOD, SYMPTOMS AND FACTORS AFFECTING PROGRESSION OF LIVER DISEASE

1. INCUBATION PERIOD 2 - 24 WEEKS
2. 80 % DO NOT SHOW ANY SYMPTOMS
3. SYMPTOMS: FEVER, FATIGUE, DECREASED APPETITE, NAUSEA, ABDOMINAL PAIN, DARK URINE, JOINT PAIN AND YELLLOWING OF SKIN AND THE WHITES OF EYES
4. VIRUS LOAD DO NOT CORRELATE TO THE LIVER DAMAGE
5. EXTERNAL AND HOST FACTORS THAT CAN INCREASE THE PROGRESSION OF LIVER DISEASE:
   - male gender;
   - age of the time of infection 40 years;
   - alcohol consumption 20g / day (one pint of beer);
   - smoking;
   - co - infection with HIV or hepatitis B - virus.

HCV infection is diagnosed in two steps:

1. Screening for HCV antibodies with a serological test identifies people who have been infected with the virus. HCV antibodies develop within 6 months (usually in 4 months.) The antibodies can be detected by rapid tests using a drop of blood, serum or mouth plaque or through a standard venous blood test.
2. If the test is positive for HCV antibodies, a nucleic acid test for HCV ribonucleic acid (RNA) is needed to confirm chronic infection because about 15–45% of people infected with HCV spontaneously clear the infection through a strong immune response and therefore do not require treatment. Although no longer infected, they will still test positive for anti-HCV antibodies. This means that a person who was cured of HCV will have HCV antibodies in the blood forever, screening for HCV antibodies should be followed up with nucleic acid tests for HCV for those who are test positive for HCV antibodies.

After a person has been diagnosed with chronic hepatitis C infection, they should have an assessment of the degree of liver damage (fibrosis and cirrhosis) they may have. This can be done by liver biopsy or through a variety of non-invasive tests (e.g. Fibroscan or APRI index). In addition, these people should have a laboratory test to identify the genotype of the strain of HCV that they have. HCV has six genotypes, labeled 1 through 6. There are also subtypes labeled with letters, for example, genotypes 1a and 1b. Most people are infected by a single, dominant genotype, but it is possible to have more than one at the same time (called a mixed infection).

All persons with chronic HCV infection should undergo treatment with direct acting antivirals (DAAs). The degree of liver damage and virus genotype are used to guide treatment decisions and management of the disease. With the new pangenotypic DAAs, it is possible to treat treatment-naïve people with chronic hepatitis C without genotyping the virus.

### 1.7 HIV TREATMENT AND DRUG USE

WHO guidelines recommend initiation of antiretroviral therapy (ART) regardless of CD4 count for all people living with HIV, including people who use drugs. ART should be started as soon as possible after the diagnosis.

There are more than 30 antiretroviral drugs belonging to six different drug classes. Some HIV medicines are available in combination, meaning that two or more different HIV medicines are combined in one pill and with some combinations, only one pill per day is needed but such pills are not yet available in all countries. It is very important that medicines are taken regularly every day. Poor adherence to an HIV treatment regimen increases the risk of drug resistance and treatment failure.

Antiretroviral drugs (ARVs) used to treat HIV are grouped by how they interfere with steps in the replication cycle of HIV. Fusion inhibitors block the virus from binding to the target cell. Nucleoside analogs prevent the transcription of virus RNA to DNA. Integrase inhibitors inhibit virus DNA from integrating into the cell genome and protease inhibitors prevent cells from making new virus particles.
HIV treatment with ARVs do not cure people of HIV. They suppress the replication of the virus to an undetectable level, but cannot remove viruses that have already integrated into a cell’s genome. If the treatment is stopped, the infected cells start producing new virus particles again and there is also risk that viruses resistant to the ARVs used will be produced. This means that the ARV that had been used may no longer be effective in treating HIV in that person. It is very important that ARVs are taken every day for the rest of the person’s life.

Treatment providers should be aware of other medicines as well as street drugs that people with HIV are taking when ARV is initiated and new drugs that are added during continuing treatment.

According to the WHO guidance, ARV drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives. Limited data suggest potential drug interactions between contraceptive hormones and many ARV drugs (especially some non-nucleoside reverse transcriptase inhibitors (NNRTIs) and ritonavir (RTV)-boosted PIs). These interactions may alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. However, current WHO contraception guidelines conclude that none of the drug interactions between currently recommended ARVs for treatment and for PrEP, on one hand, and, on the other, hormonal contraceptives are significant enough to prevent their use together. If women receiving ART decide to initiate or continue using hormonal contraceptives, consistent use of condoms is recommended both to prevent HIV transmission and to compensate for any possible reduction in the effectiveness of the hormonal contraception.

WHO recommends methadone and buprenorphine to treat opioid dependence. Co-administering efavirenz (EFV) decreases methadone concentrations. This could subsequently cause withdrawal symptoms and increase the risk of relapse to opioid use. People receiving methadone and EFV should be monitored closely, and those experiencing opioid withdrawal may need to adjust their methadone dose.

The limited evidence suggests interactions between ARVs and illicit drugs.

1.8 TREATMENT FOR HCV

Antiviral medicines can cure more than 95% of persons with hepatitis C infection, thereby reducing the risk of death from liver cancer and cirrhosis. There is currently no vaccine for hepatitis C. If the HCV-infection is not spontaneously cured, treatment for HCV should be started. The goal of hepatitis C treatment is cure. The cure rate depends on several factors including the strain of the virus and the type of treatment given. The standard of care for hepatitis C is changing rapidly. Direct-acting antivirals (DAA) can achieve cure rates above 95%. These medicines are much more effective, safer and better-tolerated than the older therapies. Therapy with DAAs can cure most persons with HCV infection and treatment is shorter (usually 12 weeks)
Tuberculosis (TB) is an infectious disease that, unlike HIV and hepatitis, is caused not by viruses but bacteria. TB affects, in the first place, people with a weakened immune system. Some people who use drugs (PWUD) are especially vulnerable to TB, due to additional risk factors including other infectious diseases, smoking and drinking, poor nutrition, poverty, homelessness and imprisonment.

All people suspected to have TB should be referred to a medical exam as soon as possible. People who have close contact with TB patients should be motivated to undergo TB screening too. Diagnosis of TB in PWUD can be more difficult because of the high prevalence of HIV and other diseases among them. Lung TB, which is negative for analysis, is most common in people living with HIV, which in turn leads to late detection, poor treatment outcomes and early mortality. Late diagnosis is particularly common among PWUD or patients of OST program, since some opiates can suppress the cough reflex. Some PWUD avoiding TB diagnostics for fear of inpatient treatment that might deny them access to their drug of choice. This is a major factor in countries with low levels of access to OST and or repressive drug policy.

Co-infection of HIV and tuberculosis:
TB is one of the main causes of death among PWUD living with HIV. TB develops easier in people whose immune system is weakened by HIV, and HIV often develops faster in people with TB. For example, for people who are infected with TB, the risk of developing active disease throughout life is 5-10%. And for HIV-positive people, the risk of developing the active disease during within one year is 5-10%. It is important to conduct regular screening among HIV-infected people so that, with the help of an earlier start of ART, it is possible to prevent the transition from latent to active TB.

Treatment of tuberculosis:
Treatment of TB requires a long time (from 6-9 months to up to two years with drug-resistant TB), during which it is necessary to take TB drugs daily. Often they have very unpleasant side effects, especially when taking ART at the same time. But for a successful, complete cure of TB, the treatment regimen must be strictly observed on a daily basis. Without this, there will be no improvement and a very high risk of developing drug resistance.
It is necessary to support PWUD so that they can complete the TB treatment. Such support includes the possibility of obtaining opioid substitution therapy (OST) and support in providing their basic life needs, such as nutrition and sleep.

With early detection and strict adherence to the regimen, tuberculosis, even with drug resistance and HIV / hepatitis co-infection, can be cured!

**KEY FACTS ABOUT TUBERCULOSIS:**

- **TUBERCULOSIS IS ONE OF THE TOP 10 CAUSES OF DEATH WORLDWIDE.**

- **TB IS THE LEADING KILLER OF PEOPLE LIVING WITH HIV.**

- **TB IS TRANSMITTED BY AIR. WHEN A PERSON WITH A CONTAGIOUS TB IN THE LUNGS OR LARYNX, COUGHS, SNEEZES, SINGS, LAUGHS OR TALKS, PARTICLES CONTAINING TB BACTERIA ENTER THE AIR. INFECTIOUS PARTICLES CAN REMAIN IN THE AIR FOR MANY HOURS. WHEN OTHER PEOPLE INHALE AIR WITH INFECTIOUS PARTICLES, THEY CAN BECOME INFECTED WITH TB.**

- **TB BACTERIA DO NOT SPREAD THROUGH HOUSEHOLD ITEMS (FOR EXAMPLE, CLOTHES, BOOKS, TOILET SEATS, ETC.), FOOD, DRINKS OR THROUGH A HANDSHAKE WITH A PERSON LIVING WITH TB.**

- **TUBERCULOSIS CAN BE «LATENT» AND «ACTIVE». A PERSON INFECTED WITH MYCOBACTERIUM TB WHICH IS IN ITS LATENT FORM HAS THE INFECTION IN HIS OR HER BODY BUT IT DOES NOT DEVELOP, AND IT IS IMPOSSIBLE TO BECOME INFECTED FROM THIS PERSON.**

- **SYMPTOMS OF ACTIVE FORM OF TB INCLUDE: PROLONGED COUGH (2-3 WEEKS); WEIGHT LOSS; MILD FEVER (ABOUT 37 DEGREES); LOSS OF APPETITE; INCREASED FATIGUE; AND SWEATING AT NIGHT.**

- **THERE ARE FORMS OF DRUG-RESISTANT TB. THIS MEANS THAT DRUGS FOR TB TREATMENT NO LONGER FUNCTION TO KILL TB BACTERIA.**

- **RESISTANCE TO ANTI-TUBERCULOSIS DRUGS IS OFTEN CAUSED BY THEIR INCORRECT, INAPPROPRIATE USE, THE USE OF INEFFECTIVE DRUGS AND THE PREMATURE DISCONTINUATION OF THERAPY. IT IS ALSO POSSIBLE TO BECOME INFECTED WITH A FORM OF TB WHICH IS ALREADY DRUG RESISTANT.**

- **DRUG RESISTANT TB IS SPREAD IN THE SAME WAY AS DRUG-SUSCEPTIBLE TB. THERE IS NO DEFINITE EVIDENCE THAT DRUG-RESISTANT TB IS MORE INFECTIOUS THAN DRUG-SUSCEPTIBLE TB.**
BEFORE THE TRAINING, COLLECT INFORMATION ABOUT THE TB SITUATION IN THE COUNTRY AND THE KNOWLEDGE LEVEL AMONG THE TRAINING PARTICIPANTS. IF THE PROBLEM OF TUBERCULOSIS AMONG PWUD IS IMPORTANT IN THE COUNTRY, WE RECOMMEND TO DEDICATE ONE FULL DAY FOR THIS TOPIC. YOU MIGHT USE A TUBIDU TRAINING OUTLINE. TUBIDU MATERIALS ARE AVAILABLE IN BULGARIAN, ESTONIAN, LATVIAN, LITHUANIAN, ROMANIAN, RUSSIAN AND ENGLISH LANGUAGES.

FOR MORE INFORMATION WE RECOMMEND:

1. Consolidated guidelines on HIV testing services. WHO 2015.


8. https://www.cdc.gov/hiv/basics/testing.html


MODULE 2.
DIFFERENT TYPES OF TESTS

OBJECTIVE:
By the end of the session participants will understand:
• What types of HIV and HCV tests exist, how they work, and what the ‘window period’ is.

TRAINING METHODS:
Lecture.

TRAINING MATERIALS:
Power-Point Presentation, working groups.

INSTRUCTION TO THE FACILITATOR:
Combine theoretical information with practical exercises. Follow the testing protocols and standards used in the country. Bring some testing kits to demonstrate.

Over the last few years, new approaches to testing have become available which address the needs of different people. New testing approaches involve: counselling as a main focus; addressing prevention; availability in low threshold settings; referral services; linkage to care; rapid tests as a standard of care. These standards should be taken in to consideration when planning and implementing testing programs.
2.1 ANTIBODY SCREENING TEST

Practically all people living with HIV and/or HCV have antibodies to the respective viruses. Antibodies usually develop during the first month of infection but it can take a longer time before tests can detect them. The time after infection and before antibodies can be detected is called ‘the window period’ and it can be as long as 3 months for HIV and up to 6 months for HCV. Antibody tests for HIV and HCV may show false negative results for HIV and HCV antibodies during this time period. During the window period an infected person can pass the virus on to others.

WINDOW PERIODS – WHEN CAN HIV BE DETECTED?

- FOURTH GENERATION TESTS
- + 3 MONTH AFTER EXPOSURE
- THIRD GENERATION TESTS
- RAPID TESTS
- SELF-TESTING KITS

YOUR HEALTHCARE WORKER WILL HELP YOU DECIDE WHICH TEST IS BEST TO TAKE

WINDOW PERIOD

- TIME FROM INITIAL INFECTION UNTIL ANTIBODIES ARE DETECTED
- IT IS USUALLY 3-8 WEEKS BEFORE ANTIBODIES ARE DETECTED
- UP TO 3 MONTHS FOR HIV AND UP 6 MONTHS FOR HCV
- TEST MAY SHOW FALSE-NEGATIVE FOR ANTIBODIES DURING THIS TIME PERIOD
- PEOPLE CAN STILL PASS THE VIRUS TO OTHERS DURING THIS PERIOD
The window period is a stage when a person has been infected with HIV or HCV, but body hasn’t yet created antibodies. “Seroconversion” is the term used to describe the change when there are enough of antibodies to produce a positive antibody test. In other words, blood is negative to HIV or HCV antibody tests during a short time period after infection, but converts to positive for antibodies after a certain period, generally, 3-8 weeks after the initial infection and not later than 3 months for HIV (Fig 8). If the HIV antibody test result is negative within three months from the exposure to the virus the test should be repeated once 3 months have passed from the time. In the case of HCV, the test should repeated once 6 months have been passed since the time of exposure to the virus.

**Figure 8.** HIV antibody window period and the evolution of HIV antibodies
• TESTING IN THE WINDOW PERIOD:

Polymerase chain reaction

The first marker for HIV infection that can be detected is the presence of HIV-RNA which can be found as early as 11 days after transmission. Even though polymerase chain reaction (PCR) tests can be used as an additional test for helping to detect HIV-infections during the window period, there are several reasons why a PCR test is not suitable alone for primary diagnostics. It is expensive, labor intensive and it needs special facilities. In addition, because of its sensitivity and specificity, all preliminary positive PCR results must be confirmed with HIV-antibody tests to confirm infection. PCR tests are mainly used to monitor the progression of infection and treatment outcomes. In addition, it is used in the diagnosis of HIV infection in infants born to mothers living with HIV.

Antibody / p24 Antigen combo assay

These assays detect both HIV antibodies and antigens. The mean time between HIV-infection to the possibility of detecting the HIV p24 antigen is 16 days. Because the HIV p24 antigen can be detected in plasma in only approximately 50% of HIV-infected individuals, these tests cannot be used alone for primary diagnostics. As in the case of PCR, all preliminary p24 antigen positive results must be confirmed with HIV-antibody test to confirm the infection.

2.2 RAPID TEST

Rapid, point-of-care tests make it easier for people to access testing and ensure that test results are received and are acted upon immediately. When people receive their test results immediately, they can more quickly access to treatment and care. Rapid tests also give a good opportunity for pre-test and post-test counseling. People who seek testing and counseling voluntarily are also often the ready for behavior change and messaging about prevention and accessing treatment can be effective.

It is recommended that health-care providers familiarize themselves with the performance characteristics of the type of test used as these inform use and counselling. Health-care providers should be aware that rapid HIV / HCV tests are less sensitive than laboratory-based tests and may therefore give false negative results in the early state of infection. Reduced sensitivity has also been reported in advanced disease/AIDS. In addition, as with all tests, the positive predictive value of a reactive test is reduced in low prevalence settings meaning that false positive results will occur to a different extent depending on the setting and population undergoing screening.
Point of care tests that use sample types other than blood, such as plaque, may be subject to more variation in assay performance and sensitivity. Obtaining a blood sample for laboratory testing is recommended in all patients with reactive or indeterminate results and in patients with a negative test if recent infection is suspected. Sites using rapid tests should be overseen by the local laboratory and have a robust quality assurance programme.

What does a rapid test mean?

- Test is rapid to perform: 1-30 min.
- The test do not require specialized equipment
- The tests are easy to perform
- Some of the tests can be done from finger prick blood or saliva
- Rapid tests do not find infections more rapidly than laboratory tests

Most rapid tests detect both HIV-1 and HIV-2 but most of these tests do not differentiate between them.

Only tests with a CE marking can be used for testing. The CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). It is manufacturer’s declaration that the product meets the requirements of the applicable CE directive. This means that performance of the test has been evaluated by the appropriate Notified Body. The approved CE mark consists CE logo and the four digit identification number (below the CE logo) of the Notified Body involved in the conformity assessment procedure. If the test is not officially CE marked and properly evaluated, the tests performance is not known.
The test should be performed strictly according to the manufacturer’s instructions. There are three possible outcomes for rapid antibody tests (Fig 9).

1. The result is positive when reaction line is shown at the control and patient window
2. The result is negative when reaction line is shown only at the control window
3. No result at all when there is no reaction line at the control window

Figure 9. Interpretation of rapid test results (may be different with different test formats)
2.3 FOLLOW-UP DIAGNOSTIC TEST FOR HIV

All reactive primary HIV test results (e.g., rapid tests) must be confirmed with a confirmatory test in the laboratory (Fig 10). HIV antibody assays typically have exceptionally high sensitivity and specificity compared with those of assays for other infectious diseases. That being the case, there is generally a trade-off that favors sensitivity over specificity for the primary HIV assay so as not to miss true positive specimens. Additional testing is required to resolve cases of false reactivity (that is, to rule out false positives) and to verify reactivity (that is, to rule in true positives).

Figure 10. Testing flow chart. (*Negative after three months Window period)

According to WHO, retesting is recommended for the following populations:

1. Individuals testing HIV-negative who:
   - have ongoing risk for HIV infection;
   - can identify a specific incident of possible HIV exposure in the preceding four weeks; or
   - are pregnant, in high HIV prevalence setting; or those who test HIV negative in the first trimester, during labour or shortly after delivery.

2. Individuals whose HIV status is inconclusive, irrespective of risk.

3. Individuals diagnosed HIV-positive should be retested to verify their HIV diagnosis prior to initiation of care and/or treatment.

Retesting is not recommended for individuals on ART.
It is recommended that people who inject drugs be retested within six months.
What does a negative HIV-antibody test result mean?

A negative result means either that person tested do not have HIV infection and can not transmit HIV infection to others or that too short time has elapsed from the infection and antibodies have not yet developed (less than 3 months). In the latter case, the person can transmit the infection to others. A negative antibody result does not mean that person is immune to infection.

What does a positive HIV - antibody test result mean?

A primary HIV-antibody positive result means that a confirmatory test should be done to make sure that the screening test result was correct. If the confirmatory test is also positive, it means that the person has HIV infection and can transmit HIV infection to others. People living with HIV are at risk to develop AIDS or other HIV related complications if they do not start ARV treatment.

2.4 FOLLOW - UP DIAGNOSTIC TEST FOR HCV

If a test is positive for HCV antibodies, a nucleic acid test for HCV ribonucleic acid (RNA) is needed to confirm chronic infection. This because about 15–45% of people infected with HCV spontaneously clear the infection by a strong immune response without the need for treatment and have HCV antibodies even though the virus is no longer in their bodies. Although no longer infected, they will still test positive for HCV antibodies.

2.5 NEW TYPES OF TESTS: HOME TESTS / SELF-TESTING AND SELF - SAMPLING TEST

Home test and self-tests are becoming more popular in European countries, which are looking for ways to increase number of people tested for HIV and HCV.

• IMPLEMENTATION OF HIV - HOME TESTS/SELF - TESTS

In most cases test kits can be purchased online and/or form pharmacies.

The self-test is an HIV rapid test, which can be easily performed at home. For this, some blood from a finger or plaque should be placed on the test kit. The test indicates a result in around 15 minutes. It shows the presence of antibodies to the HIV virus. It is important to remember, that antibodies will form after some time. The test should therefore be performed 12 weeks after the last possible exposure to the virus.
IMPLEMENTATION OF THE SELF-SAMPLING TESTS

In contrast to home tests, by self-sampling tests individual takes a plaque or blood sample by themselves and sending it to a laboratory. The results will be communicated to the person by email or phone.

HIV- and HCV negative PWUD should be re-tested every six months, or in connection with a specific on the risky situation.

POSSIBLE TOPICS FOR GROUP WORK:

1. WHAT KIND OF RAPID TESTS ARE AVAILABLE IN YOUR COUNTRY (BLOOD OR SALIVA)?
2. WHO IS ALLOWED TO PERFORM RAPID TESTS IN YOUR COUNTRY (NGO, GO, SOCIAL WORKERS, PEERS, DOCTORS AND NURSES)?
3. WHAT ARE POSSIBLE ADVANTAGES AND DISADVANTAGES OF RAPID TESTS?
4. IF YOUR ORGANIZATION DOES NOT PERFORM RAPID HIV/HCV TESTS FOR PEOPLE WHO USE DRUGS, WHAT STEPS SHOULD BE DONE, AND WHAT RESOURCES ARE NEEDED TO START THIS PROCESS?

FOR MORE INFORMATION WE RECOMMEND:

5. Guidelines for testing HIV, viral hepatitis and other infections in injecting drug users. EMCDDA, Lisbon, November 2010.
MODULE 3. PRE-AND POST-TEST COUNSELING

OBJECTIVE:
By the end of the session participants will understand:
- The standards of pre-test and post-test counselling;
- the procedure of counselling; and
- importance of counselling.

TRAINING METHODS:
Lecture

TRAINING MATERIALS:
Power-Point Presentation, working groups.

INSTRUCTION TO THE FACILITATOR:
Before the session, study questionnaires for pre- and post-test counselling used in the country.
According to World Health Organization (WHO), voluntary HIV testing and counselling (VTC) should be routinely offered to all key populations, including people who inject drugs, and is strongly recommended in both the community and clinical settings. Community-based testing and counselling with linkage to prevention, care and treatment services, is recommended, in addition to provider-initiated testing and counseling. Notably, HIV/HCV VTC must always be voluntary and free from coercion and must be part of a comprehensive prevention, care and treatment program. It is important that there are clear and robust links between testing and HIV treatment and care services for those who test positive and with prevention services for those who test negative.

The counselling must be offered only by a trained counsellor, who is able to reflect on their work. A good HIV/ HCV test counselor must:

- have deep understanding of HIV, HCV and another STIs;
- be proficient in counselling techniques;
- have a non-discriminatory and accepting position.
3.1 PRINCIPLES OF PRE-POST-TEST COUNSELLING

According to WHO, “HIV testing must always be done with informed consent, adequate pre-test information or counselling, post-test counselling, protection of confidentiality and referral to services.” When testing PWUD, the counselor has the right to not test if the client is too impaired and is unable to make an informed consent.

Prior to conducting any tests, an individualized assessment of capacity should be made in each case. The purpose of this is to verify the following:
- is the person able to understand and appreciate the nature and consequences of undergoing HCV/HIV tests?
- Is this person able to make an informed decision about whether to be tested?

THE PROCESS OF TESTING, INCLUDING PRE AND POST COUNSELING, IS:

PRE-TEST COUNSELLING ↓

INFORMED COUNSELLING ↓

RAPID HIV TEST ↓

POST-TEST COUNSELLING ↓

ONGOING COUNSELLING
Counselling is an essential component of testing. These are some fundamental general considerations for counselling:

- In order to make an informed choice, the client needs to have clear, accurate and specific information.
- Counselling differs from education, although education can be an important part of it.
- It does not intend to solve the clients’ problems for him/her or provide advice on how to solve them.
- It enables the client to: better understand the problem/issues; deal with related emotions and fears; find and evaluate different alternatives and make choices.
- It is an interactive process which actively involves the client, encouraging him or her to ask questions, providing feedback and discussing different issues as opposed to giving a lecture or questioning.
- It is private and confidential.
- It is individualized, as every client is a unique human being and the counselling should reflect the particular needs of the individual. It is centered on the needs, desires and reality of the client.
- The environment for counselling must be appropriate.

The standards formulated in the VCT concept highlighted above are an indispensable prerequisite for offering testing. The counselling takes place in two sections: the consultation before and the consultation after the test (pre-test and post-test counseling). HIV and or HCV testing should be carried out in such a way that the person being tested learns about HIV and HCV and risk management.

The consultation before the test provides: information on the expiration of the test; the meaning of a test result; clarity on personal risks; and answers to questions. Central to pre-test counselling is a detailed risk assessment (partly supported by a questionnaire), which can establish a connection between a possible transmission risk and the test procedure in such a way that it is comprehensible to the client. The content of the counselling can vary depending on the setting and the needs of the client.

**PRE - TEST COUNSELLING**

Pre-test counselling means a confidential dialogue between client and counsellor with the aim to provide accurate information about the test and the implications of a positive or negative result in order to enable the person seeking testing to make an informed choice to take responsible decisions about the test. It is a process which helps the client to define his / her feelings and to cope with stress.
The objectives of HIV/HCV pre-test counselling are:
- to assess if the client is able to undergo the test and understand the result;
- to prepare the client for the test (included test procedures) and to give information on the diseases;
- to explain the implications of knowing that one is or is not infected with HIV or HCV;
- to facilitate discussion about ways to cope with knowing one’s HIV and HCV status;
- to discuss sexuality, relationships, possible sex- and drug-related risk behaviors, in order to help the
  client understand his/her own risk behaviors and prevent infection.

This makes clear that HIV/HCV counselling encompasses two components: provision of information and prevention counselling.

**PROVISION OF INFORMATION ON TESTING (INFORMATIVE COUNSELING)**

To establish initial rapport with the client, the counsellor should convey positive regard, genuine concern, and empathy toward the client. This connection will help build trust. It is important to be professional and respectful toward the client and to recognize that some risk behaviors, such as drug use and sex work, may be sensitive topics and difficult for the client to discuss. The client should be helped to feel comfortable with the test procedures, understand the role of the counselor, and be clear about the content and purpose of the session (CDC - Guide to Comprehensive Hepatitis C Counseling and Testing).

In any setting where the testing is provided, all clients should receive information about the “basic rules” of testing: confidentiality and anonymity of the information; informed consent; the right to decline the test even after the pre-test counseling; and the need for risk assessment. Providers must also recommend the person tested to contact those who might be at risk, if the test result is positive.

Even if the majority of people are aware of the basic information about HIV and HCV, a quick assessment of the knowledge about the diseases can be helpful, depending on the time available. Some written information can also be provided (informative leaflet).

**About the test itself**, the following elements of testing and counselling should be clearly explained: the duration and testing procedures; a description of the main characteristics of the rapid test; the validity of the test and clear emphasis on the “window period”; the meaning of test results (included services available in the case of either a negative or a positive test result); and confidentiality and respect of privacy in the treatment of test results; the follow-up process in case of positive result. Moreover, during this phase, the counsellor should also: discuss what result the client is expecting; how the client would react to the result; and advantages and disadvantages of taking the test.
The counsellor should explain that the rapid test has the same specificity and sensitivity of other II/III generation tests on whole blood (except in the early phase of infection) and, as in other type of tests, there is the possibility of having false positive result, therefore, they should emphasize that a positive result must be confirmed by other more specific tests. The counsellor should also explain the procedures for confirmatory testing, when foreseen. It is important to have clear procedures in place, following national HIV/HCV testing strategies and algorithms, to confirm positive test results and to link clients to treatment and care.

It is important to stress that HIV and HCV are chronic diseases, and treatment is available. (Inform yourself about treatment options in your country!)

**PREVENTION COUNSELING**

Prevention counseling is an interactive process that consists of:
- assessing an individual’s risk for acquiring or transmitting HIV and or HCV, based on a discussion of risk behaviors;
- developing an individualized plan to reduce these risk behaviors.

When offering HIV/HCV counselling to people who use drugs, it’s important to focus on drug-related risk behaviours, encouraging clients to identify the drug use behaviours that put them at increased risk for acquiring HIV/HCV and understand the reasons why they continue to engage in them, in order to set and reach a specific, realistic, risk-reduction goal. The counselor should also explore previous attempts to reduce these risks and support clients in their successes and efforts. Strategies for reducing the risk of sexual transmission should also be addressed among clients who use drugs.

**INFORMED CONSENT**

Informed consent is the authorization of the patient to undergo a medical examination, after having received all the information about risks, advantages and methods of this examination. The client has to be informed of the right to refuse to take the test and of the fact that declining an HIV test will not affect his access to services that do not depend upon knowledge of HIV/HCV status. Community-based organizations (CBOs) must have a consent form that carefully and clearly explains (in appropriate language) the CBO’s responsibility and the client’s rights. Client participation must always be voluntary, and documentation of this informed consent must be maintained in the CBO’s records. Clients offered HIV testing in nonclinical settings may be under the influence of alcohol or drugs or may have chronic mental health conditions, any of which may interfere with their ability to provide informed consent for voluntary HIV testing and to understand test results. Counselors should be able to determine when clients are not competent to provide consent and understand the result.
• **RISK ASSESSMENT**

Traditionally, in the pre-test counselling, the focus is on risk assessment, in order to make the person aware of the risks encountered that might eventually lead to having a positive result; while strategies for risk reduction is done in the post-test counselling, when providing the client with test results. While speaking about the ways of transmission, the counsellor can check with the client what risks the client may have encountered since the last HIV/HCV test. An important aspect is also the risk behaviors of the client’s partner(s), which might affect HIV/HCV risk for the client.

• **POST-TEST COUNSELING**

Post-test counselling must always be an integral component of the HIV/HCV testing process. Everyone undergoing rapid testing must be counseled when their test results are given, regardless of the result, because counselling aims not only to help the client to understand and cope with the test result, but also to provide the client with further information required and, if necessary, referral the client to other services.

Post-test counselling must offer, among much else, support concerning disclosure of HIV/HCV status and a valuable opportunity to provide accurate information about harm reduction and safer sex that is relevant to the person being tested, reflecting the test result. Behavioral change and risk reduction counselling may also have value.

• **COMMUNICATION OF TEST RESULTS CONSIDERING THE RISK ASSESSMENT**

The communication of test results should always take into consideration the risk assessment of person tested, above all regarding the probability of false negative result in case of recent risk behaviours and, on the other hand, the probability of false positive result if person reported low or very low risk factors. If possible, the counsellor who provided pre-test counselling should also provide post-test counselling. In this way, the counsellor has already established a relationship with the client and can better evaluate the way to communicate the result and provide information in post-test counseling based on the risk assessment conducted during the pre-test counselling.
• COMMUNICATION OF NEGATIVE (NON-REACTIVE) TEST AND WINDOW PERIOD

For those who test negative (non-reactive), post-test counseling is an important opportunity to put those at risk for HIV/HCV in contact with primary prevention programs and to encourage later retesting. A negative test does not require a confirmatory test, except if person was tested too soon, before antibodies developed. That’s why it is fundamental to recommend a re-testing, if the client has had risk behavior the last three months for HIV and six months for HCV, since the period between the infection and production of antibodies lasts on three or six months respectively for HIV and HCV; this is so called “window period”. However, safer drug use and safer sexual behavior should be always stressed, no matter what the result is.

• COMMUNICATION OF PRELIMINARY POSITIVE TEST RESULT

HIV/HCV testing and counselling is the essential first step in enabling people to know their serostatus and obtain HIV/HCV treatment and care services. In the case of a HIV positive result, it’s fundamental to clearly explain that the result has to be considered a “preliminary positive” and that more specific laboratory test (on a whole blood sample) for the confirmation of the diagnosis is needed. However, it is recommended that clients with high-risk behavior are informed about the probability that the confirmatory test will be positive and receive the support necessary to acknowledge and cope with this information, as it is a very stressful moment. For that reason it is preferable that both pre- and post-test counselling are provided by the same counsellor, who has already established a relationship with the client and can better evaluate the likelihood of a reactive result on the basis of the risk assessment. Moreover, it must be taken into account that the provision of pre- and post-counselling in low-threshold services requires high skills and competencies, to keep up to standards of provision. In particular, when offering the counselling and testing in mobile street units, the space is limited and most of the clients are in a hurry. Therefore, it is important that the counsellor has adequate capacities and experience, in order to create a confidential atmosphere, understand quickly the specific needs of each client and provide him or her with the most suitable information and support. The counsellor has to be also ready to cope with the crisis situation in the case of positive result. Moreover, the clients should have chance to step out of the mobile unit without clear marks of the result.

• ETHICAL CONSIDERATIONS

The provider must ensure that the decision-making ability of the person who uses drugs is not impaired by intoxication before they discuss and decide on testing for HIV and other infections. Clients should receive adequate information enabling them to make a personal and voluntary decision whether or not to decline one or all of the proposed tests without coercion.
Confidentiality must be strongly enforced with regard to test results and information obtained during counseling and testing. In addition, when providing HIV counselling and testing to socially marginalized groups such as people who use drugs, it is fundamental that testing will not result in any harm or negative effects to the tested person. The clients should be aware of the legal regulations related to HIV disclosure in respective countries and the potential risks of knowing his own HIV status (e.g.: as discrimination, abandonment or violence). In some countries, for example, it is still mandatory to disclose the HIV status to health care workers in case that the contact with blood is required (like in dentistry, surgery, etc.), otherwise the person can be prosecuted under the criminal code. And, the disclosure of HIV status very often results in denying the services to the person.

- THE IMPORTANCE OF APPROPRIATE TRAINING OF STAFF ON TESTING COUNSELLING

Counsellors play a critical role in any VTC services, since they are the key to effective intervention. Competencies and skills are the basis upon which trainers should be evaluated and selected. When talking about VTC on HIV and HCV among people who use drugs, these competencies must include a thorough knowledge and understanding of infections, pre- and post- counseling, testing methodologies (including the methodology of the outreach approach and recruitment of clients, as well as follow-up and referral to health care services), and also of drug use and harm reduction programs for PWUD. These topics cannot be properly treated if the counsellors do not have a long working experience in the field of drug use and harm reduction and are not properly trained.

The counsellor should be:
- trained;
- empathetic (see the problem as the client sees it while remaining objective);
- non-judgmental and culturally sensitive (respect the client’s cultural and belief systems); and
- able to listen.

FOR MORE INFORMATION WE RECOMMEND:

1. World Health Organization. WHO | Consolidated guidelines on HIV testing services 2015.
2. RAPID HIV TESTING IN NONCLINICAL SETTINGS. Procedural Guide 8-09.pdf
3. European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2010. Guidelines for testing HIV, viral hepatitis and other infections in injecting drug users
OBJECTIVE:
By the end of the session participants will:
• understand philosophy of harm reduction;
• have concrete plans for developing their existing services and adding new services;
• understand public health ethical priorities of low-threshold services and negligence of not addressing behaviors that cause infections; and
• be able to engage PWUD in discussions about minimizing risks.

TRAINING METHODS:
Lecture

TRAINING MATERIALS:
Power-Point Presentation, working groups.

INSTRUCTION TO THE FACILITATOR:
Start the session with a group exercise: ask participants to draw a typical person who use drugs with images to identify: gender, age, social status, what drugs, how, how often, where. Use the picture during the session to remind participants on who their clients are and what their needs are. This exercise is participatory and interactive. The trainer should make it possible for each participant to think about his or her clients in a new way.
For planning any kind of project or activities involving local communities, the first step should be the analysis of the local situation and local needs, based on both quantitative (incidence/prevalence, mortality, access to testing and treatment by the target group through epidemiological and demographical records, surveys, reports, provided by both national and local institutions and international agencies) and qualitative data (collected, i.e. focus groups and face-to-face interviews). This is even more important when approaching health and social programs. Speaking about HIV and HCV rapid testing programs, the analysis of the local situation should include the collection of information about past and current trends of the infections among the specific target groups, the availability of testing, treatment and care facilities, as well as the needs and opinions of the selected target groups about perceived problems and constraints.

Moreover, before planning the testing methodology for HIV and HCV, as well as for other infectious diseases, it is fundamental to collect information about the current national legislation on testing procedures in order to plan activities which are in line with the national public health legislation.

**4.1 LOW THRESHOLD SERVICES**

The term “low-threshold” is used to describe a setting which aims to facilitate access by people who use drugs to social and health services, that typically includes outreach teams, street units, needle-exchange points, drop-in or contact centers, night shelters, substitution treatment programs, etc. To lower the threshold of access, such agencies choose specific locations and opening hours, require little bureaucracy, often no payment, no need to have official documents and are not linked to an obligation of the client to be or to become drug-free. They target people who are currently using drugs, “hard-to-reach” groups, high-risk groups among drug users and experimental users. Therefore, implementation of HIV/HCV testing in a low threshold center could represent an important strategy to increase the uptake of HIV/HCV testing for those populations with poorer access to traditional health care.

The implementation of testing programs in low-threshold services requires the involvement of different professionals, each of them with a specific role: outreach/social workers for approaching, informing and motivating the target group to be tested; psychologists/counsellors/social workers for providing pre- and post-counselling; doctors/nurses for administering the rapid test. This definition of roles is important for ensuring the good quality of the provided services and facilitating collaboration and teamwork. Volunteers can be also involved in these kind of programs, but it is fundamental that they receive specific training on drug use and related infectious diseases, in order to get a comprehensive knowledge of the topic and have a better work performance.

In these settings particularly important are approaching and recruitment of clients, in order to make their work more effective and valuable. It is always recommended to be flexible and ready to adapt the work to particular
needs, situations and circumstances, so that the pre- and post-counselling will not be left out or mini-
mized. In fact, it is not always easy to follow the indicated procedure step-by-step, due to the specific characteristics of the clients of this kind of services. For example, the distribution of informative leaflets should be accompanied or replaced by the verbal explanation of the aim and procedures of testing, because a high percentage of clients approached rarely read the leaflets; for clients who are in a hurry and don’t want to waste much time, it might be necessary to speed up the procedure.

• RECRUITMENT OF CLIENTS / TARGET GROUPS FOR TESTING

It is important to widely disseminate information about testing possibilities in the low-threshold services through announcement or the distribution of informative leaflets among the clients in order to reach a wide spectrum services users.

During the approaching and recruitment phase, the role of social workers and peers is fundamental. They represent the link between the target group and the health-care services because they can more effectively motivate people who use drugs to get tested (explaining the benefits and advantages of such service) and other safer behaviors, given that their relation with clients is based on trust and confidence. Staff members can use techniques typical of “motivational interviewing”, combining elements of empathy and negotiation with the aim to improve the client’s motivation toward his/her own health status.

The model of approaching must be clearly defined. Example: If someone says ‘I have been tested already and I was negative’, this is not sufficient to exclude the person from the program. Check when the person was tested for the last time and if he/she has risk behaviors since that time.

On the other hand, for the clients willing to get tested, a second important selection step is required: to check their eligibility for testing according to the specific characteristics of the target group and the basic requirements for valid HIV and HCV testing. In order to check eligibility, the recruited clients should be asked the following “supplementary” questions:
• Have you been tested for HIV or HCV before? If yes, when?
• Have you been using drugs (heroin, cocaine, methamphetamine, amphetamines, opioid analgesics, buprenorphine) regularly in the past 3/6 months both injecting and not injecting?
• Are you willing to answer a questionnaire for risk assessment/data collection, and do you consent to the follow up or possible visits to clinic?
• Do you clearly understand the purposes and procedures of testing?

If somebody is unable to understand the objectives of the intervention and to give the informed consent, he/she must be considered not eligible for the testing! Moreover, it’s necessary to bear in mind
the specific characteristics of the target group attending low-threshold services, particularly PWUD. Motivating these clients toward testing can be very hard, because they have other priorities and needs: they are in a hurry and don’t have enough time for getting tested; they are afraid of getting tested because they have engaged in risk behaviors; they want to avoid presence on the street because of fear of police. To cope with these problems, a solution can be the use of rewards and incentives such as phone cards, food or food tickets. Often, even the simple empathy, provision of a cup of coffee/tea and some biscuits helped to approach people and motivate them to dedicate some time to their own health.

- CRITERIA FOR SELECTION OF LOCATIONS FOR TESTING

The collaboration with other local services and facilities is useful for enlarging the number of potential beneficiaries and facilitating access to testing by high-risk groups of drug users such as homeless people. It is highly recommended to select places where the testing has never been offered, or is not provided on a regular basis, in order to reach people who most probably have never been tested or may prefer to get tested in non-medical settings. In addition, cooperation with other local low-threshold services can bring benefits in the long-term also, promoting the set-up of networks and referral systems which facilitate the access by people who use drugs to the required care, support and treatment programs.

Of course these networks are highly effective and fruitful if the cooperation among local actors is well-functioning and supported by a joint willingness to cooperate. This is not always easy to reach, in particular when talking about cooperation with public health services, which may have different opinions and methods of working with PWUD.

4.2 HARM REDUCTION PHILOSOPHY

- HIV / HCV INTEGRATED SERVICES IN HARM REDUCTION

“Harm Reduction’ refers to policies, programs and practices that aim primarily to reduce the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing drug consumption. Harm reduction benefits people who use drugs, their families and the community.” - Harm Reduction International (HRI)

People who use drugs are often reluctant to use traditional healthcare services and are more comfortable requesting health support in harm reduction services, opioid substitution treatment programs or addiction services. For this reason, relocating or co-locating HIV/HCV testing, treatment and care services in harm reduction
settings can have benefits related to access and adherence. Inclusion of HIV and HCV rapid testing in these programs may increase the effectiveness of diagnosis in those populations that may not access conventional health facilities.

The World Health Organization (WHO), the United Nations Office on Drugs and Crime (UNODC) and the Joint United Nations Program on HIV/AIDS (UNAIDS) strongly recommend harm reduction as an approach to HIV prevention, treatment and care for people who inject drugs. Specifically, they advocate for a comprehensive package including:

- needle and syringe programs (NSPs);
- opioid substitution therapy (OST) and other drug dependence treatment;
- HIV testing and counselling (HTC);
- antiretroviral treatment (ART);
- prevention and treatment of sexually transmitted infections (STIs);
- condom programs for people who inject drugs and their sexual partners;
- targeted information, education and communication for people who inject drugs and their sexual partners;
- vaccination, diagnosis and treatment of viral hepatitis;
- prevention, diagnosis and treatment of tuberculosis (TB); and
- overdose awareness.

Combining interventions (harm reduction, HIV/HCV testing and treatment, social support, peer education) in a single setting, such as harm reduction can be an important prevention strategy for people who use drugs. In addition, some services that are already available in harm reduction services, such as rapid testing, could also be extended to other populations exposed to sexual or drug-related risk (sex workers, MSM, some communities of migrants) and general population, creating access to those services without duplicating responses and costs.

Worldwide, the benefits of harm reduction have been proven. Early implementers of harm reduction programs such as Switzerland, the UK and Australia have considerably reduced the number of new HIV infections among people who inject drugs. An example of integration of harm reduction services and testing program is IN-Mouraria, a harm reduction centre, started in 2012 by GAT, an organization of people living with HIV/HCV in Portugal. The center is located in an urban quarter of Lisbon where migration, drug use, sex work, and homelessness coexist. The project goals include increasing awareness, activism and participation of people who use drugs and performing harm reduction interventions and HIV/HCV rapid testing. Services are provided to clients without an appointment, free of charge, and without the
need for personal identification. Trained health professionals, lay workers and peer counselors perform the tests and provide information. Active referrals to hospitals are offered to all clients newly or previously diagnosed HIV/HCV positive, regardless of migrant’s legal status. Those who request it, can be escorted by peers to medical appointments. Testing and other services (condom/lube distribution, information) are also available for general population. IN-Mouraria was included as a case example in the World Health Organization’s Consolidated guidelines on HIV testing services published in July 2015.

• **BARRIERS TO HARM REDUCTION FOR HIV PREVENTION**

A ‘war on drugs’ approach still prevails in many countries. Law enforcement authorities continue to criminalize the possession of needles and syringes and mount ‘crackdowns’ on people who inject drugs even when they are seeking treatment or visiting healthcare centers for clean needles and syringes or other services. Criminalization drives people who inject drugs away from health and HIV services and has a negative effect on HIV prevention and treatment outcomes. A paper provides an overview of the current state of HIV testing and counseling in Central Asia for PWID, highlighted that criminalization of drug use and discriminatory practices among government service providers restrict access of PWID to needle exchange programs and NGOs where HIV testing services are located. Based on interviews with drug users in Kazakhstan, Human Rights Watch (2007) reported that police often arrest clients of harm reduction services, confiscate drugs and syringes and extract bribes for possession of syringes/needles. Medical staff and government health care providers also often stigmatize and discriminate against PWID, which results in negative experiences and lower levels of trust in what the services can offer. A long Soviet initiated tradition of using health facilities for mandatory HIV testing without ensuring confidentiality of the test results contributes to the unattractiveness of these services to PWID.

Moreover, social stigma and discrimination associated with drug use is a barrier to place integration of services, as well as having a detrimental impact on the implementation of testing in this setting. Many advocate for stigma reduction initiatives as part of harm reduction programs.

In addition, the lack of sustainable funding in some countries constitutes one of the most significant barriers to harm reduction initiatives, forcing them to downsize or run at a much reduced rate.

Barriers such as people’s fears of discrimination, fears about getting a positive test result, and fears of social stigma need to be overcome to better implement HIV testing as a prevention program.
4.3 PEER INVOLVEMENT

The English term ‘peer,’ according to the Webster dictionary, refers to “one that is of equal standing with another; one belonging to the same societal group especially based on age, grade or status.”

A growing body of literature highlights a range of downstream social and behavioral impacts of the global emphasis of drug law enforcement. For example, fear of confrontations with police perpetuates unwillingness among PWUD to access essential HIV-related services. Pervasive stigma and the associated self-imposed isolation that often results can also render individuals reluctant to access services due to fears that family, community members, and employers may shun them for their drug using behaviors. Collectively, these barriers to HIV prevention and treatment highlight the urgent need for novel methods of healthcare delivery for this population.

In light of the ongoing problems in ensuring access to essential HIV prevention and treatment services for PWUD, task shifting could represent a key strategy to overcome social and structural barriers to HIV-related services. A large body of evidence indicates that peer-run initiatives can extend the reach and effectiveness of conventional public health programs by reaching high-risk PWUD. The recent availability of rapid HIV point-of-care testing (POCT) offers new strategies for improving the uptake of testing among PWUD in both clinical and community-based settings. Training peer leaders who use (and continue to use) drugs as HIV educators has been shown to be an effective mechanism for HIV prevention among PWUD. Furthermore, peer-delivery of testing has been done among PWUD with high levels of satisfaction and comfort with the level of confidentiality.

Accordingly, the WHO, UNODC, UNAIDS Technical Guide recommends community-based outreach methods as an essential approach for service delivery. However, the involvement of PWUD in providing HIV services need not be limited to those efforts that aim to extend the reach of existing programs and may have value in other areas. Shifting HIV services from professional healthcare workers to peers may also serve to address the existing stigma that people who use drugs experience within healthcare settings, thereby improving access to these services. By creating peer-involved HIV testing clinics and pairing physicians with peers, PWUD may be more likely to use these services without fear of being discriminated by healthcare workers or fear of being registered as drug users within official registries. Indeed, past research has shown that interventions led by people who use drugs are more acceptable to them than conventional public health programs. This is due in part to perceived acceptance of their drug use behaviors by their peers.
By shifting delivery of care from healthcare professionals to peers, or by incorporating peer workers into professionally-led services, a reduction in stigma and discrimination in these settings may be achieved. Likewise, this type of shift in service delivery may address some concerns among PWUD about information sharing between public health systems and law enforcement officials. Given the evidence indicating positive benefits of peer-led interventions for PWUD, as well as the success of task shifting in settings with human health resource shortages, shifting the delivery of conventional HIV/AIDS programs and services to PWUD themselves may serve to address the severe stigmatization and discrimination that characterizes the existing healthcare context in many settings hard hit by PWID-driven HIV epidemics. In turn, this novel approach to task shifting may foster a new era in the response to HIV among PWUD.

Organisations, that have peer workers should provide management and appropriate supervision to ensure dissemination of information is accurate and up-to-date. Peers should be compensated for their time and effort like other workers. In some countries, payment is provided at minimum level not to effect social benefits.
POSSIBLE TOPICS FOR GROUP WORK:

1. List possible advantages and challenges of peer involvement
2. What are the possible barriers to accessing services provided by your organization
3. Ways to overcome barriers, using limited resources/or without extra resources

FOR MORE INFORMATION WE RECOMMEND:

OBJECTIVE:
By the end of the session participants will be able to:

• offer suggestions for mainstreaming gender into existing services for PWUD;
• expand access to women who use drugs (WUD) through appropriate gender-sensitive and gender-specific services;
• address gender issues within existing services and/or to develop gender-specific services;
• setting targets for scale-up to improve access to comprehensive HIV and care services, expanding coverage among WUD;

TRAINING METHODS:
Lecture

TRAINING MATERIALS:
Power-Point Presentation, working groups.

INSTRUCTION TO THE FACILITATOR:
Together with participants, try to find out why there are less women clients then men and discover ways to address specific needs of women who use drugs. If possible, invite women who use drugs to talk about their needs and wishes.
There are marked differences between the genders in almost all aspects of the drug phenomenon, and there are many sound public health and human rights recommendations that indicate the need for Harm Reduction (HR) and other HIV related services to specifically address the needs and preferences women who use drugs. Such reasons are evidence-based and are supported by relevant international agencies and institutions. Nevertheless, HR services are generally primarily target men and women who use drugs often feel that their specific needs are unacknowledged and that the sites they need to access to are not “women-friendly.” HR programs and projects often do not succeed in guaranteeing women’s personal safety and confidentiality; in providing sexual and reproductive health (SRH) services; prevention of mother-to-child transmission (PMTCT) services; and providing child care. In many cases, staff are not trained to offer gender-specific services, support for sex workers or for the victims of gender-based violence (GBV).

The failure to address the needs of women who use drugs (WUD) contributes to the spread of blood borne infections and other infections. In fact, first of all, WUD are actually at higher risk of acquiring HIV, viral hepatitis and other sexually transmitted infections (STIs) than their male counterparts. Specific risk factors include the fact that women are more likely than men to be “second on the needle”—i.e., they inject after, and often are injected by, a male partner. Data by gender shows that women who inject drugs (WID) are more vulnerable to HIV infections and STIs than are males who inject drugs. The likely reasons for such a gender difference include both social factors, e.g. WID are much more likely to be involved in sex work than males are, and biological factors, such as women’s higher risk of contracting genital infections. WUD are likely to be more often in a vulnerable position when attempting to protect themselves from infection within partnerships and networks.

Those of them engaged in sex work increase their vulnerability to HIV and other blood-borne infections. When involved in sex work, they often experience physical and sexual violence from clients and other intimate partners, as well as from the police; abuses can also occur while they are detained in prison.

Gender-based violence prevents WUD from accessing services and the criminalization of sex work heavily affects their willingness and possibility to access HIV-related services and to negotiate condom use.

Other factors which prevent WUD from accessing health services include policies or laws suggesting that drug use can be a reason for loss of child custody, coerced sterilization and abortion. Such practices are examples of gender-related stigma and discrimination that is still widespread in some countries.

WUD are often diagnosed with HIV late in pregnancy or when they are already in labor. Mother-to-child transmission rates among WUD living with HIV are significantly higher than for other HIV positive women. Many maternity clinics do not provide opioid substitution therapy (OST), a situation that may compel drug-dependent women or those on OST to leave appropriate care in order to seek drugs or medication.
The following are some of the most frequent problems experienced by WUD:

- Many countries have organized their health systems in a way that requires separate access for HIV, TB, viral hepatitis, HR and SRH services. This makes it difficult for WUD to take good care of their health needs.

- WUD reported many times that SRH services are very important but that they feel stigmatized when accessing them; stigma and discrimination constitute a huge barrier. Negative experiences with health services include judgmental attitudes and/or disrespectful treatment on the part of healthcare staff and perceived lack of privacy and confidentiality. WUD are afraid to seek advice and care.

- Pregnant WUD access antenatal care and PMTCT services less frequently than the other pregnant women and consequently face an increased risk of passing HIV to their babies.

- In some countries, a conservative social climate makes it harder for WUD, especially girls and young women, to access SRH services.

### 5.1 ALCOHOL & OTHER DRUGS, SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS (SRHR) & PREGNANCY

Alcohol and other drug (AOD) use have many various effects on sexual and reproductive health which can sometimes be serious and cause severe consequences.

Problematic AOD use can decrease fertility indirectly by undermining both general health and nutrition of WUD, while heroin can affect fertility directly. The effects of heroin on menstruation and fertility are heightened by the associated chaotic lifestyle and poor nutrition. Drug use, and especially heroin use, can cause amenorrhea and an ovulation, but not necessarily at the same time. Many women and even some service providers mistakenly assume that conception cannot occur in the absence of menstruation; this is not true and leads to unexpected and, very often unwanted, pregnancies.

Methadone prescription to opiate users increases WUD’s fertility with the resumption of menstruation, but it is important to be aware that any treatment improving their general health and the adoption of correct nutritional habits will also increase fertility. This can happen before menstruation are resumed.

WUD who do not plan to become pregnant should therefore use effective contraception, since their bodies often do not follow the average menstrual cycle and experience irregular periods. It is practically impossible to determine when ovulation occurs and peak fertility days. It is extremely important that service providers are trained to offer appropriate information on fertility issues and effective contraception.
Contraception helps to ensure that WUD have planned pregnancies, i.e. that they get pregnant only if and when they choose to have a baby. Planned pregnancies improve the likelihood of good medical and social outcomes and optimize treatment efficacy, since during this very special period, WUD are motivated to stay in good health so that they can be good caregivers.

WUD may be concerned about infertility and seek advice to restore their menstrual periods. The stabilization of AOD use and lifestyle habits may be sufficient to restore them. It must be noted, though, that infertility treatment for WUD is often viewed as inappropriate by conservative and judgmental public health services, which believe WUD should not have children and take on the related parental responsibilities. This is exactly where specific services targeted to WUD are needed, in order to help and support WUD to conceive and plan a pregnancy, by providing the opportunity to address AOD use and associated medical and social problems.

The alleged failure of WUD to appeal early for antenatal care is sometimes attributed to a lack of awareness about their pregnancy, since it is not infrequent that ovulation and fertility are restored even in the absence of menstruation. Free pregnancy testing available in HR gender-specific services increases early detection of pregnancy and brings important benefits:

- earlier referral for termination if pregnancy is unwanted;
- provision of effective contraception if WUD are not pregnant and do not want to conceive; and
- provision of pre-pregnancy care including prescription of folic acid if planning pregnancy.

**5.2 CONTRACEPTION IN WUD**

The main objective of contraception for WUD is - as it is for all other women- to avoid unwanted pregnancies and prevent abortion. It is important that WUD are in the condition to choose the type of contraception they feel more comfortable with and are able to manage the way in which it is administered.

Gender-specific HR services should therefore make sure that the different needs for contraception are met and support their clients with appropriate information. Contraceptives should be made available free of charge, since their cost might be a great barrier for WUD.

WUD need to be made aware that no other contraceptive apart from condoms protects them against sexually transmitted infections (STIs). Male and female condoms should therefore be highly recommended, especially in those cases in which WUD engage in sex work. For those women who do not envisage the need to use condoms as a mean of protection from STIs (they have a steady sexual partner, may be allergic to latex, etc.), other contraceptives should be made available in order to prevent unwanted pregnancies.
It is important that staff are trained to discuss the following issues related to contraception during counselling sessions offered in gender-specific services:

• the opportunity to avoid pregnancy;
• chances of serious side effects like thrombosis when assuming oral contraceptives;
• medical contraindications of some contraceptives in case of smoking, high blood pressure, overweight, thrombosis in immediate family;
• benefits/availability of contraceptives that last over time;
• visible vs invisible contraceptives;
• medications that might reduce or eliminate the effect of contraceptives;
• availability of / access to contraceptives; and
• emergency contraception (a tablet that is to be taken as quickly as possible and within 72 hours after unprotected intercourse or condom breakage).

**TERMINATION OF PREGNANCY**

When WUD find out they are pregnant and they do not want to have a child, abortion services should be available free of coercion and offered in a respectful and non-judgmental manner. Health workers offering abortion, as it should be with all health workers, must respect the rights of WUD, especially when they are living with HIV, by providing access to abortion if desired and by ensuring that women make the choice for themselves. If only one type of abortion (medical or surgical) is offered in a specific setting, WUD should have access to that option. Limited options for all women should not result in barriers to access for WUD.

**WOMEN WHO USE DRUGS AND PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT)**

All pregnant women should be offered screening for blood-borne viruses (BBVs); interventions to prevent mother to child transmission should be immediately offered in case of positive results. In the case of screening for BBVs during pregnancy there is no need for detailed pre-test counselling, but in case of positive results, good post-test counselling and support are essential, in order to make women aware of their condition and the related impact on their lives, and to ensure linkage to care and treatment to protect their health and prevent MTCT.
• **HEPATITIS AND VACCINATION**

Pregnancy is not discouraged for women living with hepatitis C. The risk of maternal-fetal transmission of viral hepatitis during pregnancy is relatively low. It is essential to note that the risk greatly increases if the mother is co-infected with HIV. Hepatitis B virus (HBV) vertical transmission rates are around 10–20% for most women co-infected with HIV. The screening for Hepatitis B - (HBV) surface antigen identifies women who are infectious; the immunization of newborns prevents vertical transmission of HBV from the mother to her baby.

WUD should be offered combined immunization against HBV (Hepatitis B) and HAV (Hepatitis A), since immunization is safe during pregnancy. An accelerated vaccination regime is recommended – vaccinating at 0, 1 and 2 months or even 0, 7 and 21 days. After having accelerated regime, another booster dose is required at month 12.

The HBV vaccine is beneficial for all babies and, provided that the baby is immunized at birth, breastfeeding is not contraindicated. Although the hepatitis B and C viruses have been found in breast milk, HCV is not transmitted through breast milk. Most experts agree that it is safe for women with hepatitis C to breastfeed their babies if specific precautions are followed. For example, if the mother has cracked and bleeding nipples, breastfeeding should be stopped until the nipples have healed and bleeding has ceased.

As yet there is no vaccine available for HIV or HCV.

• **WUD LIVING WITH HIV**

WUD living with HIV should receive special, multidisciplinary care, especially when they learn about their HIV status during pregnancy. The following services need to be put in place:

- specific counselling and possibly peer support on HIV related issues, in order to sustain adjustment and coping with the new condition in a delicate phase of their lives;
- interventions to reduce risk of vertical transmission from mother to baby;
- counselling and support for treatment adherence, correct nutrition, parental training, stabilization of drug use and OST;
- antenatal and intrapartum antiretroviral HIV treatment, along with antiretroviral treatment for the newborn;
- delivery by Caesarean Section in selected cases.

• **SOCIAL EFFECTS OF DRUG USE**

The social impact of alcohol and other drug (AOD) use during pregnancy is as important as the physical impact, as its produces consequences for women’s health. Due to socioeconomic deprivation, WUD need multidisciplinary care embedded in maternity services.
The use of AOD, often associated with a chaotic lifestyle, can cause or exacerbate effects of socio-economic deprivation on health and may negatively influence engagement with services. Parental duties and tasks are often compromised by intoxication, but also by the lifestyle associated with AOD use. Caring for a sick baby is demanding for any mother and especially stressful for women with additional issues such as drug use.

The interlinked relationship between medical and social factors demonstrates why pregnant WUD need multidisciplinary care, with joint collaboration and input from both health and social services. It is a fact that WUD have high risk pregnancies and poorer pregnancy outcomes. As for all women with high risk pregnancies – (e.g. those with diabetes), maternity care should be provided by an obstetrically-led multi-disciplinary team. Services and support should include resources for care for the baby after birth, information on infant feeding options, nutritional counselling and support, information on vaccines and other preventive measures, post-partum examination of the mother, HIV treatment, care and support for both mother and child when needed and referral for prophylaxis and treatment of HIV-related conditions and other commonly associated conditions (e.g., TB), provision of support to WUD living with violence.

Drug using women should receive analgesia during birth, with increased doses of opiates as necessary; newborns should be accommodated at the postnatal ward with their mothers, unless their medical conditions recommend admission to special care. Drug use is not necessarily a contraindication for breastfeeding and should in general be encouraged. Breastfeeding mothers should be advised that using a high dose of drugs such as cocaine or benzos is incompatible with successful breastfeeding, and that babies should not be exposed to these drugs. After birth, maternal drug use should not be considered as a child protection issue per se. If child protection issues are identified, they need to be addressed separately. Planning of future pregnancies should be discussed during pregnancy and appropriate contraception needs to be commenced before postnatal discharge.

**HARM REDUCTION DURING PREGNANCY**

Even when WUD cannot stop using drugs, even when methadone or buprenorphine are not available, there are many things that can be done to improve their health and that of their babies. Many HR strategies can be suggested to improve their lifestyle.

First of all, it is important that they are advised and supported in improving their nutrition: it is crucial that they adopt a balanced diet and take vitamins - especially Folic Acid.

Pregnant WUD should attend early, regular prenatal care, starting as soon as they are aware they are
pregnant. Referral to non-judgmental gynecologists and obstetricians is key to avoiding that they refuse to access proper care or decide not to attend follow-up visits. They should be helped to find ways to reduce the stress they experience as women using drugs and to establish better sleeping habits.

Gender-specific HR services should provide their clients with accurate information on the effects of AOD consumption during pregnancy and should support them in reducing tobacco and alcohol use, if possible. WUD should be also supported in keeping drug use at a steady level in order to minimize cycles of withdrawal, which can be very stressful also for the fetus. They should also be made aware that street and Internet drugs are of unknown strength and purity and may threaten their pregnancies and lives.

After delivery, every effort should be made to try and keep the babies with their mothers. Women should be supported in developing parental skills and in taking good care of the newborns. Breastfeeding should be encouraged in all cases in which it is not harmful for the baby.

- **OPIOID SUBSTITUTION THERAPY (OST)**

Lots of evidence has been collected in support of the medical and social benefits of OST for opiate users, including during pregnancy. All medicines prescribed during pregnancy and breastfeeding, should be considered with special protective measures not only towards the woman, but also in regard to the unborn child.

Methadone is the most common OST medicine prescribed. Unlike heroin, it does not increase the risk of preterm delivery and its safety during pregnancy is proven. It is important to know that, like heroin, it may cause withdrawal symptoms in the newborn. By offering protection against early delivery, it is of great importance for the baby’s long term health. Antenatal opiate detoxification is safe and management of detox should be dictated by women’s willingness to go through it and their ability to cope.

Buprenorphine also does not harm the fetus during pregnancy. As with all opiates, deprivation may result in neonatal withdrawal, although the severity and duration of withdrawal may be less than with methadone substitution. Switching to buprenorphine from street drugs or methadone can lead to withdrawal symptoms and should be carried out during pregnancy in an inpatient setting. During the process of switching, contractions may be triggered by withdrawal symptoms. Buprenorphine has a slight antidepressant effect and is non-sedative. The resulting “clear head” could be an undesirable effect for the patient!

There are a number of reasons to recommend OST treatment to WUD during pregnancy. It improves medical outcomes for pregnant women and their babies as well as social outcomes and physical and mental health of pregnant women and mothers. It contributes to prevention of overdose and other drug-related deaths. It increases individual stability and social functioning while reducing offending behaviors, crimes and illicit drug use. It also has a positive impact on the health and wellbeing of communities.
• VIOLENCE AGAINST WUD

Violence against women is endemic worldwide and, despite all the HR efforts, campaigns and interventions at all levels, it seems to have no easy solution. Some specific groups of women are particularly vulnerable to it, yet their needs are continually ignored. This becomes evident when addressing violence against WUD. WUD are the victims of many different layers of violence. They even suffer structural violence deriving from punitive drug enforcement, which increases harms associated with drug use.

Despite their vulnerability to the many forms of violence and abuse, the majority of WUD are not allowed to access shelters. The failure to ensure access to shelter and specific support to WUD is caused by various structural inequalities from the denial of access by shelter managers to state policies that intentionally ignore the needs of WUD. HR service providers should establish strong relationships with women’s shelters and ancillary social services to ensure that WUD have access to the support they need and receive non-judgmental services.

There is evidence that intimate partner violence is also more commonly experienced by WUD than women in the general population. Many WUD experience violence and abuse within the relationship with their partners. The low social status of many among these vulnerable women increases such risk. Over 80% of WUD have been abused in their homes.

Violence against women can both lead to substance use and contribute to the development of patterns of problematic drug use. The European Monitoring Center for Drugs and Drug Addiction (EMCDDA) reports that problematic drug use can lead to women engaging in sex work as a source of income, and sex work can increase their vulnerability to violence.

It is widely acknowledged that women victims of violence need specialized services, but in many countries social services or general shelters are not organized to support women who experience violence. Furthermore, shelters lack the specialized services that are necessary for specific health problems. WUD often experience barriers to access health services and very few services are targeted towards them. In most countries, women account for a smaller proportion of people who use drugs than men and services are often equipped to suit mens’ needs.

It is recommended to provide counselling sessions for women’s partners to reduce violent reactions when at home. Partners might be included in post-test counselling sessions. Partner notification can be conducted in the counsellor’s office and role playing can help prepare client.
• **SEXUAL AND INTIMATE PARTNER VIOLENCE (IPV)**

Problematic drug use among women is often linked to a history of sexual abuse and WUD experience high rates of IPV. Violence has a direct effect on a woman’s ability to practice safer sex and safer drug use and contributes to continued drug use.

Where a history of trauma instigates problematic drug use or risky behaviors, it is important that HR and drug treatment programs and staff are aware of how to deal appropriately with these issues.

• **GENDER BASED VIOLENCE**

WUD are highly vulnerable to gender-based violence (GBV), i.e. physical, mental, emotional and other forms of abuse and harassment directed towards women. HR programs and other HIV-related services can address GBV by providing direct support or referral to specialized organizations. Sometimes extra measures and means of protection may be required to enable WUD to report abuse. In order to address GBV, gender-specific services need to:

• ensure that WUD are aware of their rights and informed about where and how to report on police misconduct;
• provide survivors of sexual assault with, or offer accompaniment to, clinical care for post-exposure prophylaxis (PEP) and emergency contraception;
• offer STI services and psychosocial support;
• support the development of violence prevention sessions specifically tailored towards WUD.

• **VIOLENCE BY LAW ENFORCEMENT AGENCIES**

When WUD are HIV positive and engage in sex work, discrimination and violence double and they become more vulnerable to violence by the police. In countries where drug use and sex work are criminalized, there is limited access to legal aid and basic health care and WUD are left powerless and unprotected at the hands of police.

Evidence indicates that WUD in the EECA region are the victims of police violence and of physical, emotional and sexual violence during and/or after detention. Human rights violations, including ill treatment and torture, are commonly used to get confessions or false testimonies. There is solid evidence of unjustified detentions, refusal of right to a lawyer and violation of personal security for WUD.

Police violence affects WUD in many ways, including serious and often life-threatening physical and psychological health problems. It increases stigma and discrimination against women and barriers to access health services,
which contribute to the HIV epidemic. It also discredits police as an institution and contributes to expanding gender inequality and social injustice.

In 2014, the Eurasian Harm Reduction Network, (now the Eurasian Harm Reduction Association (EHRA)), in partnership with organizations of women who inject drugs and HR organizations from Central and Eastern Europe and Central Asia, launched a campaign to reduce or eliminate police violence against WUD. The objective was to raise awareness of law enforcement on police violence against WUD by building their capacity to document and communicate police violence.

Key initial activities included:
• developing community-based online tools to document and report cases of police violence;
• capacity-building for WUD to report about police violence;
• using UN human rights instruments to advocate against police violence toward WUD;
• organizing meetings with stakeholders, media and decision-makers to present results of data collection and mapping.

Outputs in later stages of the campaign included:
• developing national and local strategies and action plans to respond to police violence against WUD; and
• establishing dialogue between WUD, decision makers and other stakeholders.

FEMALE SEX WORKERS WHO USE DRUGS

Drug using sex workers constitute another vulnerable group needing special attention and specific services. There is the risk that the working standard of safer sex, and setting ones’ own limits, may be compromised; safer sex is often not considered as a top priority for WUD engaged in sex work. Services set up specifically for WUD engaged in sex work should differ from the services in other sex workers organizations.

Most organizations focus on drug issues (e.g. HR), whilst sex work aspects are addressed only in the second place.
• WUD IN PRISON SETTINGS

The United Nations Office on Drugs and Crime (UNODC) has identified and published a comprehensive package of 15 key HR interventions and services to safeguard the health and safety of all people who inject drugs in prison settings, including women and WUD, who are often abused during detention:

1. Information, education and communication
2. Condom programs
3. Prevention of sexual violence
4. Drug dependence treatment, including OST
5. Needle and syringe programs
6. Prevention of transmission through medical or dental services
7. Prevention of transmission through tattooing, piercing and other forms of skin penetration
8. Post-exposure prophylaxis
9. HIV testing and counselling
10. HIV treatment, care and support
11. Prevention, diagnosis and treatment of tuberculosis
12. Prevention of mother-to-child transmission of HIV
13. Prevention and treatment of sexually transmitted infections
14. Vaccination, diagnosis and treatment of viral hepatitis
15. Protecting staff from occupational hazards

HR service providers should advocate for the implementation of as much of this package as possible and, where possible, should coordinate directly with local prisons to provide the interventions.

WUD in prisons should have equivalent access to gender-sensitive health and HIV services as their non-incarcerated counterparts in the community. WUD as well as all other prisoners are better able to reintegrate into communities when pre-release preparations start early. All services within the prison, especially prison health services, should develop individual plans for client support after release. A client-based and gender-sensitive approach is the most effective strategy to ensure continuity of care and access to health and other services after release. It is most likely to address the needs of WUD when it is developed in conjunction with each of them and identifies referral processes and mechanisms to track access to services.
• DEVELOPING A “MENU” OF SERVICES FOR WUD

Harm Reduction International developed the following lists which draw on examples of existing gender-specific HR services and provide a ‘menu’ of options to improve and expand care for WUD. Since HR strategies and programs are implemented very differently (and sometimes not at all implemented) in the different countries, ideally services should be tailored to the needs of women in a given context. WUD should always be involved in the design and implementation of these programs to ensure their effectiveness, appropriateness, and respect of the human rights of WUD.

• ADJUSTMENTS AND SMALL ADDITIONS TO EXISTING SERVICES

The following improvements have been suggested for those organizations that can only afford to bring adjustments or small additions to their existing services/programs:

• addition of women-specific items to basic HR kits (women’s hygiene materials and female condoms along with syringes, male condoms, wipes, lubricant);
• additional basic services/material assistance for women at HR sites (pregnancy tests; diapers and other supplies for children; short-term babysitting while women get counselling; informational gender-specific materials; help in learning to inject oneself to eliminate dependence on partners);
• staff training on gender issues (counselling techniques for women, needs of WUD etc.);
• gender balance in HR staff, including active involvement of WUD in service provision and design;
• special time for women only (‘Ladies’ Night’);
• women-only support groups, women-specific counselling programs;
• relationships with trusted gynecologists, obstetricians and other specialists for client referrals;
• secondary syringe exchange program focusing on expanding coverage of women;
• training OST providers and obstetricians-gynecologists on drug use and drug treatment in pregnancy (for OST programs/policymakers): take-home doses, flexible clinic hours;
• basic training on drug use for primary care and women’s healthcare providers to enable effective and prompt referrals to HR and related services when needed;
• links between services for people who use drugs and for sex workers, including discreet provision of HR for sex workers unable to openly visit a HR site in opening hours.
• **NEW SERVICES ADDED BY EXISTING ORGANIZATIONS**

The following list relates to the addition of new resources or space/services (e.g. hiring a new staff member, adding new types of services to an existing program, designating permanent space or significant equipment to women):

- specialist to work with women’s children and give counselling on parenting skills;
- counselling services to respond to sexual violence, IPV, other trauma, and to address the links between trauma and risky behaviors;
- women-only drop-in center or space in the HR center devoted especially to women;
- appointments with a gynecologist and other medical specialists at the HR site;
- multidisciplinary case management for women and their children, including pregnant women;
- mobile HR, OST, basic medical services for women unable to visit service sites;
- legal aid to help women resolve problems with documents, access to social support, legal problems, etc.;
- free, low-threshold sexual and reproductive healthcare, including PMTCT;
- job training, job placement assistance and economic empowerment programs to increase women’s economic independence;
- social support for women released from prison, including support related to parenting.

• **NEW STAND - ALONE SERVICES**

This last list refers to brand-new gender-specific services that would surely be extremely helpful but need dedicated, considerable financial resources (e.g. creation of an entirely new center/service site):

- Open separate rehabilitation centers for women (if possible, where children can also stay).
- Establish comprehensive maternity and post-natal services for pregnant women who use drugs.
- Provide short-term/transitional housing for homeless women and their children.

• **BUILDING A SUPPORTIVE, ENABLING ENVIRONMENT**

Finally, it is important to keep in mind that the components of an enabling environment that need to be addressed across the individual, relationship, community and societal levels to support SRHR for WUD should always include the following:
• psychosocial support
• healthy sexuality throughout the lifetime
• economic empowerment and resource access
• integration of SRHR and HIV services
• protection from violence and creating safety
• social inclusion and acceptance
• community empowerment
• supportive laws and policies and access to justice
• interventions at the relationship level to ensure that health workers at health-care facilities respect and support WUD instead of judging or stigmatizing them. This helps WUD to have easier access to contraceptive or fertility support services.
• interventions at the community level to shift social norms relating to violence and stigma. It helps WUD to more easily have a healthy sexual life if they experience less violence and feel that all their sexual identities are accepted.
• interventions at the societal level to enact law and policy reforms. WUD will more likely exercise their agency if they can benefit from health system policies providing them a wide range of contraceptive options or fertility support services.

The health system should intervene in matters that influence health outcomes across the levels of the social ecological framework and consider how they may interact to support women to achieve healthy sexuality.

FOR MORE INFORMATION WE RECOMMEND:

OBJECTIVE:
By the end of the session, participants will understand:
• integrated approaches in relation to substance use and HIV/HCV testing;
• the role of low threshold settings in improving linkage;
• main barriers to service integration;
• what can be done to support linkage.

TRAINING METHODS:
Lecture

TRAINING MATERIALS:
Power-Point Presentation, working groups.

INSTRUCTION TO THE FACILITATOR:
Try to show importance of the work each participant is doing already to link their client to care and treatment. Encourage participants to think about barriers in different dimensions: structural, systemic, physical etc. Motivate participants to think very practically about how to overcome the barriers and to develop recommendations they can use later.
INTRODUCTION

Low threshold services play a crucial role in HIV/HCV testing and linkage to care. People who inject drugs (PWID) are a vulnerable group and they have reduced access to health care. HIV and HCV care typically involves repeated, regular contact with different services to which PWID may have more poor access and adherence to than the general population. For most chronic illnesses, successful engagement in the continuum of care begins with testing and diagnosis and linkage to care followed by retention in care over time. While initial linkage to care following testing is a crucial stage in the care continuum, many individuals are never successfully linked and thus may never receive the treatment, care and support they need. Ensuring that people who use drugs receive appropriate care is critical for preventing progression of various diseases and for preventing HIV/HCV transmission within the community.

Early knowledge of HIV/HCV infection is now recognized as a critical component in controlling the spread of these infections. Cohort studies have demonstrated that people living with HIV tend to reduce behaviours that might transmit the virus through sex or needle sharing once they know about their own positive status. Access to OST improves access to ART as well as adherence to it. Access to OST improves treatment outcomes among PWID who live with HIV and who are HIV-HCV co-infected. Needle and syringe exchange programs that are co-located with OST programs have achieved good uptake of HIV/HCV screening.

The linkage to care module is designed to help learn how to offer testing in low threshold settings and help people who use drugs overcome the many challenges they often face getting into care. It also addresses what practical steps can be implemented to improve the linkage and control HIV/HCV among vulnerable and hard-to-reach populations.

There is little guidance for threshold settings on how to plan and implement integrated HIV/HCV testing systems. Too often, providers focus only on a single service, rather than the patient’s overall well-being. By taking a more comprehensive approach, integrated care offers patients higher quality, more efficient care that better meets their needs.

“We need a comprehensive, integrated approach to service delivery.
We need to fight fragmentation.” WHO Director-General, 2007

• What are some integrated services that you use in your everyday life?
• What are some integrated services you have seen implemented in your area of work?
WHAT IS INTEGRATION?

The word “integration” stems from the Latin verb “integer” which means “to complete.” The adjective “integrated” means “organic part of a whole” or “reunited parts of a whole.” It is mostly used to express the bringing together or merging of elements or components that were formerly separate.

“Integration” is used by different people to mean different things. There is no unifying definition or common conceptual understanding of integrated care. The concept of integrated care is strongly shaped by perspectives and expectations of various users in the system, making a unified definition difficult. Interestingly, all definitions converge around highlighting the central role of population and individual needs.

The approaches can be grouped into three broad categories:
- individual models of integrated care;
- group- and disease-specific models;
- population-based models.

WHAT IS INTEGRATED CARE?

Integrated Care is a concept bringing together inputs, delivery, management and organization of services related to diagnosis, treatment, care, rehabilitation and health promotion. Integration is a means to improve the services in relation to access, quality, user satisfaction and efficiency.
Integrated care is care that is person-centred and co-ordinated. For care to be integrated, organisations and care professionals need to bring together the different elements of care that the patient or service user needs. This includes care provided at the same time or at different stages of the care pathway, to address all the patient’s or service user’s needs and to seek to improve their outcomes and experience of care.

Integrated care brings together the different groups involved in patient care so that, from the patient’s perspective, the services delivered are in a consistent and coordinated way. A person’s care may be provided by several different health and social care professionals, across different providers. As a result, people can experience health and social care services that are fragmented, difficult to access and not based around their (or their carers’) needs.

In many cases, the increased efficiency of integrated care also helps control costs. Staff shortages, continuing cost inflation and service demand have intensified the call for more effective and efficient use of scarce resources through integrated service models.

**BENEFITS OF INTEGRATED CARE**
- better patient experience
- improved outcomes
- improved adherence to treatment
- improved quality of life
- improved efficiency

**POORLY INTEGRATED CARE**
- duplication and gaps in service and infrastructure
- under- and over-use of resources
- medical errors and adverse events
- accessibility problems and discontinuity in care
- unmet healthcare needs

Delivering integrated care is essential to improving outcomes for people who use services in low threshold settings. Treatment services are most effective and attractive to PWID patients when they are: easily available; voluntary; unconditional; free of any legal consequences; address individual needs; and different harm reduction and treatment services are available in one place (syringe/needle exchange, OST, ARV, HCV treatment etc). The most successful linkage-to-care rates were seen in settings where testing, care, and treatment are provided in one place.

This test-and-treat model eliminates the need to refer patients to an outside care provider, except in extenuating circumstances. In collaboration with public health agencies and other service providers, community health centers are optimally positioned to play a pivotal role in expanding access to recommended testing, care, and treatment for people who use drugs.
People who use drugs (PWUD), including people who inject drugs (PWID), are marginalized and stigmatized in most societies and are often at increased risk of acquiring and transmitting HIV, hepatitis, and other blood-borne pathogens. These populations are hard to reach and often the least able to access and the least likely to utilize HIV prevention, care, and treatment services. Therefore, HIV prevention programs need to be developed or tailored to effectively target, reach, and address the particular needs of PWUD. Any patient whose socioeconomic conditions or lifestyle makes it difficult to access health services, self-administer treatment, and attend regular healthcare appointments.

In addition to the type of integration, strategies for improving the links between services may be linked-widely varying goals: some strategies are mainly implemented to reduce costs, while others additionally focus on quality, access, and user satisfaction. Integrated care may be deemed successful if it: contributes to better care experiences; improves care outcomes; or delivers services more cost-effectively. Without integration at various levels, all aspects of health care performance can suffer. Patients get lost, needed services fail to be delivered, or are delayed, quality and patient satisfaction decline, and the potential for cost-effectiveness diminishes.

- **BARRIERS TO LINKAGE**
  1. Quality of post-test counseling including the lack of adequate time for post-test counseling
  2. Lack of coordination between HIV testing and care
  3. Limited health facility access
  4. Stigma associated with the health facility
  5. Inefficient service delivery
  6. Inadequate patient-provider interaction
  7. Inadequate program incentives
Multiple factors may hinder the successful uptake of testing and linkage to care and prevention. These include patient-level factors (such as depression, lack of social or family support, and fear of disclosure), as well as structural or economic factors such as stigma and discrimination, distance from care sites, lack of or cost of transportation, and long waiting times at the facility. Hepatitis C and HIV also disproportionately affects individuals with co-morbid mental health or substance use issues.

Traditionally, services for hepatitis and HIV, mental health and substance use have been provided by separate clinicians or teams often located in different health facilities, which may contribute to HCV/HIV treatment dropout and/or treatment failure.
KEY MASSAGE

- ENGAGING HIV/HCV PATIENTS IN CARE, IMMEDIATELY AFTER DIAGNOSIS AND CONSISTENTLY THEREAFTER, HAS A PROFOUND IMPACT ON EFFORTS TOWARDS ‘ZERO NEW INFECTIONS’

- MAIN BARRIERS: FINANCIAL (LACK OF INSURANCE OR UNDERINSURANCE, COMPETING SUBSISTENCE NEEDS, FOOD, HOUSING.)

- STRUCTURAL (UNAVAILABLE OR INCONVENIENTLY LOCATED SERVICES, LONG APPOINTMENT WAIT TIMES ETC.)

- ADMINISTRATIVE, PERSONAL (STIGMA OF HIV, SEXUAL IDENTITY, DRUG USE, LACK OF TRUST IN MEDICAL SYSTEM ETC.)
WHAT CAN BE DONE TO SUPPORT INTEGRATED CARE?

Integrated care can be supported by investing in and applying the tools available for integrated care. There are many different ways in which professionals and providers can work directly with communities, patients/clients to support integrated care. These ‘tools’ of integrated care focus on the ‘how’ of clinical and service integration.

Different approaches have been used to integrate care, but they share this trait: they design all stages of care delivery around what is best for patients. The main strategy to improve access is to concentrate services in one location and provide them free-of-charge. An integrated service provision model minimizes the chances of stigmatization based on the fact that a client has come to receive certain services.

Effective linkage is based on an understanding of who is using drugs, which drugs are being used, what kinds of risk behaviours are related to drug use (e.g., sharing injection equipment and increased frequency of unprotected sex) and what steps need to be taken to reach out to and encourage PWUD to engage with HIV prevention activities and services.

There are clearly many issues going on “behind” this general definition and it is useful to look at “integration”-from various perspectives.

**For the user,** integration means health care that is seamless, smooth and easy to navigate. Users want a coordinated service which minimizes both the number of stages in an appointment and the number of separate visits to a health facility required. They want health workers to be aware of their health as a whole (not just one clinical aspect) and for health workers from different levels of a system to communicate well. In short, clients want continuity of care.

**For providers,** integration means that separate technical services (and their management support systems) are provided, managed, financed and evaluated either together, or in a closely coordinated way.

It is also important to understand factors related to HIV prevention, care, and treatment services, including: the kinds of services currently available; whether the services are user-friendly (i.e., appropriate, accessible, and acceptable and affordable to PWUD); and the policy and regulatory context within which drug use and HIV transmission occur and interventions will be implemented.
WHEN ESTABLISHING REFERRAL TO CARE SERVICES IT IS RECOMMENDED TO HAVE A MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN ALL INVOLVED ORGANIZATIONS SIGNED. THE MOU SHOULD PROVIDE CLEAR INFORMATION ABOUT WHAT EACH ORGANIZATION WILL PROVIDE TO THE CLIENTS REFERRED TO THEM.

THE MOU ALSO MIGHT HAVE INFORMATION ABOUT ELIGIBILITY REQUIREMENTS TO REVIVE SERVICES, POINT PERSONS FOR TROUBLESHOOTING, AND AVERAGE WAITING TIME WHEN CLIENT ARRIVES (PWUD WILL NOT WAIT TOO LONG, SO IT IS THE BEST TO INFORM THE PERSON ABOUT THE LENGTH OF THE EXPECTED WAIT SO THAT THEY CAN PLAN AVOID WITHDRAWAL SYMPTOMS).

1. COMPREHENSIVE SERVICES ACROSS THE CARE CONTINUUM

PWID and their families have emotional, social, physical and spiritual needs that change over time. They often must cope with the effects of stigma and discrimination, poverty, loss, neglect and abandonment. Integrated care may be seen as a response to the fragmented delivery of health and social services. This fragmentation in delivery has become an acknowledged problem in many health systems. The purpose of the Continuum of Care (CoC) is to address illegal drug use as a chronic disease and develop systems that provide humane, effective, high-quality comprehensive and continuous care to PWID and their families. When implementing a testing program, it is fundamental to establish close collaboration and a referral system between clinical centres providing HIV, HCV and TB diagnosis, treatment and care, and other services where testing and/or counselling may be offered.

2. PATIENT FOCUS

The integrated service delivery system should meet the needs of patients needs rather than the needs of service providers. Organizations that fail to place the patient at the centre of their integration efforts are unlikely to succeed. The provision of health care, social services and related support (e.g. housing) at the right time and place to such individuals can be challenging. Problems typically include difficulties with: conducting needs assessments; putting together comprehensive service packages; co-ordinating multiple providers and services; ensuring continuity; monitoring health and functional status; responding to crises; supporting family carer; and, finally, performing all of these essential activities within existing funding and resource constraints.
Why ask the patient?

- Patients are witnesses of and participants in integration.
- Patients are sometimes the only connection between providers / sectors / specialties.
- Patients have knowledge that will help to establish the baseline that can be used to measure change over time.
- Patients' experiences relate to many, though not all, aspects of integrated care.

Patients must be engaged in making decisions about their own care and support.” – ‘no decision about me without me.’

3. GEOGRAPHIC COVERAGE

Similarly, integrated services provide the opportunity for people-centred prevention, care and treatment for PWID, who have complex health and social care needs. Such services also facilitate better communication and multidisciplinary care, and are likely to increase efficiency and cost–effectiveness. Thus, wherever feasible, programs should work towards delivering integrated services for PWID in ways that are informed by PWID and that foster trust in service delivery settings and providers. When this is not possible, strong links among health and social services working with PWID should be established and maintained.

4. STANDARDIZED CARE DELIVERY

PWID commonly experience multiple comorbidities, often in a context of marginalization and deprivation. Rates of TB, HIV, viral hepatitis and other infectious diseases are high among PWID, as are mental health conditions. If the client is not ready to make a medical appointment, the linkage goal then becomes to get the client “as close to comprehensive medical care as possible” through one or more of the following referrals:

- to a case manager at medically-linked site; or
- to a case manager at non-medically linked site.

5. INFORMATION SYSTEM

Information technology that supports the linkage, especially via the electronic medical record and the use of clinical decision support systems, and through the ability to identify and target ‘at risk’ patients.

6. LEADERSHIP

There may also be policies that prevent HIV-positive people who use drugs from accessing care. It will be important for program planners to understand which laws exist and which behaviours the laws criminalize (e.g.,
drug possession, drug use, etc.). Understanding the policy and legal environment will provide insight into potential barriers to implementation and uptake of services. Effective leadership at all levels with a focus on continuous quality improvement is essential.

7. FINANCIAL MANAGEMENT

Effective linkage to HIV/HCV care and treatment following a positive diagnosis is expected to improve programme effectiveness, support earlier treatment initiation and reduce loss to follow up before treatment initiation, thus resulting in potential cost savings along the continuum of care.

The international framework for measuring integrated care encourages:

- coordination within care teams;
- coordination across care teams;
- coordination between care teams and community resources;
- continuous familiarity with patient over time; and
- continuous proactive and responsive action between visits.

POSSIBLE TOPICS FOR GROUP DISCUSSION:

- IDENTIFY THE KEY BARRIERS TO THE CLIENT ACCESSING TESTING SERVICES AND ENGAGING WITH TREATMENT. CONSIDER THE PERSONAL AND PUBLIC HEALTH IMPLICATIONS.
- ARE SERVICES AVAILABLE FOR PEOPLE WHO USE DRUGS IN THE AREAS WHERE THIS POPULATION IS CONCENTRATED?
- ARE SUFFICIENT NUMBERS OF THE TARGETED POPULATION ACTUALLY RECEIVING SERVICES?

FOR MORE INFORMATION WE RECOMMEND:

1. Accessibility and integration of HIV, TB and harm reduction services for people who inject drugs in Portugal, World Health Organization 2012


MODULE 7. QUALITY IMPROVEMENT

OBJECTIVE:
By the end of the session participants will understand:
• quality improvement tools;
• how to choose the right tool; and
• the meaning of quality.

TRAINING METHODS:
Lecture

TRAINING MATERIALS:
Power-Point Presentation, short movie, practical group exercise.

INSTRUCTION TO THE FACILITATOR:
Visit the website: http://www.qualityaction.eu
Before the session, download a short movie about PIQUA tool:
http://www.qualityaction.eu/piqa.php
and make sure that the equipment works properly.

Try to apply it yourself, before introducing to the participants of the training. The tool is available in English, German, Italian, Lithuanian, Croatian and Slovakian languages.
Quality improvement (QI) is an important part of work for every organization, especially those, providing lifesaving services for people. The work we are doing and the services we are providing must not only be appropriate to the current situation, but also be at a highest level of effectiveness. Quality improvement makes it possible to have a deep look inside a project, analyse its strong and weak parts and look where possible improvements might be made. QI recognizes and documents what works well and why and builds on and multiplies success.

There are different tools, which were created to help you to assure the quality of a project/program and find solutions for its improvement. The tools are easy to use and you can find supportive information on the website. To use one or even all of the tools doesn’t cost any money but brings a lot of benefits. They help to review and monitor the work you are doing and encourage participation of stakeholders.
• PURPOSE OF QUALITY IMPROVEMENT TOOLS

The purpose of the quality improvement tools depends on time you decided to devote to it. Quality improvement tools might be used during project planning or during implementation of a project. At the end of the project, using a QI tool can enable monitoring and evaluation, assessing what was working well and identifying areas for improvement in future projects.

• WHAT TOOL SHOULD I USE?

There are many quality improvement tools available, of which some are specific to health promotion activities. Quality Action – a Joint Action Project - offers a selection of five practical tools adapted or developed for HIV prevention to suit a wide range of projects and programs. They are based on scientific evidence, practical experience and expert advice. All five tools encourage self-reflection and participation as important prerequisites for creating a culture of quality improvement. The tools themselves are complemented by a Tool Selection Guide, a Workshop Facilitation Guide, training materials and online learning resources.

Criteria used to select and develop the tools offered by Quality Action:
The PIQA tool was adopted especially for health promotion activities targeting people who use drugs and can be used for projects that are intended to prevent HIV, STI, Hepatitis, TB and other infections that are common among people who inject drugs/people who use drugs (PWID/PWUD). It can also be used for other health promotion projects targeting PWID/PWUD and for quality assurance of the health promotion aspects of other PWID/PWUD-focused projects. PIQA can be used by those implementing the project, by project coordinators and by representatives from the target group who know about the project.

PIQA is a self-assessment tool. It is most useful when a range of people are involved in the assessment process, including members of the project team, the target group and other key stakeholders in the project.

The tool contains an introduction to its use and clusters of questions on seven important areas that have been shown to be important for success in health promotion. The respondents assess to what extent the project has managed to fulfill requirements in these areas. Depending on the score, you might consider your project to be strong, moderate or weak in an area and then consider possible improvements.

The tool has been developed in close collaboration with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), looking specifically at health promotion and prevention targeting PWID.

**FOR MORE INFORMATION WE RECOMMEND:**

http://www.qualityaction.eu
9 REASONS TO GET INVOLVED IN QUALITY ACTION

1. BECOME AWARE OF WHAT YOU ARE ALREADY DOING WELL

2. LEARN ABOUT WHEN, HOW AND WHY YOU ARE ALREADY SUCCESSFUL AND SOMETIMES FAIL

3. GET NEW IDEAS ON HOW TO IMPROVE WHAT YOU ARE DOING

4. INCREASE PARTICIPATION AND BENEFIT FROM STAKEHOLDER INPUT

5. PROVIDE YOURSELF WITH SPACE AND TIME TO REFLECT ON YOUR WORK AND BUILD YOUR TEAM AND INTERNAL COMMUNICATION

6. ENHANCE YOUR CO-WORKERS’/EMPLOYEES’ WORK SATISFACTION

7. BUILD DIFFERENT TYPES OF EVIDENCE THAT SUPPORTS YOUR HIV PREVENTION INTERVENTIONS

8. SIMPLIFY AND ENHANCE THE PLANNING, IMPLEMENTATION, MONITORING AND EVALUATION OF YOUR PROJECTS AND PROGRAMS

9. NETWORK WITH OTHER EUROPEAN ORGANISATIONS TO MAKE HIV PREVENTION MORE EFFECTIVE
OBJECTIVE:
By the end of the session participants will know:
• about an example of a German testing intervention for prisons
• requirements for a test interventions in prison settings
• standards for HIV and HCV testing in prison settings

TRAINING METHODS:
Lecture

TRAINING MATERIALS:
Power-Point Presentation

INSTRUCTION TO THE FACILITATOR:
Mention to the participants that the content of this Module is based on a pilot project “HIV-and HCV testing and consultation within prison settings. One pilot intervention 2016-2018” in Germany. For this module, prepare national statistic about prison population and HIV/HCV/TB infection rates among prisoners.

Make clear to participants that standards of medical services in prisons must be not worse than those outside prison.
• PRISONS AS PLACES FOR PUBLIC HEALTH INTERVENTIONS

Each year about 110,000 people get imprisoned for the first time in Germany. There is a high turnover rate: citizens arrive and depart on a daily basis. Among those incarcerated are highly vulnerable people who use drugs (PWUD) due to prohibitive drug laws. The so-called DRUCK study from the Robert Koch Institute carried out between 2011-2015 demonstrates: that HCV and HIV prevalence among PWUD is way above average (HCV: 37-73%, HIV: 0-9%); that testing rates for PWUD are high but newly discovered infections indicate that tests are less frequent and more could be done to offer tests for PWUD, in particular in prisons. The prevalence of HBV vaccination among PWUD was low (15-52%).

Data from 2010 indicates that chronic HCV in prison is 32-fold and HIV 24-fold higher compared to the general population. Given the fact that there are prison-related risks to acquiring blood borne diseases (the DRUCK study found out that 40% of study participants reported drug consumption by injection in prison and that 3% claimed that they had started consuming drugs by injection in prison). It makes sense to offer HIV/HCV counseling and testing services for prisoners and HAV/HBV-vaccination. However, due to suboptimal testing standards in prison, NGOs in Germany have been reluctant so far to offer counseling and testing services in prison. The risks for prisoners were perceived as too high with the result that community-led testing campaigns carried out countrywide for vulnerable populations, such as for gay men and PWUD, have not been available for incarcerated populations so far.

The rate of HIV late presenters (those with CD4 counts of less than 500) in Germany (approximately 30-50%), is still too high. More efforts are needed to detect undiagnosed PLHIV including in prison. Prison health must be perceived as part of public health. Supporting health in prison will contribute to ‘leave no one behind’ and achieving the 90-90-90 goals, that are identified as necessary to achieve the end of AIDS by 2030, an important element of the Sustainable Development Goals (SDG) that countries of the world have agreed upon.

• VOLUNTARY COUNSELING AND TESTING STANDARDS (VCT) IN PRISON

VCT standards demand that HIV testing be performed with informed consent, which is difficult in punitive systems, such as prisons. Any community-led intervention needs to ensure that the confidentiality of test results is secured and that interventions will not create negative consequences for prisoners tested.

A breach in confidentiality can lead to:
• exclusion from social activities (sports etc);
• exclusion from work places, such as laundry or kitchen;
• discrimination by other inmates and/or by prison staff or health care personnel.
The discriminative nature of such internal restrictions is obvious. Germany has an anti-discrimination laws and regulations that secure the rights and safety of PLHIV throughout the country. However, positive test results in prison can, at the individual level, lead to extremely difficult situations. They can destroy wellbeing, careers and lives.

• **LINKAGE TO CARE**

HIV testing without an offer to link it to care is problematic. In this respect, it is problematic that prisoners cannot choose the doctor who treats them. Prisoners might mistrust their assigned doctor. This maybe because of general fears, of previous experiences or because of what they heard from other inmates. In this case, it is more difficult for prisoners to build up a trusting relationship with their doctors and linkage to treatment and care can become difficult. A good doctor-patient relationship, based on trust, sympathy and mutual understanding, is often described as the basis to start livelong HIV-treatment outside prison. We know that achieving good adherence to treatment without this basis may be quite difficult.

From a financial perspective, linkage to HIV-treatment in Germany’s prisons does not remain a problem. However, linkage to HCV treatment is! Most prisoners tested HCV-positive in prison will very likely not receive treatment to cure their chronic infection. The high costs of modern HCV treatment, limited budgets for prison health and the high number of PWUD with HCV in prison are the reasons.

The fact that friends and family of incarcerated people are often hard to reach is an additional barrier, especially when medical decisions are necessary or emotional/psychological problems occur.

The most important question for the development of a pilot program in Germany was to guarantee that participating prisoners have control over the information about their HIV/HCV status in cases where the prisoner was not ready to consult prison health authorities to avoid the above-mentioned negative consequences. Furthermore, prison authorities needed to be convinced that cooperation with the community is not threatening but will instead offer added value for prisoners, prison doctors and staff alike.

To tackle the challenges, the German AIDS Federation developed a concept of an exemplary intervention to address these issues. As a first step to develop the concept, a group of community experts with work experience in prisons, met for a weekend to share their knowledge and to brainstorm about possible community-led interventions. Information collected guided further process. The results of the above-mentioned DRUCK study and the community testing guidelines (already existing for the community-led VCT activities outside prison) were very important for the development of the intervention.
The security of the prisoners was above all the highest concern. Based on the discussions, a consultant was hired to write the concept, which was send to all Ministries of Justice (MOJ) in Germany in order to find the approval. The intervention is realized in one of Germany’s male prisons. First results will be presented in autumn 2018. The process from the first idea to its realization took 3 years.

**FIRST LESSONS:**

1. The implementation of such a project requires an analysis of the situation and thorough discussions. The time required to get support from the MOJ and to find project partners in prison should not be underestimated.
2. To limit possible negative consequences for prisoners, VCT testing programs should be established by NGOs (with NGOs involvement) that know the system and already have experience working in prison.
3. The programs should establish good cooperation between NGOs and prison health authorities/staff members.
4. A nice atmosphere in the space where VCT should be created.
5. Informational materials and condoms must be provided.

**THE CONCEPT OF HIV/HCV COMMUNITY-BASED COUNSELLING AND TESTING IN PRISON**

After its development, the concept described here was shared with the Ministry of Justice. Its purpose was to convince prison health authorities to participate as partners and to explain certain measures planned. The original concept is available in German language only.

**AIM OF THE INTERVENTION**

If carefully undertaken, VCT in prison needs a lot of time. Physicians in prison with their multitude of other responsibilities sometimes do not have adequate amount of time. The intervention aims include:

- to reduce the work load for physicians and health care personnel by offering complementary HCV/HIV VCT to prisoners carried out by external NGOs/physicians;
- to establish examples how VCT guidelines can be utilized in prison settings; and
- to offer prisoners time to discuss questions related to: risk behavior patterns; testing procedures; risk reduction strategies (safer sex, safer drug use); risks related to incarceration.

The ultimate aim is to identify new HIV/HCV-infections, reduce the amount of late HIV presenters and close the gap in the care system (linkage to care).
• PRECONDITIONS AND PREPARATION

Initially, an analysis of the situation should be written up including a concept explaining the aims and tasks as well as the willingness of all parties involved (MOJ, prison health authorities, NGOs with good contacts within prisons) to cooperate and agree on the aim and tasks in accordance with agreed procedures and standards. As a safeguard, all needs should be documented and an agreement between the parties involved reflecting a common vision of these should be signed. To secure the cooperation and limit risks, trainings on the aims and the scope of the intervention and themes relevant to it, such as: basic information on HCV/HIV, prevention, risk situations, harm reduction, safer use, safer sex etc. should be offered to everyone involved (including prison health authorities, staff, guards, NGO participants etc.).

The participation of prisoners must be voluntary. The cooperating partners inside prison should advertise among prisoners, communicating the dates of the intervention and procedures and bring prisoners with the interest to participate to the agreed appointments. Leaflets and other advertising materials, test-kits and other materials may be supplied by the NGO. The cooperation of partners inside the prison should guarantee that prisoners are not pressured to participate. A clean room (if possible with a wash basin) that guarantees anonymity between prisoners and test counselors should be provided.

• REGULAR CONSULTATION HOURS FOR PRE- AND POST- TEST COUNSELING AND TESTING

Consultation hours are often made available for three hour periods and should be offered on a regular basis, for example every 14 days. The dates and hours should be convenient for prisoners and prison staff. Prisoners willing to participate have might have one to three appointments.

Rapid test. The first appointment is for pre-test counseling (and testing if the prisoner decides he or she wants to get tested – should a rapid test be used (and in case the test is not reactive, the test result will be delivered during the same appointment, in such cases only one appointment is necessary.

Laboratory. The second appointment is to present and explain the test result (in case no rapid tests were used or a rapid test needed to be confirmed) and to talk about treatment options.

Follow-up consultation. A third appointment may be arranged in cases where the prisoner has further questions related to risk behavior, consequences of the test results, further diagnostics, treatment options and linkages to care, and or to discuss next steps etc.

Prisoners should be given opportunities to tell prison staff that they want to participate. Prisoners should not have to explain why they want to participate. After the first meeting, prisoners should receive a card
with a code and the date for the next appointment. This is for logistic reasons only; there should be no other information on the card to secure the confidentiality (other inmates, prison staff). The usage of the program is completely voluntary, without any pressure. Prisoners should be able to decide at any point to end their participation.

- **BEST TIME FOR COUNSELING AND TESTING**

The time to deliver VCT services in prison needs to be considered. Many prisons offer tests during medical examinations at entry, which is certainly a good idea when health problems or acute symptoms appear, however:

- The best time for HIV/HCV VCT in prison is some weeks after incarceration: Prisoners, familiar with the new environment, are emotionally more balanced, which is an important pre-condition to digest information delivered or test results. Even if HIV/HCV+ test results are now much less dramatic: coping with test results varies among individuals and it depends as well on the knowledge prisoners have.

- A good time for VCT counseling is after prison-specific risks are taken counseling (on safer use and safer sex): offers chances to change risky behaviors, which fosters the safety of the prisoner, other inmates and staff alike.

- Another good time for VCT is close to release: this offers chances to prepare drug consuming prisoners with information related to referral and support structures (housing, linkage to HCV treatment etc) available outside and risks related to drug relapse, new psychoactive substances, overdose etc.

- **PRE-TEST COUNSELING, CONTENT COVERED**

Community counselors or a physician may be involved in confidential pre-test counseling. Translators should be offered and arranged beforehand if needed. The average time allocated for counselling is about 20 minutes, depending on knowledge and information needs of the prisoner. The basis of the counseling is a 13 page long anonymous questionnaire assessing knowledge and risky behavior that serves as a guideline for consister through the consultation. The main topics covered in the questionnaire relate to knowledge, questions and risks related to:

- basic information on HIV/HCV (treatment options);
- risky situations (sex, drug consumption, tattoo, piercing) in the past and in prison;
- transmission routes (HIV, HCV, other STI if needed);
- safer use, safer sex, personal risk behaviors, emotional stability.

Based on the information related to risks and questions raised by the prisoner, information about the tests used, next steps, possible other diagnostic tests (including for STIs) and the relevance of hepatitis A/B vaccination should be delivered, including:
• information about test results and procedures;
• advantages and disadvantages of tests provided;
• information around procedures, waiting hours and possible emotional challenges related to a positive test result (Elisa, PCR);
• information on next steps should a test be positive (next diagnostic steps, treatment options within prison, the possibility and freedom to include the prison doctor based on the individual decision, relevance of confidentiality);
• compulsory registration by the laboratory of newly detected HCV/HIV cases to the national health surveillance authorities.

The counseling session will include information about possible negative consequences within the prison system should the test be positive. Emotional capacities and coping strategies should be addressed should the test be positive. The ultimate aim is to secure that the prisoner can make an informed decision to take or not to take the test (informed consent).

• TESTING, BLOOD EXTRACTION

Tests should only be carried out with the approval of the prisoner and after all information is provided and discussed. All tests performed should be coded and kept anonymous according to the usual processes used outside prison.
• Tests should be carried out by an external cooperating physician (or under close surveillance of him/her).
• Test samples (Elisa tests, PCR) should be send to local laboratories (the result should never be shared with the prison health authorities, unless the prisoner allows it in order to secure further diagnostics and treatment etc.)

POST - TEST COUNSELING / REPORT THE RESULTS

The prisoner should come to an appointment with the code provided in the first meeting.
• Test results should only be delivered face to face by the physician involved.
• The information about the test results should only be given to the prisoner.
• The decision to communicate the test result to others should only be make by the prisoner. No one should no pressure the prisoner about decisions related to communication about test results.
• Enough time will be granted to discuss questions related to next steps, other diseases (STIs) etc.
• Results from rapid tests should be presented immediately. Should the test be reactive, the result and possible next steps (confirmation tests: Elisa, if necessary PCR) should be explained to the prisoner.

• Blood extraction for the confirmation test should be offered of the test is positive but this can be done at the next appointment should the prisoner need time to decide upon next steps as well.

• Should the HIV/HCV test be positive, treatment options, next necessary steps and/or other tests to clarify the health status, the importance of HAV/HBV vaccination etc. should be explained/discussed. Since treatment is only possible within the prison system, it is obvious that good cooperation between the initiators of the intervention and prison health authorities is key.

• Possible benefits of disclosing the result to the prison health authorities (for example to initiate treatment) should be explained to the prisoner. Again here, no pressure should be applied: the decision should be made solely by the prisoner.

• Information should only be delivered to the prison health authorities if the prisoner releases the involved parties from the confidentiality agreement.

• Meetings between the prisoner, the prison health authorities and the physician involved in the project can be initiated to discuss next steps, possible treatment options, compliance etc.

The points raised here clarify the importance of mutual respect and good cooperation between all parties involved in the project. Huge disadvantages for the prisoner can be created should this not be guaranteed.

COSTS

All costs related to the intervention in Germany are covered by the initiator (Deutsche AIDS-Hilfe). This relates as well to costs for the development of the project, materials for advertisement and information, educational purposes for the involved participants and travel costs.

Every 14 days, for pre- and post test counseling and testing are made available for 4 hours. The costs involved include: the physician: 53.- Euro/ hour and costs for counselors (external social workers): 30.- Euro/ hour. If necessary the costs for translators are provided for on an hourly basis.

Expenses for tests carried out (rapid tests, Elisa, if necessary PCR tests) are covered by the initiators of the project as well.
BEFORE PLANNING A SIMILAR INTERVENTION, ORGANIZERS SHOULD CONSIDER ALSO SOME OTHER COSTS:

- 7,20 Euro - HIV Rapid Test
- 17,20 Euro - HCV Rapid Test
- 5,25 Euro - HIV Antibody Test
- 28 Euro - Western Blot
- 7 Euro - HCV Antibody Test
- 38,50 Euro - HCV PCR Test

POSSIBLE TOPICS FOR GROUP DISCUSSION:

- THINK OF POSITIVE AND NEGATIVE CONSEQUENCES FOR PEOPLE GETTING HIV/HCV TESTS IN PRISONS
- LINKAGE TO OUTSIDE SERVICES: MAKE A LIST OR ILLUSTRATION OF POSSIBLE WAYS TO CONNECT HIV/ HCV POSITIVE INMATES WITH OUTSIDE SERVICES
- THINK OF A SIMILAR INTERVENTION IN YOUR COUNTRY: MAKE A MAP WITH POSSIBLE ALLIES AND ENEMIES; BARRIERS AND

FOR MORE INFORMATION WE RECOMMEND:

1. UNODC, UNAIDS, WHO. HIV testing and counselling in prisons and other closed settings. 2009.

2. Hepatitis C In European Prisons: A Call For An Evidence-Informed Response; Amber Arain, Geert Robaey, Heino Stöver; BMC Infectious Diseases 2014, 14 (Suppl 6):S17

3. Prisons and Drugs in Europe. The Problem and Responses 2012, EMCDDA.
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