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for Drugs and Drug Addiction

Norwegian Institute of Public Health

Guidance on Provider-initiated Voluntary Medical Examination, Testing and Counselling for Infectious Diseases in Injecting Drug Users

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CONTENTS

Summary

This document addresses basic operational guidance on provider-initiated medical examination, testing and counselling with regard to infectious diseases in injecting drug users (IDUs). This is accompanied by a recommended package of prevention and primary care in relation to injecting drug users and infections. Treatment and other specialist care are not discussed in detail here but are dealt with by indicating referral to appropriate services.

Infectious diseases are among the most serious health consequences of injecting drug use and can lead to important health care costs. Injecting drug users are vulnerable to a range of infectious and communicable diseases through a variety of risk behaviours and underlying conditions like poor hygiene, homelessness and poverty. This leads to higher morbidity and mortality in this group as compared with the same age groups in the general population. In addition, IDUs can act as a core group or pocket of infection that may pose a risk of spread to the general population.

Although HIV- and hepatitis C infections remain the most important public health problem in IDUs, the document recognizes that other blood borne viral infections as well as various bacterial infections play an important role in the general health situation and well-being of IDUs. As the coverage of effective antiretroviral treatment and treatment for other infections in IDUs are being scaled up, the document points to the need to increase access to and uptake of testing for HIV and other infectious diseases in IDUs. The document is rooted in the concept that prevention of drug-related infectious diseases through evidence-based measures such as opioid substitution treatment, needle exchange programmes and other elements of the 'comprehensive package' for IDUs continues (1) to be the mainstay of the response to HIV, hepatitis and other infections in this group, given that prevention of injecting drug use itself, even as the central long-term goal, proves still to be difficult.

The recommendations are primarily targeting high-income countries with low level or concentrated HIV epidemics where recorded infections are largely confined to individuals with risk behaviour, such as IDUs, as is the case for most European countries.

The objectives

The objectives of provider-initiated examination, testing and counselling of IDUs are to:

- Improve the general health of the individual IDU
- Improve testing uptake for HIV and other drug related infections
- Increase access of IDUs to treatment for HIV and other infectious diseases
- Improve diagnosis of chronic infections which need specialist care
- Increase vaccination coverage in IDUs
- Make IDUs more actively engaged in their own health care
- Improve access of IDUs to prevention counselling and information
- Improve surveillance of HIV infection, hepatitis and other infections in IDUs

The consultation

The guidelines recommend that health providers should initiate examination, testing and counselling in IDUs in different health settings like primary health care, special health services for IDUs, low threshold service centres visited by IDUs, rehabilitation centres dedicated STI clinics and prison health care facilities. Elements included in the consultation should include:

- Medical history and physical examination
- Pre-test counselling, informed consent and possibility to decline tests
- Testing for infections
- Post-test counselling
- Prevention counselling
- Vaccination
- Follow-up and referral routines
- Frequency of examination and testing
- Ethical considerations

Testing for infections

This guidance document recommends a provider-initiated, voluntary and confidential approach to testing and counselling. Provider-initiated means that examination, testing and counselling is recommended by a health care provider to persons attending facilities as a standard component of medical care. Voluntary means that although testing is a standard part of the medical care the individual is informed about the tests and its potential consequences and gives (informed) consent to taking the test(s). The individual should always be able to decline testing for one or various infections after receiving pre-test information without fear for coercion or negative consequences. This approach stresses that no tests should be done against a person's wishes or without their knowledge, that informed consent must be given and that test results will remain confidential. In situations where these conditions are likely not to be met (like in closed settings such as prisons) it is recommended to refrain from provider-initiated testing and to make voluntary counselling and testing available on the individual's request.

In provider-initiated testing the following tests are recommended as a standard offer to all IDUs;

- Serology testing for HIV, hepatitis B, hepatitis C, hepatitis D (if evidence of chronic or recent hepatitis B), hepatitis A and syphilis
- Swab for culture from abscesses and skin lesions
- Tests for biochemical analysis (ALAT, ASAT, bilirubin)
- Other general blood tests (ESR or CRP, haemoglobin and white blood cell count
- Tests for tuberculosis

The frequency with which a client should be re-examined and re-tested depends on the individual risk of exposure to infectious agents. For individuals with ongoing injecting drug use this risk is usually very high and frequent re-examination and re-testing are recommended. It is important to reduce the period of undiagnosed carrier state following infection and thus reduce the risk of transmitting infections to others. For practical reasons and taking into account the mentioned considerations it is recommended to offer examination and testing to IDUs at least once every 6-12 months.

While this document supports a strategy of increased testing of HIV and other infections in IDUs in health care settings, it does not support a policy of testing without informed consent, without pre- and post testing counselling or where confidentiality of test results cannot be guaranteed. No tests should be done against a person's wishes and without their knowledge, and adequate information should be provided on which the individual can decide to take or decline one or more tests. The conditions under which IDUs undergo testing for HIV and other infections must be anchored in a human rights approach, where the client is an equal partner in the process, and pay respect to ethical principles detailed in the document such as

confidentiality of test results. Health care providers must follow equally high standards as in other patient groups with regard to confidentiality and unauthorized disclosure of test results. It must be made explicit that in case of declining to be tested or in case of positive test results that this will not influence the accessibility of services, such as drug dependence treatment. The health care provider is the final responsible for ensuring that adequate procedures and conditions exist before a test is taken.

Policy makers should implement or safeguard and monitor adequate conditions for testing vulnerable populations such as IDUs at local and national level. However, this is beyond the scope of these guidelines and for these aspects we refer to specific HIV testing guidance being developed by UNODC, WHO and UNAIDS.

Methodology and scope

This document is a result of discussions at the annual EU expert meetings on drug-related infectious diseases (DRID) held by the EMCDDA. While the main objective of the work on drug-related infectious diseases at EMCDDA is to develop indicators for more reliable and comparable monitoring of hepatitis B/C and HIV in injecting drug users, a need emerged to develop methods and guidance to improve the quality of testing and counselling processes among IDUs and to increase testing uptake for HIV and other drug-related infections. The development of these guidelines has been based on ongoing review of materials such as research reports, position statements, policy documents, journal articles and clinical guidelines. Recommendations given here are generally based on good clinical practice as well as information from epidemiological and other studies among IDUs. The scope of these guidelines, however, is not to express all benefits of tests, counselling and preventive measures in evidence based terms, nor to provide a thoroughly documented literature review of the health risks associated with injecting drug use, but rather to present a short and readable document that is directly useful for the primary health care provider who is in contact with IDUs regarding the decisions to test for infectious diseases. In addition, although increasing testing among IDUs is essential for improving access to treatment and specialised follow-up care of IDUs with an infectious disease(s), the description of specific treatments of various infections is not within the scope of these guidelines.

Between July and December 2008, participants of the 2008 DRID expert meeting and other members of the EMCDDA DRID expert network were invited to give comments to a consolidated draft version of the guidelines which was also made available on Internet. The document has then been revised to take all comments received into account.

IDUs are a well-defined population and they are at very high risk of infectious diseases. For the purpose of these guidelines, an IDU is defined as any person who has ever in his/her life injected a substance for non-medical purposes at least once. IDUs who continue to inject are at very high risk of contracting a new infection and likely to benefit from frequent repeat testing. These guidelines are primarily aimed at offering a medical examination and testing to active IDUs (those who have injected at least once since their last test) and IDUs who have stopped injecting, however health care providers may apply the same procedures to other (’never-injecting’) drug users if they are at risk of infection, for example through sexual transmission through sex work or other high-risk sex, through other drug-related infection risks such as sharing of straws to snort cocaine, through tattooing etc. Similarly the guidelines may be applied to other vulnerable populations than drug users who are at risk of infections (e.g. sex workers, prisoners), although the health care provider should then check if specific issues may need to be taken into account which are not covered in these guidelines. In particular, prisoners and people in other closed settings may be specifically

vulnerable to non-voluntary testing, breaches in confidentiality; discrimination etc. and even more care should be taken to ensure that testing occurs under adequate conditions. These are described in more detail elsewhere (2).

Structure of the document

While the document may be useful for a wider audience, it is mainly intended as a practical tool for health care providers in the public and private sectors who provide primary health care to (injecting) drug users. Thus it is mainly aimed at general practitioners and family doctors, substance abuse treatment and rehabilitation centres, correctional health care facilities as well as hospital emergency departments and inpatient services. For this reason, the practical guidance on voluntary medical examination, testing and counselling for infectious diseases is covered in Part 1 of this document. Although the guidelines may also be useful in more specialised health care settings, it should be noted that the recommended tests and follow up procedures are primarily intended as guidance for personnel in primary health care settings and therefore tests and procedures that were deemed more appropriate for specialist care are not discussed in detail.

In addition, the guidelines can be used by policy-makers, drug use and HIV programme planners and coordinators and non-governmental organizations in providing services for drug users. For these groups, the recommended methods, background and rationale behind the guidelines, and their implementation in health facilities, are described in Part 2.

Part 1. Guidelines for Voluntary Medical Examination, Testing and Counselling

1.1 Background

Injecting drug users (IDUs) are through risk behaviour and underlying conditions like poor hygiene, homelessness and poverty vulnerable to a range of infectious diseases (table 1). This leads to higher morbidity and mortality in this group compared with the same age groups in the general population. As a result, IDUs are more likely than non-injectors or non-users to contract a variety of infectious diseases and, when infected, to progress to serious illness and death.

Table 1. Infectious diseases often found in injecting drug users

- HIV infection
- Hepatitis C
- Hepatitis B
- Hepatitis D
- Hepatitis A
- Skin and soft tissue infections caused by *Staphylococcus aureus* (including methicillin-resistant *Staphylococcus aureus,* MRSA) and Streptococcal infections (e.g. endocarditis, necrotising fasciitis)
- Severe systemic sepsis (e.g. infections with *Clostridium novyi, Bacillus anthracis)*
- Sexually transmitted infections (STIs) other than HIV or hepatitis (e.g. chlamydial infections, syphilis and gonorrhoea)
- Respiratory infections such as pneumonia, diphtheria and influenza
- Tuberculosis (TB)
- Wound botulism
- Tetanus
- Human T-cell lymphotropic virus (HTLV) - infections

The types of infections more common in IDUs can be divided into:

- **1.1.1 Blood-borne viral infections**

  The relationship between drug injecting and the transmission of blood-borne viral infections like HIV and hepatitis B, and C is well established (3-6). Drug-related infectious diseases such as HIV and hepatitis B and C are among the most serious health consequences of injecting drug use. Blood-borne infections may have the largest economic impact on health care systems of all consequences of drug use (7). In recent years, some European countries have reported outbreaks of hepatitis A among IDUs (8-10). Recent studies have shown that hepatitis A is spread among IDUs both by fecal-oral transmission, contaminated drugs and by use of contaminated injection equipment (10) Hepatitis D (delta hepatitis) is relative rare among the general population in most high

income countries and is mostly associated with injecting drug use. Hepatitis D can only occur in conjunction with hepatitis B infection and superinfection or coinfection with hepatitis D-virus results in more severe complications compared to infection with hepatitis B-virus alone.

Studies have also shown an association between human T-cell lymphotropic virus (HTLV) infections and drug users (11). HTLV types I and II can be transmitted through breast feeding, sexual contact, and exposure to contaminated blood through sharing of contaminated needles and equipment, with HTLV-II particularly associated with injecting drug use. While HTLV-I can cause T-cell leukemia and T-cell lymphoma, HTLV-II may be involved in paraparesis-like neurological disease.

- **1.1.2 Bacterial skin and systemic infections**

  IDUs can be exposed to a range of bacteria in various ways that can give rise to local or systemic disease (12). Sharing contaminated needles and other drug injection paraphernalia, otherwise injecting under non-sterile conditions or injecting environmentally contaminated drugs are all situations that may transmit bacteria. In addition, poor hygiene may exacerbate the risk of infection with the drug user's commensal flora.

  Studies have shown that drug users have a higher rate of nasal or skin colonization with Staphylococcus aureus than non-drug users (13). Common bacteria like *Streptococcus* or *Staphylococcus* may cause infections that vary in severity from minor skin and soft tissue infections to life-threatening disease like bacteraemia/septicaemia, necrotizing fasciitis or infection of the heart valves (endocarditis) (14). Recently, infection with methicillin resistant Staphylococcus aureus (MRSA) has been reported as a growing problem in IDUs in both Europe and in USA (18). Cutaneous abscesses and cellulitis at injection sites are a frequent problem among IDUs due to subcutaneous or intramuscular injecting (known as skin and muscle popping) (15-17). Infections caused by spore-forming bacteria such as *Clostridium novyi* , *Clostridium botulinum* , *Clostridium tetani*, *Clostridium histolyticum*, *Bacillus cereus* and *Bacillus anthracis* have in recent years emerged as a serious health problem with high mortality rates in IDUs (19-30).

  Acidulant, such as citric acid, is likely to increase the resulting tissue damage when injected subcutaneously or intramuscularly, and is thus important for the initiation of wound infections. Intravenous injection may be associated with phlebitis or thrombophlebitis, in which the vein may be infected.

  Drug use can cause significant tooth decay, tooth loss and periodontal diseases. This can be attributed to the drugs itself and the lack of a user's concern about oral hygiene combined with drug induced dry mouth and teeth grinding, as well as the craving for carbohydrates and sweets (31). In addition to causing pain and discomfort, oral abscesses and infections may be foci for more serious systemic bacterial infections.

- **1.1.3 Sexually transmitted infections**

  There is evidence supporting an association between drug use and sexually transmitted infections (STIs). In a US study of injection drug users, 60% reported a history of sexually transmitted infections (40). Besides HIV infection and hepatitis B, syphilis seems to be the most commonly notified STI among IDUs. At the same time gonorrhoea and genital chlamydia infections are seen more frequently among IDUs in many European countries (41,42). Non-injection drug use can also contribute to STI transmission, and the drug most associated with STIs is smokeable freebase (crack) cocaine, because of increases

in risky sexual behaviours and reduced awareness or concern about STIs in drug users (43). Injecting and non-injecting drug users who trade sex for drugs or who engage in unprotected sex while under the influence of drugs increase their risk of infection.

- **1.1.4 Respiratory infections**

  Injecting drug use is associated with increased risk of tuberculosis (TB) infection and disease. This is primarily due to high rates of incarceration, homelessness and poverty which are all factors that increase the risk of tuberculosis (32,33). Co-infection with HIV increases the risk of developing tuberculosis. The immunosuppression in HIV infection is associated with an increased risk of tuberculosis, and the risk of tuberculosis in IDUs varies with the duration of HIV infection (34). A study in Amsterdam showed that HIV-infection increased the risk for active tuberculosis in drug users 13-fold. The incidence of tuberculosis in HIV negative drug users was still six times higher than in the overall population of Amsterdam (34). In addition, IDUs have an increased risk of TB-reactivation and increased risk of developing multi-resistant tuberculosis (35, 36). Lower tuberculosis treatment completion rates in drug users and in prison settings (often with multi-drug resistant tuberculosis) increase the risk of multi-resistant tuberculosis in drug users (37).

  Aspiration pneumonia and pneumonia caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus* and *Klebsiella pneumoniae* are among the most common reasons for hospitalization of IDUs (38, 39).

  Some IDUs may be at higher risk of contracting influenzae due to general poor health.

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1.2. How to provide medical examination, testing and counselling to IDUs

A thorough medical examination, testing and counselling of IDUs should include all the elements listed in table 2.

Table 2. Elements included in provider-initiated routine medical examination, testing for infectious diseases in and counselling of IDUs

- Medical history and physical examination
- Pre-test counselling, informed consent and possibility to decline tests
- Testing for infections
- Post-test counselling
- Prevention counselling
- Vaccination
- Follow-up and referral routines
- Frequency of examination and testing
- Ethical considerations

1.2.1 Medical history and physical examination

A thorough anamnesis and physical examination should be carried out, including history of present or previous drug injecting and other risk behaviours and present or previous illnesses and symptoms. A thorough medical history should be recorded. Special attention should be given during the consultation to the following signs and symptoms:

- General: Weight loss and general appearance and temperature
- Skin and mucous membranes: Anaemia, jaundice, burns, scars, painless eruptions. Look for needle tracks or sores on the neck, inside of the trunk, elbows, groin area, penis, legs, feet etc. Injection sites should be inspected for local infections. Inspect the skin and the hairy surfaces for skin conditions, e.g. scabies or eczema.
- Lungs: Coughing and abnormal lung sounds could indicate pneumonia. Symptoms like fever, weight loss, night sweats and cough for more than 2 weeks may be signs of tuberculosis.
- Heart: Blood pressure, heart rate and heart rhythm irregularities, inflammation of the inner layer of the heart (endocarditis)
- Digestive system: Infections in oral cavity and dental condition. Enlarged spleen and liver.
- Genitourinary system: Amenorrhea, pregnancy, erectile dysfunction. Urethral discharge, painless chancre, swollen lymph nodes.

Depending on symptoms and clinical findings the IDU should be referred to specialist care when required. This should include a referral to a dentist for teeth extractions and more long-term dental care.

Pregnant women should be referred immediately to appropriate antenatal care services. Since many pregnant IDUs experience difficulty assessing these services, the health care provider should make contact with an antenatal clinic in the presence of the client and schedule an appointment.

1.2.2 Pre-test counselling, informed consent and possibility to decline tests

Since the objective of provider-initiated testing and counselling is timely detection of HIV and other infections and adequate access to health care services, pre-test information can be simplified and individual risk assessment and risk reduction measures can be covered during post-test sessions. Pre-test information can best be provided individually but if this is not possible group sessions may be an alternative. Informed consent should, however, always be given individually in private between the client and the health care provider and should be recorded by the health care provider in the patients medical file or elsewhere. There should always be a real possibility for the IDU to decline one or more tests without fear for coercion or negative consequences. This is especially important in settings where the IDU may perceive a reduced freedom of decision, e.g. in prisons and other closed settings.

This can for example be aided by putting the following information in writing on an informed consent form and reading it up for the client:

“You are completely free to decline some or all tests and declining some or all tests will not have any negative consequences for you. Please could you tick any tests you do not want to have and sign that you have understood that you are going to be tested and that you are free to decline these tests.”

Use of this document in closed setting (prisons and some types of treatment like compulsory residential rehabilitation) requires additional training and articulation of the principles of confidentiality, voluntariness and counselling.

The provider must ensure that the IDU is in a satisfactory condition with regard to intoxication before making decisions about testing for HIV and other infections.

Information for informed consent should as a minimum include the following, either orally or, preferably, both orally and in written form;

- Reason why testing for HIV and other infections is recommended
- What tests are included in the panel of tests and that the client can decline them. The client should be given the possibility to decline some or all tests.
- The clinical benefits of testing with regard to treatment possibilities.
- Tests results will be treated confidentially and will not be shared with anyone without permission of the client
- Declining HIV or other specific tests will not affect the client's access to services
- A positive HIV test or other tests may make it necessary to inform partners or others that they may have been exposed to an infectious disease (contact tracing). In some countries this may be mandatory and the client must be informed of the existence of any such legislation.

Whether or not a client declines an HIV test or other recommended tests, this decision should be documented in the medical record. In some situations documented oral communications may be regarded as adequate in obtaining informed consent, however as described above preferably informed consent should be in written form.

The health care provider should discuss with the IDU how he/she wishes to receive the test results prior to testing for HIV and other infections.

1.2.3 Testing for infections

A medical examination of IDUs should always include voluntary testing for various infectious diseases. What test to perform depends on different factors like the IDU's symptoms or signs and the length of time of substance abuse. In addition, the local epidemiological situation among drug users for the various diseases should be considered when choosing which tests to perform. Supplementary tests may be needed depending on clinical signs or symptoms.

Access to treatment of the various infections identified by provider-initiated testing and counselling should be ensured prior to testing. Likewise, efforts must be made to ensure that a supportive social and legal framework is in place to minimize potential risks of negative effects of testing like discrimination and stigmatisation. The provider should also ensure that mechanisms are in place for referral to care and support services provided by community-based organisations and civil society groups. For more detail see (2,44)

1.2.3.1 Basic recommended tests

A panel of basic recommended test is shown in table 3. These should be included in a standard offer to all IDUs. The need for retesting IDUs who have previously been diagnosed with or are known to have chronic infections like HIV infection, hepatitis B or hepatitis C infections should be considered in each case.

Table 3. Basic panel of tests recommended in provider-initiated routine medical examination

- Serology testing for :
  - HIV
  - hepatitis B
  - hepatitis C
  - hepatitis D (if evidence of chronic or recent hepatitis B)
  - hepatitis A
  - syphilis
- Other general blood tests
  - ESR or CRP (C-Reactive Protein)
  - haemoglobin
  - White blood cell count
- Swab for culture from abscesses and skin lesions
- Tests for biochemical analysis
  - ALAT (alanine aminotransferase)
  - ASAT (aspartate aminotransferase)
  - Bilrubin
- Tests for tuberculosis disease or latent tuberculosis (see comments below)

Comments to the various tests:

HIV-infection
The standard screening test for HIV is a combined HIV-1/2 antibody enzyme immunoassay (ELISA). The 4th generation HIV screening tests detect anti–HIV and p24 antigen. A diagnosis of HIV infection cannot be based on a single positive ELISA test alone. A positive ELISA- test should therefore always be confirmed by a Western blot test in the same sample and with ELISA in a subsequent sample collected separately.
Detection of the virus during the window period is possible using nucleic acid amplification tests (NAAT), like polymerase chain reaction (PCR), however this will normally not be necessary. Modern HIV tests have a high specificity and sensitivity and the window period (period after infection where HIV is not yet detected) is normally no more than 1-2 weeks.

Rapid HIV tests are available in most countries. Using these tests is often referred to as point of care testing (POCT). These tests have the advantage of offering a result from either a fingerprick or mouth swab sample within minutes. The tests, however, have reduced specificity and reduced sensitivity versus current fourth generation antibody enzyme immunoassay test. If using such rapid tests, all positive results must be confirmed by serological tests.

When to refer: IDUs with a confirmed positive HIV-test should be referred to a specialised clinic. The care provider should try to ensure with the specialist colleague that the client will have an intake appointment within 1-2 weeks from receiving the test result.

Hepatitis A
Hepatitis A serology should include testing for :

- Hepatitis A IgG antibody (anti-HAV IgG)
- Hepatitis A IgM antibody (anti-HAV IgM) – only in acute infections

IgM antibody normally develops early in the infection and peaks about 1 to 2 weeks after the development of jaundice. It diminishes within several weeks, followed by the development of protective IgG antibody, which persists usually for life. Thus, anti-HAV IgM is a marker of acute infection, whereas anti-HAV IgG merely indicates previous exposure to HAV and immunity to recurrent infection. Presence of anti-HAV IgG may also indicate previous vaccination. Anti-HAV IgM should only be used in case of suspected acute hepatitis.

Hepatitis B
The diagnosis and stage of infection can be determined from the serology profile. The following tests should be included in the panel of hepatitis B tests:

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B surface antibody (anti-HBs)
- Hepatitis B core antibody (anti-HBc total)
- Hepatitis B core IgM antibody (anti-HBc IgM)

Interpretation of the tests may be difficult and it is not within the scope of these guidelines. It is recommended to consult a specialist in case of uncertainty of the test results. The window period is 4 to 6 months.

When to refer: IDUs diagnosed with an acute or chronic hepatitis B (HBsAg positive > 6 months) should be referred to a specialised clinic. Liver function status is important in the evaluation of the need for medication therapy.

Hepatitis C
The standard screening test is the hepatitis C antibody (anti-HCV) ELISA test. A positive test should be confirmed by using nucleic acid amplification test (PCR-test), or if this is negative with a recombinant immunoblot assay, RIBA. A positive antibody test alone is evidence of previous exposure to the hepatitis C virus, but gives no indication of whether the virus is still present. The window period is 4 to 6 months.

When to refer: All IDUs with a positive antibody test and a positive PCR should be followed up by a repeated test after 3-6 months, and if the test is still positive, it should be evaluated if they are candidates for eradication therapy. Liver function status is important in the evaluation of the need for medication therapy.

Specific guidelines exist for the treatment of hepatitis C both national and at European level (45). It is important to note that although some guidelines still exclude active IDUs or IDUs on opioid substitution treatment from viral treatment study results indicate that IDUs can be successfully treated and may avoid reinfection (45,46)

Hepatitis D
Hepatitis D should be considered in individuals who are HBsAg positive or who have evidence of recent HBV infection. The diagnosis of superinfection or co-infection with hepatitis D-virus is made following serologic tests for the virus (total anti-HDV antibodies).

Syphilis
The diagnosis of syphilis in persons with early infectious lesions (chancre) is based on clinical examination and demonstration of *T. pallidum* by dark field microscopy, of treponema specific DNA by PCR or DFA-TP test (direct fluorescent antibody test for *T. pallidum*). Serological tests aid the diagnosis and are also used for screening in

asymptomatic individuals. An important principle of syphilis serology is the detection of treponemal antibody by a screening test, followed by another reactive screening test for confirmation.
The immune response involves production of specific treponemal antibodies as well as non-specific antibodies. Various serological techniques allow detection one or the other according to the particular objectives of screening. Various methods combined enable detecting early infections, as well as forms of the infection that were acquired earlier and that have either been treated adequately or have remained untreated. Serology may remain positive for life in persons who have previously contracted syphilis and been adequately treated.

Most laboratories now use specific enzyme immunoassays (ELISA-tests) for screening. These are newer blood tests that check for treponema-specific IgG and IgM antibodies. A positive ELISA test should be followed up by other serological tests such as the:

- TPHA-test (Treponema Pallidum Haemagglutination test) or often its modified version with higher specificity and sensitivity, the TPPA –test (Treponema Pallidum particle agglutination test), both detecting specific antibodies and having high enough sensitivity and specificity to be used either for screening or confirmation, the more for monitoring the change in antibody levels following adequate therapy.

At the same time providers often use the

- VDRL-test (Venereal disease research laboratory test) or the
- RPR-test (Rapid plasma reagin test), (both detecting non-specific antibodies), because of their valuable ability to quantify the immunoreaction, or the
- FTA-abs - test (Fluorescent treponemal antibody absorption test), a gold standard in earlier days that can nowadays be replaced by immunoblotting, and is probably best reserved for reconfirming discrepant results

IDUs, a high-risk group for STIs, need to be screened by 1) EIA methods capable of detecting specific antibodies early on, from 10-14 days following infection, as well as suitable for screening asymptomatic patients and by 2) equivalent methods such as TPHA/ TPPA (also able to quantify specific antibodies) as reactive confirmatory methods. The use of non-specific methods such as the RPR/ VDRL (otherwise ideal methods for screening) in case of IDUs is questionable, because of their possible co-infection with HIV.

Interpretation of serologic tests for syphilis may be difficult and it is not within the scope of these guidelines. It is recommended to consult a microbiologist or a venereologist and to refer the patient to a STI centre in case of uncertainty of the test results.

Cultures from abscesses and other lesions
A bacteriological test from pus, tissue, or other material properly obtained from an abscess or other lesions should be taken and sent to the laboratory for examination using standard procedures. Transport medium should be used whenever appropriate. Abscess specimen should always be cultured for anaerobes and this should be clearly stated on the request form. For anaerobic culture biopsy or needle aspirates are the specimen of choice, while anaerobic swabs are the least desirable. Generally, any specimen should not be stored for more than 24 hrs. Specimens for anaerobic culture should be stored at room temperature, other specimens at 4°C.

Tests for biochemical analysis
Optional liver function tests recommended for possible liver function damage are:

- ALAT (alanine aminotransferase)
- ASAT (aspartate aminotransferase)
- Bilirubin

ALAT is an enzyme present in hepatocytes which rises dramatically in acute liver damage, such as viral hepatitis. ASAT is similar to ALAT in that it is another enzyme associated with liver parenchymal cells. It is raised in acute liver damage, but is not specific only to the liver. The ratio of ASAT to ALAT is sometimes useful in differentiating between causes of liver damage. Bilirubin is a product that results from the breakdown of hemoglobin. Total and direct serum bilirubin are usually measured to screen for or to monitor liver or gallbladder problems.

Tests for tuberculosis

Methods to use in screening for latent tuberculosis or current tuberculosis disease depend on the epidemiological situation in the country/setting as well as among IDUs with regard to tuberculosis and HIV infection. In addition, screening methods depends on presence of any symptoms of tuberculosis disease. Ideally, all IDUs should be screened for active tuberculosis disease or for latent TB infection.

The following methods should be used for all European countries and in IDUs with symptoms or signs of tuberculosis disease[1]:

Sputum smear microscopy

Sputum specimens should be obtained for microscopic examination from all IDUs suspected of having pulmonary TB. Microbiological diagnosis is confirmed by culturing M. tuberculosis (or, under appropriate circumstances, by identifying specific nucleic acid sequences in a clinical specimen) from any suspected site of disease. However, in many settings where resources are limited, neither culture nor rapid amplification methods are currently available or feasible. In such circumstances, the diagnosis of TB may also be confirmed by the presence of acid-fast bacilli (AFB) in sputum smear examination. Repeated sputum smear microscopy may diagnose pulmonary TB in up to two-thirds of active cases. In nearly all clinical circumstances in settings of high TB prevalence, identification of AFB by microscopic examination is highly specific for the M. tuberculosis complex.

The optimum number of sputum specimens to establish a diagnosis has been evaluated. The first specimen was found positive in 83–87% of all patients in whom AFB are ultimately detected; the second specimen was positive in an additional 10–12% and the third specimen in a further 3–5%. On this basis, WHO recommends the microscopic examination of two sputum specimens (formerly three).[2] Because the yield of AFB appears to be greatest from early morning (overnight) specimens, WHO further recommends that at least one specimen should be obtained from an early morning collection.

The procedures for collecting sputum involve the production of droplets that are highly infectious if the patient has untreated pulmonary TB. Sputum collection should therefore be organized in areas with good ventilation or, if not available, outside the building . Sputum smear specimens should be examined by microscopy immediately but no later than 5 to 7 days after they have been collected.

Culture

Sputum smear microscopy is the first bacteriological diagnostic test of choice however, where adequate and quality-assured laboratory facilities are available, the evaluation of patients should also include culture. Culture adds extra cost and complexity but greatly increases the sensitivity and specificity of diagnosis, resulting in better case detection. Although the results of culture may

[1] Initially, the IDUs should be applied a questionnaire and have a clinical examination to identify the presence of signs and symptoms.

[2] A reduction in the number of specimens examined for screening TB suspects from three to two was recommended by WHO and endorsed by the Strategic Technical and Advisory Group for Tuberculosis in June 2007.

not be available until after a decision to begin treatment has been made, treatment may be stopped subsequently if cultures from a reliable laboratory are negative and if the patient has not responded clinically to treatment and the clinician has sought other evidence in pursuing the differential diagnosis.

Chest X-ray
As no chest radiographic pattern is absolutely specific for pulmonary TB, the diagnosis of smear-negative TB is always presumptive and should be based on other clinical and epidemiological information, including failure to respond to a course of broad-spectrum antibiotics and exclusion of other pathology. Reliance on chest radiography as the only diagnostic test for TB results in either overdiagnosis of TB or missed diagnoses of TB and other diseases and is therefore not recommended. Radiographic examination, however, is most useful when applied as part of a systematic approach to evaluate patients whose symptoms and/or findings suggest TB but whose sputum smears are negative. The use of chest radiography to diagnose pulmonary TB may be compromised by poor film quality, low specificity and difficulties with interpretation.

HIV infection diminishes the reliability of chest radiographs for the diagnosis of pulmonary TB because the disease commonly presents with an atypical pattern. Furthermore, the chest radiograph may be normal in a proportion of HIV-infected patients with sputum culture-positive TB (observed in up to 14% of such cases). Chest radiography remains an important adjunct to the diagnosis of smear-negative pulmonary TB in people living with HIV.

Fluoroscopy results are not acceptable as documented evidence of pulmonary TB.

Sputum same microscopy and culture require skill and experience by the health care provider. If health care providers who are doing the medical examination, testing and counselling for infectious diseases in IDUs do not have the necessary skill or the necessary safety precautions are not in place, tuberculosis screening should not be a part of the basic screening test and all IDUs should be referred for tuberculosis screening to competent health institutions.

The screening procedures in IDUs with no signs or symptoms of tuberculosis disease can be limited to screening for latent tuberculosis. The screening methods for latent tuberculosis in asymptomatic IDUs include:

The tuberculin skin test (TST)
This skin test has traditionally been used to diagnose latent infection with *Mycobacterium tuberculosis*. The skin test has however several limitations, particularly poor specificity because of cross-reactivity with the antigens of the BCG vaccine, as well as many of the nontuberculous mycobacteria. In addition, false-negative TST is more likely to occur in IDUs because of the high rate of anergy that occurs in this population, most commonly found in HIV-seropositive IDUs. For this reason less emphasis should be put on TST results in IDUs in areas where HIV prevalence in this group is high, and more on potential exposure to tuberculosis as well as signs and symptoms.

Blood tests
IFN-gamma release assays (IGRA tests) have in recent years been proposed as alternatives to the TST. The potential for false-positive tests due to cross-reactivity is significantly lower with IGRAs than with the TST. In addition, the use of this test in IDUs is more likely to diagnose latent tuberculosis infection compared with traditional TSTs (48). However, IGRAs have as yet limited potential in high burden TB and HIV settings

When to refer: IDUs with symptoms or signs of active pulmonary tuberculosis as well as IDUs with positive bacteriological results (sputum smear microscopy or culture) or X-ray finding consistent with suspected tuberculosis disease should immediately be referred to a tuberculosis clinic or other specialists for further examination, diagnosis and treatment

Asymptomatic IDUs with a positive TST or IGRA test, in which tuberculosis as a disease is excluded should be considered for tuberculosis preventive therapy and referred to a specialist. Anergic HIV-seropositive persons who come from a population with a high prevalence of tuberculosis infection should also be considered for preventive therapy and therefore referred to a specialist.

1.2.3.2 Additional recommended tests

In addition to the recommended basic panel of tests, testing for other blood and sexually transmitted infections may be indicated depending on the local epidemiological situation and the condition of the individual IDU. Such tests should be carried out in both sexes in case of IDUs reporting commercial sex work. Studies have shown that the presence of a sexually transmitted disease may facilitate transmission of HIV (49).

Table 4. Additional panel of tests recommended in provider-initiated routine medical examination

- Serology for HTLV-infections
- Swab or urine testing for genital chlamydial infections
- Swab or urine testing for gonorrhoea

Comments to the various tests:

Genital chlamydial infections
Asymptomatic chlamydial infection is common among both men and women, and to detect chlamydial infections healthcare providers frequently rely on screening tests. Nucleic acid amplification tests (NAAT) for *Chlamydia trachomatis* are currently the preferred tests for genital chlamydial infections and are widely used. The advantage of these tests is that they are generally more sensitive and specific than a conventional culture and can therefore identify more positive specimens. Recommended specimens used for NAATs are first catch urine in men and swab of the vaginal introitus or urine in women.

Gonorrhoea
IDUs presenting with symptoms of urethritis should have a swab test of secretion or discharge from the infected area such as the cervix, urethra, glans of penis, anus or throat. This specimen should be both cultured and tested for antibiotic susceptibility. Nucleic acid amplification tests (NAAT), like PCR are available for testing on swabs as well as female and male urine. Some NAATs have the potential to cross-react with non-gonococcal *Neisseria* and related organisms that are commonly found in the throat.

Since so many gonorrhoeal infections are symptomatic, screening for gonorrhoea in asymptomatic individuals is rarely indicated. If the local epidemiological situation among IDUs (e.g. an outbreak) should favour screening of asymptomatic individuals, endocervical swabs or male urethral swabs should be collected and cultured. Alternatively, NAAT testing on urine sample could if available be used.

HTLV-infection
HTLV-infections are diagnosed using combined HTLV-1/HTLV-II antibody ELISA- tests and they are confirmed by a Western blot test where one can decide if it is a HTLV-I or HTLV-II virus, the later one being frequently positive in IDUs.

1.2.4 Post-test counselling

Post-test counselling is an important and integral part of the testing process. All clients must be counselled when the test results are given, regardless of the outcome of the tests. The results should be given in person by a health care provider or other trained personnel. Ideally, the result should be given by the same health care provider who initiated testing and counselling. If for some reason the client does not show up to his/her follow-up consultation, the health care provider should make every reasonable attempt to ensure that he/she receives and understand the test results in a confidential manner. All available channels should be considered in trying to contact the client, involving social services. Result of tests should not be given via any third party, including relatives or other clinical teams unless the IDU have specifically agreed to this.

Written information about test results should never be sent to the client tested in case he/she does not show up to get the results. The client has a right to decide not to know the results of the various tests.

The focus of post-test counselling should be on positive results. In particular, a client with a positive HIV test result should be given psychosocial support to enable him/her to cope with the emotional impact of the test result. Elements to be included in post-test counselling are:

- Ensure that the client understands the results
- Ensure that in a case of hepatitis, syphilis or tuberculosis, the client understands the difference between acute infection, chronic infection and past infection, possible longer term consequences and whether he/she can transmit the disease to others
- Describe follow-up services available in health care facilities and in the community, with special attention to available treatment and care and support services including non-governmental support groups
- Describe in detail how to prevent further transmission of the various diagnosed diseases
- Provide information on other health issues related to the test results such as nutrition
- Encourage and offer referral for testing and counselling of recent sexual partners or if relevant family members. If possible, in the follow-up process the client should be offered support for disclosure and couples counselling. Testing, treatment and vaccination of partners and children may be necessary
- Provide information on the possibility of post-exposure prophylaxis with regard to relevant infections, e.g. HIV infection and hepatitis B.
- Plan follow-up and referral to specialised health services or clinics (within a short period, arrange with those services that the client is scheduled for an appointment soon).
- Briefly test if the main provided information has been understood by asking the client to repeat the main points discussed.
- Give the client a clearly written (or pre-existing) memo with a summary of those points and any relevant contact details and provide the possibility to re-contact you (the health care provider) in the case of doubts or new questions.

Individuals who test HIV negative should be offered advice around risk reduction and behaviour changes including discussion relating to post-exposure prophylaxis (PEP) for HIV. The need for a repeat HIV test should also be considered if still within the window period. A repeat HIV test is recommended at three months following a specific exposure.

1.2.5. Prevention counselling

During the examination and testing process the client should be given individual general information on how to reduce the risk of acquiring drug related infections and sexually transmitted infections. Ideally, this information should be provided at the follow-up visit when the results of tests are given. Some IDUs, however, will not turn up to the follow-up visit and information, or part of it, is often best (also) given within the pre-test discussion. Client-centred prevention counselling involves tailoring a discussion of risk reduction to the patient's individual situation.

Reducing or stopping the use of drugs is the safest way to prevent drug related infectious diseases. This goal, however, may not always be possible and the counselling should include information on how then to reduce the risk of acquiring infections (table 5).

Table 5. Information with regard to the prevention of blood-borne and bacterial infections in injecting drug users

- Always use a new (sterile) needle and syringe each and every time injecting. Syringes and needles are not designed to be used more than once
- Never share needle, syringe, water, cooker, filter or cotton with anyone
- Never reuse needle, syringe, water, cooker, filter or cotton
- If you are sometimes forced to reusing or sharing needles and/or or sharing syringes, clean them thoroughly each time by
    1) cleaning the needle and syringe (twice) with cold running tap water to remove blood, blood clots, and other organic material,
    2) disinfecting with bleach (twice): 30 seconds exposure to undiluted commercially available household bleach is the best method to eradicate viable HIV-1 virus (50).
    3) rinsing with clean running tap water (twice) to remove the bleach

    or

    4) cook the needle and syringe for 10 min after first cleaning them thoroughly with running tap water
- If reusing the cooker, clean it thoroughly every time by cooking in boiling water for 10 minutes, or clean it with isopropyl alcohol (alcohol prep/swab)
- Use clean water to prepare your injection, by:
    - cooking water for 5 min in a clean pot
    - using cold running tap water
    - using a newly opened bottle of mineral water or a soda pop / fizzy drink
- Improve safer injection practices by:
    - washing hands before and after injecting (especially when helping others)
    - boiling the drug if possible
    - cleaning the skin before injecting with alcohol or any other disinfectant solution
    - avoiding the use of dangerous injection sites like the neck and the groin
    - avoiding subcutaneous or intramuscular injections
    - cleaning all materials used, including the table surface, with disinfectant
- Use (if available) treatment facilities and harm reduction measures like :
    - needle exchange programmes and other sources of sterile injecting materials (e.g. pharmacies)) – ask for enough equipment to avoid reuse
    - drug assisted rehabilitation or opioid substitution programmes (e.g. methadone programmes or other drug treatment services)
    - medically supervised injection facilities
- Try to reduce or stop using drugs. Replace injecting practices with non-injecting practices such as smoking and sniffing and if possible reduce the frequency of injecting
- Avoid unprotected sex – always use a condom – and avoid or reduce sex with multiple partners
- Improve personal hygiene including oral cleanliness

The provider should be familiar with local community resources available. During the consultation, the client should be given any available written information on preventive measures (folders, leaflets, brochures).

1.2.6 Vaccination

Vaccination against drug related infections should if available be offered to the clients. Which vaccines to offer depends on the country's vaccination programme (including potential specific programmes for IDUs), on any documentation regarding previous vaccination or results of tests taken at the first consultation. Self-reported vaccination status is usually not reliable and decision on what vaccines to offer should not be based on self-reporting. A plan for provision of additional or booster doses should be made in consultation with the client. Recommended vaccines specific for IDUs are shown in table 6.

Table 6. Recommended vaccinations for injecting drug users

- Hepatitis A +B combination vaccine (or separate hepatitis A and hepatitis B vaccines)
- Diphtheria / Tetanus vaccine (every 5-10 years)
- Influenzae vaccine (seasonally)
- Pneumococcal vaccine (esp. if HIV positive and > 50 years of age)

Hepatitis A + B combination vaccines or separate hepatitis B vaccine can be administered as a 3-dose schedule at 0, 1 and 6 months or as a 4-dose schedule administered on days 0, 7 and 21 followed by a booster dose at month 12. The rate of non- or low responders to the vaccine is higher in drug users, especially when infected with HIV, than in the general population. It is therefore recommended to test for antibody to hepatitis B surface antigen (anti-HBs) 1–2 months after completing the third dose of the vaccine series. In case of low antibody titre, additional boosterdose(s) may be needed.

BCG-vaccination against tuberculosis should be considered depending on the country's BCG vaccination programme policy.

Human papillomavirus (HPV) vaccine targets certain sexually transmitted strains of human papillomavirus associated with the development of cervical cancer. HPV strains covered by the vaccine are normally acquired soon after onset of sexual activity, and HPV vaccine should ideally be given to girls at the age just before sexual debut. HPV vaccination should be considered in female IDUs depending on the country's HPV vaccination programme policy.

In general, depending on the cost of the vaccine, it may be more cost-effective to provide a standard vaccination offer to IDUs rather than to let the decision depend on serological results or self-report, and given the difficulty of following up IDUs for follow-up vaccination (51).

Vaccinations should in general be avoided during pregnancy.

1.2.7 Follow-up, treatment and referral routines

Any diagnosed localised skin infections or other minor infections, pneumonia or sexually transmitted diseases (such as gonorrhoea or genital chlamydial infections) should be treated during the routine examination process.

Conditions which need specialist follow-up and care (like HIV infection, tuberculosis, hepatitis and syphilis) should be referred to competent clinics or specialist services. Patient referral works best if the health care provider makes contact with the specialist in the presence of the client and schedules an appointment. Where possible, primary health services and specialist care should be located near each other and/or be linked through case-based management where primary service providers and different specialists (e.g. drug treatment and infectious diseases treatment) work together and keep each other informed regarding the patient.

1.2.8 Frequency of examination and testing

The recommended frequency of routine medical examination, testing and counselling in IDUs depends on various factors like the local epidemiological situation of HIV infection or other infections, and availability of human and financial resources. In addition, frequency with which a client should be re-examined and re-tested depends on the individual risk of exposure to infectious agents. For individuals with ongoing injecting drug use or ongoing high-risk sex (e.g. sex work or male-to-male sex with multiple partners) this risk is usually very high (it should be noted that a client may intentionally or unintentionally under-report the frequency of risk behaviours) and frequent re-examination and re-testing are recommended, to reduce the period of undiagnosed carrier-ship after infection and thus the risk of infecting others. For practical reasons and taking into account the mentioned considerations it is recommended to offer examination and testing to IDUs at least once every 6-12 months.

1.2.9 Ethical considerations

(see also 1.2.2 ‘Pre-test counselling, informed consent and possibility to opt-out’)

The provider must ensure that the drug user is in a satisfactory condition with regard to intoxication before making decisions about testing for HIV and other infections.

Patients should receive adequate information enabling them to make a personal and voluntary decision whether or not to decline one or all the proposed tests without coercion.

Confidentiality must be strongly enforced with regard to tests results and information obtained during the examination. This must however not prevent the provider to document findings in the patient’s medical record. It is recommended that the offer of an HIV test is recorded explicitly as well as that informed consent and pre and post-test counselling have taken place and in case of refusal the reasons for it. Such medical records should only be accessible to those (other health care providers) who have a direct role in the outgoing management of the patient. Administrative personnel at the institutions (e.g. prisons) should never have access to a patient’s health records.

It is the health care provider’s responsibility to ensure that the examination and testing will not result in any harm or negative effects to the IDU. This includes ensuring that the police or other authorities do not keep the examination / testing site under surveillance. In situations where these conditions are likely not to be met it is recommended to refrain from provider initiated testing and to make voluntary counselling and testing available on the individual’s request, while making sure that the individuals are well aware of this possibility.

Part 2. Background and implementation of the guidelines

2.1 Existing guidelines and need for separate guidelines for IDUs

The main existing guidelines on HIV-testing and IDUs are:

- *Guidance on provider-initiated HIV testing and counselling in health facilities (WHO/UNAIDS, 2007)* (52).

  This document offers on basic operational guidance on provider-initiated HIV testing and counselling in health facilities on a global basis. The document is consistent with WHO policy options developed in 2003 and with a 2004 UNAIDS/WHO Policy statement on HIV testing (53), although it states that for highly vulnerable populations an opt-in approach may merit consideration. The guideline addresses testing of the IDUs at needle and syringe access and other harm reduction interventions', including referral to opioid substitution therapy. It recommends testing higher risk individuals every 6-12 months, depending on the epidemic situation. The guidelines, however, have no specific section on testing in IDUs.

- *Guidance on testing and counselling for HIV in settings attended by people who inject drugs (WHO /UNDOC, 2009)* (54)

  This document offers basic operational guidance on HIV testing and counselling in settings attended by people who inject drugs. HIV testing is recommended for all patients who clinical presentation might result from underlying HIV infection and as a standard part of medical care for all patients attending specialized health care facilities for people who inject drugs. The document recommends a proactive approach to HIV testing and counselling by care providers in these settings. It includes simplified pre-test information consistent with WHO and UNAIDS policy. Individuals offered an HIV test must specifically accept or decline the test after discussion of their right to decline, the risks and benefits of HIV testing and disclosure, and the social support available.

- *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings" (CDC, 2006)* (55)

  The objectives of these recommendations are to increase HIV screening of patients in health-care settings including substance abuse treatment clinics and correctional health-care facilities. The recommendations do not apply to non-clinical outreach programmes or community centres. In these guidelines HIV screening is recommended for all individuals aged 13 to 64 in all health-care settings following the patient's notification that the testing would performed unless the patient declines (opt-out screening). It is recommended that persons at high risk for HIV infection (like IDUs) should be screened for HIV at least annually. More controversially, the document states that separate written consent for HIV testing should not be required and that prevention counselling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings. Although these recommendations mentioned IDUs as a high risk group that should be offered annual HIV-testing, there is no specific information (section) about testing IDUs.

- *Policy and Programming Guide for HIV/AIDS Prevention and Care Among Injecting Drug Users (WHO, 2005)* (56)

  This guide concentrates on distilling the principles from policies and programmes that have worked well in responding to HIV/AIDS epidemics among IDUs. It emphasizes that the issues involved in developing and sustaining effective responses to HIV/AIDS and injecting drug use are complex, and every society and community is different. How these

principles are expressed in a specific society depends on the characteristics of that society. The guide aims at helping people in applying principles that proved to be effective in dealing with HIV/AIDS and injecting drug use. HIV testing and counselling is mentioned as an integral part of a comprehensive prevention approach, links to other interventions are emphasized, but little detail is provided on issues around HIV testing in IDUs

- *Policy guidelines for collaborative TB and HIV services for injecting and other drug users- an integrated approach (WHO, 2008) (57)*

  WHO has in cooperation with UN Office on Drugs and Crime(UNODC) and UNAIDS, and in consultation with a group of technical experts, published policy guidelines for collaborative HIV and tuberculosis services for injecting users and other drug users in general. The aim of this guidance is to provide a strategic approach to reducing tuberculosis and HIV-related morbidity and mortality among drug users and their communities, in a way that promotes holistic and person centred services

In addition, UNODC/WHO/UNAIDS have developed specific guidance on “HIV testing and counselling for people who use drugs” and on “HIV testing and counselling in prisons and other closed settings”. These background papers which will serve as the basis of a policy statement on HIV testing and counselling propose that an opt-in approach to HIV testing should be considered for these most-at-risk populations, given the risks of coercion, discrimination or other negative consequences and confidentiality breaches (2,44).

Similar to IDUs, men who have sex with men (MSM) are a population most at risk for acquiring HIV in addition to other sexually transmitted infections. In 2006, CDC published the document “Sexually transmitted disease treatment guidelines 2006” (58). In this document, routine laboratory screening for common sexually transmitted diseases is recommended for all sexually active MSM. These tests are recommended to be performed at least annually for sexually active MSM, including men with or without established HIV infection. Similar recommendations for routine testing in MSM have been published in Australia, and Norway (59). In UK, national guidelines for HIV testing were published in 2008 by the British HIV Association. These guidelines are intended to facilitate an increase in HIV testing in all health care settings in order to reduce the proportion of individuals with undiagnosed HIV infection. The guidelines stresses that HIV testing should remain voluntary and confidential, and that universal opt-out testing in all settings may not be the most feasible approach but supports the use of opt-out testing in certain situations (60).

IDUs have specific needs and encounter specific challenges for testing, care and treatment, warranting specific approaches for the group. Lack of testing uptake in IDUs may have serious consequences for the prevention of further spread of the infections, as well as for the early treatment and care for those infected, and the quality of diagnostic surveillance data regarding this group. Efficient testing approaches needs to include testing combining with low-threshold drug services, including opioid substitution treatment, care and antiretroviral treatment. Most existing guidelines on HIV-testing do not cover the special needs of IDUs satisfactorily and there is a lack of guidance on other infections, many of which (e.g. viral hepatitis) are highly prevalent among IDUs. It appeared therefore timely that separate guidelines for testing HIV and other infections in IDUs were developed. These guidelines should integrate HIV testing into a standard provider-initiated offer to IDUs of voluntary and confidential medical examination, that also includes testing for other infections, counselling and preventive measures like vaccination as well as referral to specialist services. In addition, improving testing uptake for HIV and other drug related infections will improve the general health situation of the individual IDU and it is likely to lower the risk of secondary spread from infected individuals.

2.2 Recommendations at policy level to create and ensure the necessary conditions for provider-initiated testing for IDUs (adapted from references 44 and 56)

A number of important recommendations can be drawn from the general guidelines mentioned above and draft documents currently being developed by UNODC/WHO/UNAIDS that are relevant for the present document and should be considered by national and local policymakers when considering implementation of provider initiated testing for IDUs. These are:

- Implementation must include measures to prevent compulsory testing and unauthorised disclosure of results
- Implementation should be accompanied by the comprehensive package of prevention and care for IDUs (e.g. NSP, OST, ART etc.)
- If ART is not available there must be a reasonable expectation that ART is or will become available for all who need it
- A supportive social, policy and legal framework must be in place to maximise effects and minimise harms
- Training should be provided for staff and supervision to uphold ethical standards
- Additional discussion may be needed on the right to decline testing
- Referral mechanisms should be reviewed and optimised
- If conditions for provider initiated approaches are not met testing should be made available for highly vulnerable populations on the individual's request
- Most at risk populations or their representatives (e.g. NGO's) should be involved in protocol development and monitoring
- Before implementing provider initiated testing countries should develop clear plans and pilot projects to evaluate and address possible coercion, discrimination or other negative consequences of disclosure of HIV status

2.3 Provider-initiated voluntary medical examination, testing and counselling

These guidelines recommend a provider-initiated approach to voluntary (informed-consent based) and confidential medical examination, testing and counselling of IDUs provided the conditions for safe and ethical implementation are met. Where this is not the case (e.g. this may apply to prisons or other closed settings) testing should be limited to making voluntary counselling and testing available on the individuals request.

Provider-initiated

Provider-initiated means that examination, testing and counselling is recommended by a health care provider as a standard component of medical care offered to persons attending the facilities. The person involved may attend the facility for various reasons, for instance specific medical or other health problems, rehabilitation, use of harm reduction services or because of social and economic needs. The objective of provider-initiated testing is to timely identify specific infections in persons at a high risk of contracting HIV and other infections. In addition, suspected infections can be confirmed in individuals with specific signs or symptoms. This strategy is not new in relation to injecting drug users while testing for HIV. Ever since injecting drug users were recognized as a most-at-risk population for HIV in the

early 1980s, national health authorities have actively promoted provider initiated voluntary HIV testing in various settings where IDUs are being contacted by health or social services (like prisons, health or rehabilitation centres) and through harm reduction programmes or different types of outreach. For many years IDUs have been regarded as a target group for such opportunistic testing approaches since in contrast to other most-at-risk populations (e.g. MSM) IDUs have been seen as a harder to reach group within the traditional health systems. Many European countries have introduced provider-initiated HIV testing and counselling in prenatal care. Such programs have resulted in considerable increases in HIV testing uptake in Europe and elsewhere, including the United States, the United Kingdom, Norway and Canada (61).

Opt-out versus opt-in approaches

Different guidelines have taken different standpoints regarding 'opt-in' or 'opt-out' strategies. Published literature suggests that the testing uptake is increased where universal routine ('opt-out') strategies have been adopted (62,63) An opt-out testing strategy stresses that testing is a standard part of the medical care and that the individual must specifically decline testing for some or all infective agents following pre-test counselling. It must be emphasized that in an opt-out approach no tests should be done against a person's wishes or without his/her knowledge. Moreover, when (written) informed consent and pre-test counselling are included as obligatory elements of the testing procedure and when the client is, as part of a standard procedure, asked to indicate which tests he or she wishes to decline the risk of coercion or misuse of testing will be near to that risk in provider initiated opt-in approaches where the client is asked to explicitly agree that he/she wishes to take the tests.

In these guidelines we have chosen to refrain from using 'opt-in' or 'opt-out' as during their development it has became apparent that some confusion surrounds these terms. Even when explicitly coupling them with informed consent and counselling, opt-out approaches are sometimes understood as testing without informed consent.

In a Policy Statement of HIV testing published by the WHO and the UNAIDS in 2004 four types of HIV testing are clearly distinguished (53).

- Voluntary counselling and testing (VCT) based on client's initiative
- Diagnostic HIV testing (when there are symptoms or following exposure)
- Routine offer of HIV testing by health care providers
- Mandatory HIV testing

Of these four types of testing approaches, all but mandatory HIV testing is recommended for testing in IDUs. EMCDDA, like UNODC, WHO and UNAIDS, do not support compulsory or mandatory testing of individuals on public health grounds.

Populations most-at-risk such as injecting drug users may be more susceptible to coercion and discrimination upon disclosure of HIV-status and the status of other viral and bacterial infections. In addition, for an IDU who is admitted to a health institution, disclosure of acute or chronic bacterial infections like tuberculosis or an infection with methicillin-resistant *Staphylococcus aureus* (MRSA), subject to general hospital hygiene regulations, may result in strict contact precautions and isolation. The conditions under which IDUs undergo testing for HIV and other infections must therefore be anchored in a human rights approach and follow ethical principles, and health care providers must follow the highest standards with regard to confidentiality and unauthorized disclosure of test results.

2.4 Rationale for provider-initiated medical examination and testing in IDUs

Many of the infections that are more common in IDUs as compared to non-users are asymptomatic and the individual will in general benefit from knowing their status for these infections. If diagnosed, most of these conditions can be treated and infection control measures can prevent further spread of the disease. Most IDUs are familiar with injection-related diseases and are often able to recognise signs and symptoms of their illnesses. Nevertheless, only a minority of IDUs seek the necessary medical or prophylactic treatment. Provider-initiated voluntary examination, testing and counselling is expected to:

- Improve the general health of the individual IDU
- Improve testing uptake for HIV and other drug-related infections
- Increase access of IDUs to treatment for HIV and other infections
- Improve diagnosis of chronic infections that need specialist care
- Increase vaccination coverage in IDUs
- Improve access of IDUs to prevention counselling and information
- improve surveillance of HIV, hepatitis and other drug related infections in IDUs

2.5 HIV testing uptake in IDUs

One of the objectives of these guidelines is to increase the uptake of HIV testing in IDUs. Available data suggest that, by the end of 2006, the transmission of HIV among IDUs was low in most countries of the European Union and Norway 2, 4, 63, 64). This may at least partly follow from the increased availability of prevention, treatment and harm-reduction measures including substitution treatment and needle and syringe exchange programs, although other factors, such as the declines in injecting drug use observed in several countries, may also have played an important role. However, less is known about the proportion of IDUs with HIV who are unaware of their HIV status. For several EU countries and regions it is likely that IDU-related HIV transmission has still continued at relatively high rates.

Since the beginning of the HIV/AIDS epidemic that started in the early 1980s HIV testing in populations most-at-risk has been regarded as a major part of the prevention strategy. Several studies have shown that IDUs who know their HIV serostatus might reduce their risk behaviour, especially if diagnosed HIV positive (66). In addition, since effective ARV treatment became available in the mid 1990s, knowledge of HIV status is critical for expanding access to successful treatment, care and support in a timely manner.

Some studies on testing uptake based on sentinel surveillance with large IDU samples have been carried out in EU countries. A study from Estonia in 2005 showed that 90% of the examined IDUs had ever been tested for HIV and 62% had been tested the previous year (67). In the UK, 30% of IDUs who took part in a survey reported never having had a voluntary test for HIV. Of those who had antibodies to HIV, 64 % were aware of their infection (19).

2.6 Summary of research findings regarding HIV testing and counselling in people who use drugs (adapted from reference 44 and 56)

It is not within the scope of this document to provide a review of research on HIV testing and counselling thus for more detail and references the reader is referred to reference 43 and 55 and the EMCDDA. The main findings can be summarised as follows:

- Many drug users are not aware of their HIV serostatus (in Europe perhaps 30-50%) and this is likely higher for other infections such as hepatitis C.
- Reported rates of HIV testing vary widely in Europe.
- Drug users have inequitable access to HAART as compared to other risk groups, whereas access to HCV viral treatment is generally low.
- Staff attitudes to drug users resulting in stigma and discrimination may be a major barrier to accessing health services.
- Outreach, mobile testing vans, peer outreach and anonymous testing sites have been recommended as alternative testing delivery options.
- Improved HIV testing uptake may result from providing additional services (NSP, OST) and additional testing such as for hepatitis C.
- IDUs delay testing more and more often fail to return for test results than other groups, but if they do they may be more likely to enter treatment.
- Factors related to testing or returning for test results include knowledge about HIV/AIDS (+), convenience to attend the testing site (+), risk perception (+), fear for results (-), fear for police or medical staff or employer or others (-), fear of needles and difficulty drawing blood (-), education (+), frequency of IDU (-), perceived lack of confidentiality (-), limited access to treatment (-), desire not to know status (-), drug use taking precedence over self care (-), negative test by sexual partner (-), recently having had a test (-), costs (-), desire to protect oneself or others (+), support from others (+), monetary incentives (+), perception that HIV is a problem (+).
- Testing is often coercive in low and middle income countries and is often associated with serious confidentiality problems.
- There is little or mixed evidence for a reduction in risk behaviour in IDUs (sexual or injecting risk).
- Predictors for continued risk include poor health, lack of social support, low knowledge. Coping mechanisms may play an important role as well.
- There is little evidence whether testing increases prevention and care uptake in IDUs and delays in onward referrals is an important barrier.
- In low and middle income countries legislation often hampers prevention access, e.g. syringe prescription or drug paraphernalia laws, or illegal classification of opioid substitution treatment.
- HIV and HCV testing can be successfully implemented in low-threshold NSPs and is readily used even if other testing sites are available
- Combining VCT with other services such as OST results in higher willingness to test, high testing rates and return rates, higher access to services, including for cocaine users while no adverse effects are found on drug treatment outcomes

2. 7 Implementation in heath facilities

Ideally, all health facilities should be able to offer provider-initiated voluntary medical examination, testing and counselling for infectious diseases to IDUs. However, health

providers must have the necessary knowledge and skills to be able to provide IDUs with satisfactory health services.

Suitable settings for implementation

The most likely venues for implementation of the recommendations are shown in table 7.

Table 7. Facilities most suitable to offer provider-initiated voluntary medical examination, testing and counselling for infectious diseases to IDUs

- Primary health care including general practitioners and family doctors
- Special health services for IDUs delivered through mobile clinics, in other community settings, through harm reduction programmes or through other types of outreach.
- Low threshold service centres visited by IDUs
- Prison health care facilities
- Rehabilitation centres and other drug treatment services
- Sexual health clinics
- Infectious diseases clinics
- Tuberculosis clinics (countries with high incidence of tuberculosis among IDUs)

Clinicians and other health professionals should assess the risks of drug use related infections among patients or clients, including a non-judgemental standard inquiry about drug habits and use. Sufficient time should be made available for the individual consultations.

The specific case of prisons and other closed settings

As discussed throughout this document, specific attention is needed to safeguard patients' rights and avoid coercion or misuse of test results in prisons and other closed settings (2). At the same time it is important that such settings provide ethically high-standard health care and services, including voluntary counselling and testing for HIV and other infections.

EU policy guidance on this point is currently in development. The revised European Prison Rules published by the Committee of Ministers of the Council of Europe in 2006 state that prisoners are entitled to a medical examination at the point of first admission (§42) and that prison authorities have to safeguard the health of all prisoners (§39) (68). In addition, a proposal for a Council recommendation is being developed to introduce harm reduction measures (including voluntary counselling and testing for infectious diseases) in prisons in the EU, following action 21 in the EU drugs action plan (2009–12) which states "To develop and implement prevention, treatment, harm reduction and rehabilitation services for people in prison, equivalent to services available outside prison. Particular emphasis to be placed on follow-up care after release from prison."

The present guidelines recommend a provider-initiated approach for IDUs in most settings, provided that the client has a true possibility to decline some or all the tests and that this does not result in any negative consequences for the IDU. It is important to note that in

settings where these conditions are unlikely to be met (or where it is not possible to ensure an truly independent monitoring of those conditions) provider initiated testing and counselling should not be implemented other than for patients with clinical signs and symptoms. Testing should then generally be limited to making available voluntary counselling and testing only on request of the client, making sure that the clients are well aware of this possibility.

2.8 Health care provider training

Training and ongoing supervision and monitoring of health-care providers doing routine medical examination, testing and counselling in IDUs is required for the successful implementation of the service.

Training programmes for personnel should be developed and implemented well in advance of setting up the service in various health facilities settings. Training should be based on protocols that besides medical issues should address specifically the following key areas:

- Ensuring an ethical process including obtaining informed consent and the possibility to decline testing for HIV or other infections
- Protecting confidentiality and privacy of the IDUs
- Avoiding stigmatisation and treating all patients with respect and without discrimination on the basis of HIV-status or risk behaviour.
- Opposing negative attitudes among health-care providers towards IDUs.

It is of particular importance that such training is provided to health-care providers in prisons and other closed settings like compulsory residential rehabilitation where IDUs are more likely to undergo any kind of coercion.

2.9 Adaptation of the guidelines

Success of implementation of the routine medical examination, testing and counselling in IDUs will depend on an assessment of the situation in a particular country with regard to the epidemiological situation, the health care system, as well as of the financial and human resources. In addition, a country's social, policy and legal frameworks for protection against discrimination of persons living with HIV or other chronic drug related infections must be taken into consideration.

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Abbreviations

ALAT	alanine aminotransferase (liver function test)
ART	antiretroviral therapy
ASAT	aspartate aminotransferase (liver function test)
BCG	Bacille Calmette Guérin (vaccine)
CDC	Centre for Disease Control and Prevention
CRP	C-reactive protein
DNA	deoxyribonucleic acid
EIA	enzyme-linked immunoassay
ELISA	enzyme-linked immunoassay
EMCDDA	European Monitoring Centre for Drugs and Addiction
ESR	erythrocyte sedimentation rate
FTA	fluorescent treponemal antibody absorption test (syphilis test)
HAART	highly active antiretroviral treatment
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HTLV	human T-cell lymphotropic virus
HPV	human papillomavirus
IDU	injecting drug user
IGRA	IFN-gamma release assays (tuberculosis test)
MRSA	methicillin resistant Staphylococcus aureus
MSM	men who have sex with men
NAAT	nucleic acid amplification tests
NGO	non-governmental organization
NSP	needle and syringe program
OST	opioid substitution treatment
PCR	polymerase chain reaction
POCT	point of care testing (using rapid test).
RPR	rapid plasma reagin test (syphilis test)
STI	sexually transmitted infections
TB	tuberculosis
TST	tuberculin skin test
TPHA	Treponema Pallidum Haemagglutination test (syphilis test)
UNODC	The United Nations Office on Drugs and Crime
UNAIDS	Joint United Nations Programme on HIV and AIDS
VCT	voluntary counselling and testing
VDRL	Venereal disease research laboratory test (syphilis test)
WHO	World Health Organization

Terminology

Client-initiated examination, testing and counselling means that the individual actively seeks examination, testing and counselling at a facility that offers these services. It usually involves a risk assessment by the individual, and management by the counsellor addressing issues like desirability and implications of testing for various agents. It may be conducted in a wide variety of settings including health facilities, stand-alone facilities outside health institutions, through mobile services, in community based settings and even in people's homes.

Provider-initiated examination, testing and counselling means that examination, testing and counselling is recommended by a health care provider to persons attending facilities as a standard component of medical care. The person involved may seek the facility for different reasons for instance specific medical or other health problems, rehabilitation, use of harm reduction measures or social and economic needs. The objective of provider-initiated testing is to identify specific infections in persons with signs or symptoms that could be attributable to HIV and other infections. In addition, unrecognised or unsuspected infections can be identified in individuals with no specific signs or symptoms. Both client-initiated and provider-initiated examination, testing and counselling are voluntary and the “three C‘s” – informed consent, counselling and confidentiality- must be strictly observed.

Informed consent is a process of communication between the client and provider that results in the patient’s authorization or agreement to voluntarily undergo testing or any other specific medical intervention. Elements of informed consent typically include providing oral or written information to the client including stressing the voluntary aspect of taking the test or intervention.

Opt-in approach means that the clients are offered testing, and if they agree to testing, they must after receiving pre-test information provide explicit consent.

Opt-out approach means that the clients are informed that testing will be performed as a part of their care, unless they explicitly decline. Informed consent is assumed unless the patient declines testing. In an opt-out approach, no tests should be done against a person’s wishes or without their knowledge.

Screening is performing a laboratory test for all persons in a defined population

Drug-related infections are any infections disproportionally found in (injecting) drug users as compared to the general population.

Client-centred prevention counselling involves tailoring a discussion of risk reduction to the patient’s individual situation.