European Monitoring Centre
for Drugs and Drug Addiction

EMCDDA
MANUALS

Guidelines for testing HIV, viral hepatitis and other infections in injecting drug users

A manual for provider-initiated medical examination, testing and counselling

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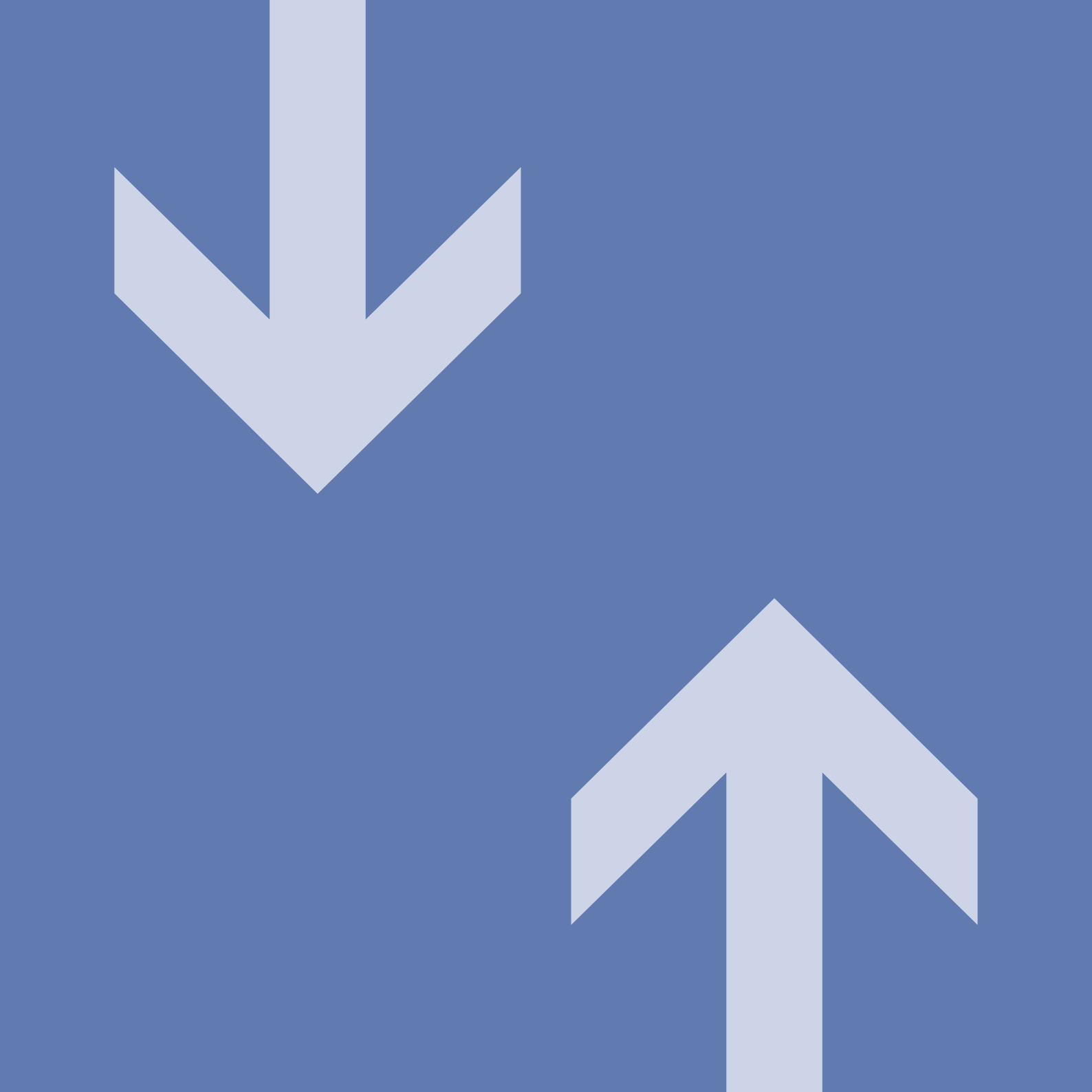

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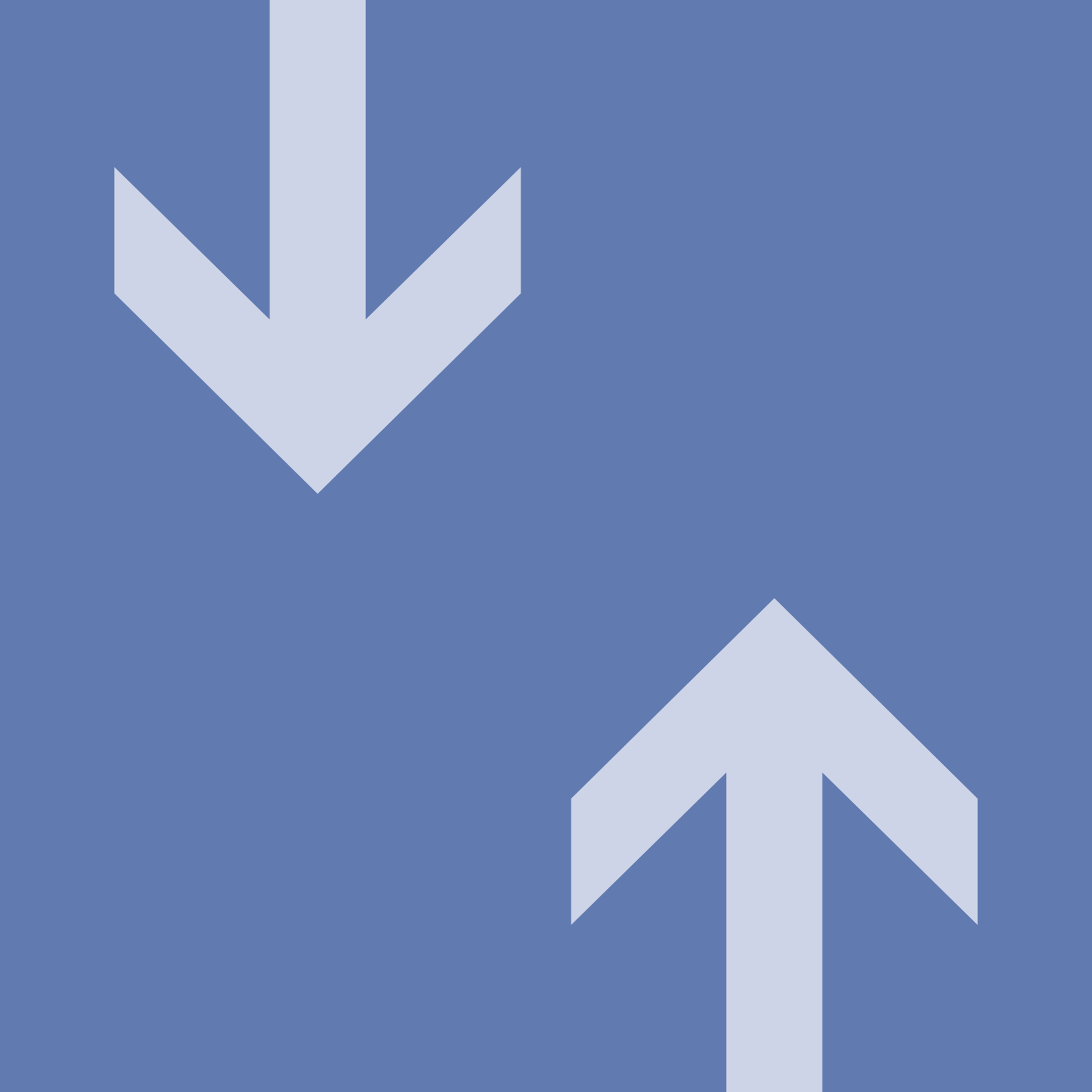

Preface

The EMCDDA has been monitoring infections in injecting drug users since 1996 through its 'Drug-related infectious diseases' project (DRID). This project is one of the five 'key epidemiological indicators' used by the EMCDDA and its partners in the Reitox network to monitor drug use and health consequences in Europe. Data are collected annually on the prevalence of HIV and viral hepatitis (hepatitis B and C) in samples of IDUs tested routinely in drug or health services or recruited in sero-epidemiological studies.

Since about 2006, attention in the DRID project has shifted from setting up the Europe-wide collection and analysis of available prevalence data to giving more attention to improving comparability of the primary data collection systems, resulting in a draft DRID protocol which is currently being finalised. One of the new aspects in the DRID data collection is the development of behavioural data monitoring, including the collection of HIV and hepatitis C testing uptake, as important indicators of service access in IDUs.

Data from different studies including those presented in the annual DRID expert meetings indicated that testing uptake of HIV, viral hepatitis and other infections among IDUs are low in many European countries. IDUs are still often a relatively 'hidden' population that is not easily in contact with health services and where various infectious diseases may go unnoticed for many years. In this group, with often frequent risk behaviours, it is crucial that those infected are aware of their infection in order that they can avoid passing the infection to others and can be referred to appropriate treatment.

Therefore, EMCDDA and DRID experts recognised a need for guidance on providing IDUs with a medical examination and testing for HIV, viral hepatitis and several other infections on a regular basis. In addition, improving testing uptake in this group would benefit epidemiological surveillance and monitoring as carried out at the national and international level.

These operational guidelines are 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 but are dealt with by indicating referral to appropriate services.

Summary

Infectious diseases are among the most serious health consequences of injecting drug use and can lead to significant healthcare costs. Injecting drug users are vulnerable to a range of infectious and communicable diseases through a variety of risk behaviours, and because of underlying conditions such as 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 carrying infections that may pose a risk to the general population.

Although HIV and hepatitis C infections remain the most important public health problem among IDUs, this document recognises that other blood-borne viral infections and various bacterial infections also play an important role in the health and well-being of IDUs. As the coverage of effective antiretroviral treatment and treatment for other infections in IDUs is being scaled up, access to and uptake of testing for HIV and other infectious diseases in IDUs also needs to be increased.

Evidence-based interventions such as opioid substitution treatment, needle exchange programmes and other elements of the 'comprehensive package' for IDUs are important measures to prevent HIV infection, hepatitis and other infections in this group (WHO, UNODC and UNAIDS 2009), given that prevention of injecting drug use itself still proves to be very difficult.

The recommendations in this document are primarily targeted at high-income countries with low-level or concentrated HIV epidemics where recorded infections are largely confined to individuals with risk behaviour, such as IDUs. This includes 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 the uptake of testing for HIV and other drug-related infections;
- increase IDUs' access to treatment for HIV and other infectious diseases;
- improve the diagnosis of chronic infections that need specialist care;
- increase vaccination coverage among IDUs;

- encourage IDUs to be more actively engaged in their own healthcare;
- improve IDUs' access to prevention counselling and information;
- improve surveillance of HIV infection, hepatitis and other infections in IDUs.

The consultation

These guidelines recommend that health providers should initiate examination, testing and counselling in IDUs in different health settings including primary healthcare, special health services for IDUs, low threshold service centres visited by IDUs, rehabilitation centres, dedicated sexually transmitted infections (STI) clinics and prison healthcare facilities. 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 healthcare provider to people 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 their potential consequences and gives (informed) consent to taking them.

An individual should always be able to decline testing for one or more infections after receiving pre-test information without fear of 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 (for instance in closed settings such as prisons) it is recommended that provider-initiated testing is not implemented, and instead voluntary counselling and testing are made available at 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 there is evidence of chronic or recent hepatitis B) hepatitis A, and syphilis;
- swab for culture from abscesses and skin lesions;
- tests for biochemical analysis – alanine aminotransferase (ALAT, liver function test), aspartate aminotransferase (ASAT, liver function test), bilirubin;
- other general blood tests – erythrocyte sedimentation rate (ESR) or C-reactive protein (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 infections being transmitted to others. For practical reasons, and taking into account the mentioned considerations, it is recommended that examination and testing are offered to IDUs at least once every 6 to 12 months.

While this document supports a strategy of increased testing of HIV and other infections among IDUs in healthcare settings, it does not support a policy of testing without informed consent, without pre- and post-testing counselling or where the confidentiality of test results cannot be guaranteed. It should be stressed that no tests should be done against a person's wishes and without their knowledge, and adequate information should always be provided to enable the individual to make an informed decision about whether or not to take each test being offered.

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 must respect the ethical principles detailed in this document, such as guaranteed confidentiality of test results.

Healthcare providers must follow equally high standards as for other patient groups with regard to confidentiality and unauthorised disclosure of test results. It must be made explicit that when an individual declines to be tested, or in cases where test results are positive, this will not affect an individual's access to other services, such as drug dependence treatment. The healthcare provider takes the final responsibility for ensuring that adequate procedures and conditions exist before a test is taken.

Policymakers should implement or safeguard and monitor adequate conditions for testing vulnerable populations such as IDUs at local and national levels. 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 (see Part 2 of these guidelines).

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 European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). While the main objective of the work on drug-related infectious diseases at the EMCDDA is to develop indicators for more reliable and comparable monitoring of hepatitis B/C and HIV in injecting drug users, a need was identified for methods and guidance to be developed 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 an 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 document the 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 healthcare provider who is in contact with IDUs regarding the decisions to test for infectious diseases. In addition, although increased testing among IDUs is essential for improving the 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 comment on a consolidated draft version of these guidelines, which was also made available on the Internet. The document was subsequently revised to take into account all the comments that were received.

IDUs are a well-defined population and they are at very high risk of contracting 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 are likely to benefit from frequent repeat testing. These guidelines are primarily aimed at active IDUs (those who have injected at least once since their last test), and IDUs who have stopped injecting. However, healthcare providers may apply the same procedures to other ('never-injecting') drug users who are at risk of infection – for example through involvement in sex work or other high-risk sex, through other

drug-related infection risks such as sharing straws to snort cocaine, through tattooing, etc. The guidelines may also be applied to other vulnerable populations than drug users who are at risk of infections (e.g. prisoners), although the healthcare provider should check whether specific issues need to be taken into account that 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 in these circumstances extra care should be taken to ensure that testing occurs under satisfactory conditions. These are described in more detail elsewhere (Jürgens, 2008).

While this document may be useful for a wider audience, it is mainly intended as a practical tool for healthcare providers in the public and private sectors who provide primary healthcare to (injecting) drug users. Thus, it is mainly aimed at general practitioners and family doctors, substance abuse treatment and rehabilitation centres, correctional healthcare facilities, 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 healthcare settings, it should be noted that the recommended tests and follow-up procedures are primarily intended as guidance for personnel in primary healthcare settings, and therefore tests and procedures considered more appropriate for specialist care are not discussed in detail.

The guidelines can also be used by policymakers, drug use and HIV programme planners and coordinators and non-governmental organisations 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 ONE

Guidelines for voluntary medical examination, testing and counselling

CHAPTER ONE

Chapter 1
Introduction

Injecting drug users (IDUs) are vulnerable to a range of infectious diseases because of their risk-taking behaviour and underlying conditions like poor hygiene, homelessness and poverty. These include:

- HIV infection;
- hepatitis A;
- hepatitis B;
- hepatitis C;
- hepatitis D;
- 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*);
- 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.

This group therefore has higher morbidity and mortality compared with the same age groups in the general population. 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.

The types of infections more common in IDUs can be divided into blood-borne viral infections, bacterial skin and systemic infections, sexually transmitted infections and respiratory infections.

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 (EuroHIV, 2006; Tefanova et al., 2006; EMCDDA, 2007; Wiessing and Nardone, 2006). 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 healthcare systems of all consequences of drug use (Jager et al., 2004). In recent years, some European countries have reported outbreaks of hepatitis A among IDUs (Perrett et al., 2003; Blystad et al., 2001; Stene-Johansen et al., 1998). Recent studies have shown that hepatitis A is spread among IDUs by fecal–oral transmission, contaminated drugs and use of contaminated injection equipment (Stene-Johansen et al., 1998). Hepatitis D (delta hepatitis) is relatively rare among the general population in most high-income countries and is generally associated with injecting drug use. Hepatitis D can only occur in conjunction with hepatitis B infection, and super-infection or co-infection with the hepatitis D virus results in more severe complications than infection with the hepatitis B virus alone.

Studies have also shown an association between human T-cell lymphotropic virus (HTLV) infections and drug users (Krook and Blomber, 1994). HTLV types I and II can be transmitted through breastfeeding, 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 leukaemia and T-cell lymphoma, HTLV-II may be involved in paraparesis-like neurological disease.

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 (Gordon and Lowy, 2005). Sharing contaminated needles and other drug injection paraphernalia, injecting under non-sterile conditions or injecting environmentally contaminated drugs are all situations that facilitate the transmission of 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 colonisation with *Staphylococcus aureus* than non-drug users (Kluytmans et al., 1997). Common bacteria like *Streptococcus* or *Staphylococcus* cause infections that vary in severity from minor skin and soft tissue infections to life-threatening disease like bacteraemia/septicaemia, necrotising fasciitis or infection of the heart valves (endocarditis) (Wilson et al., 2002). Recently, infection with methicillin

resistant *Staphylococcus aureus* (MRSA) has been reported as a growing problem in IDUs in both Europe and the USA (Fleisch et al., 2001). 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) (Brown et al., 2002; Irish et al., 2007; Binswanger et al., 2000). 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 (Akbulut et al., 2005; Anon., 2003; Brazier et al., 2004; Brett et al., 2004; Brett et al., 2005; Christopher et al., 2002; Hahné et al., 2003; Health Protection Agency, 2006; Jones et al., 2000; Murray-Lillibridge et al., 2000; Ringertz et al., 2000, Vermeer de Bondt and Vos, 2004).

Acidulant, such as citric acid, is likely to increase the resulting tissue damage when injected subcutaneously or intramuscularly, and is therefore a significant cause 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 a craving for carbohydrates and sweets (Robinson et al., 2005). In addition to causing pain and discomfort, oral abscesses and infections may be foci for more serious systemic bacterial infections.

Sexually transmitted infections

There is evidence to support 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 (Nelson et al., 1991). 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 (Norbert Scherbaum et al., 2005; Hwang et al., 2000). Non-injection drug use can also contribute to STI transmission, and the drug most associated with STIs is smokeable freebase (crack) cocaine, because it increases risky sexual behaviour and reduces awareness or concern about STIs (Van den Hoek, 1997). 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.

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, all of which are factors that increase the risk of TB (Story et al., 2007; Keizer et al., 2000). The immunosuppression of HIV infection is associated with an increased risk of TB. The risk of TB in IDUs varies with the duration of HIV infection (Van Asten et al., 2003). A study in Amsterdam showed that HIV infection increased the risk of active TB in drug users 13-fold. The incidence of TB in HIV-negative drug users was still six times higher than in the overall population of Amsterdam (Van Asten et al., 2003). In addition, IDUs have an increased risk of TB-reactivation and increased risk of developing multi-resistant TB (Jones et al., 1996; Morozova et al., 2003). Lower TB treatment completion rates in drug users and in prison settings (often with multi-resistant TB) increase the risk of multi-resistant TB in drug users (WHO, 2008a).

Aspiration pneumonia and pneumonia caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus* and *Klebsiella pneumoniae* are among the most common reasons for hospitalisation of IDUs (Scheidegger and Zimmerli, 1989; Boschini et al., 1996). Some IDUs may be at higher risk of contracting influenzae due to general poor health.

CHAPTER TWO

Chapter 2

Providing medical examination, testing and counselling to IDUs

A thorough medical examination, testing and counselling of IDUs 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.

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, physical 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 such as fever, weight loss, night sweats and a cough for more than two weeks may be signs of TB;

- 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 tooth extractions and longer-term dental care.

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

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 healthcare 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 healthcare provider and should be recorded by the healthcare provider in the patient's medical file or elsewhere. The IDU should always feel able to decline one or more tests without fear for coercion or negative consequences. This is especially important in settings where the IDU may feel their freedom of decision is restricted, such as in prisons and other closed settings.

Informed consent can be facilitated by adding the following text to an informed consent form and reading it out to the client:

> 'You are completely free to refuse some or all of the tests, and refusing some or all of the tests will have no 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 a 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's decision-making ability is not impaired by intoxication before they choose whether or not to be tested for HIV and other infections.

It is important to provide clients with enough information to enable them to give informed consent. They should be told, both orally and in written form:

- the reason why testing for HIV and other infections is recommended;
- what tests are included;
- that the client has the right to refuse them (the client should be allowed to decline some or all tests);
- about the clinical benefits of testing with regard to treatment possibilities;
- that test results will be treated confidentially and will not be shared with anyone without the client's permission;
- that declining HIV or other specific tests will not affect the client's access to services;
- that a positive HIV test or positive results from 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, it is preferable to obtain informed consent in writing.

The healthcare provider should discuss with the IDU how they wish to receive the test results before the tests are carried out.

Testing for infections

A medical examination of IDUs should always include voluntary testing for infectious diseases. Which test to perform depends on factors such as 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.

Providers should ensure that the IDU will have access to suitable treatment of the various infections identified by provider-initiated testing and counselling before testing begins. Likewise, efforts must be made to ensure that a supportive social and legal framework is in place to minimise the potential risks of any negative effects of testing, such as 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 Jürgens, 2008 and Jürgens and Betteridge, 2007.

Basic recommended tests

The tests that should be included in a standard offer to all IDUs in provider-initiated routine medical examinations are:

- Serology testing for:
  - HIV;
  - hepatitis A;
  - hepatitis B;
  - hepatitis C;
  - hepatitis D (if evidence of chronic or recent hepatitis B);
  - syphilis.
- Other general blood tests:
  - ESR or CRP;
  - haemoglobin;
  - white blood cell count.

- Swab for culture from abscesses and skin lesions.
- Tests for biochemical analysis:
    - ALAT (alanine aminotransferase);
    - ASAT (aspartate aminotransferase);
    - Bilirubin.
- Tests for TB disease or latent TB (see comments below).

The need to re-test 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. Comments on the various tests are outlined below.

HIV infection

The standard screening test for HIV is a combined HIV-1/2 antibody enzyme immunoassay (ELISA) done on venous blood. The fourth 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' (the period between the onset of HIV infection and the appearance of detectable antibodies to the virus) is possible using nucleic acid amplification tests (NAAT), like polymerase chain reaction (PCR); however, this will not normally be necessary. Modern HIV tests have a high specificity and sensitivity and the window period is normally no more than 1 to 2 weeks.

Rapid HIV tests are available in most countries. Use of these tests is often referred to as point of care testing (POCT). These tests have the advantage of giving a result within minutes and are used on whole blood (e.g. fingerprick) plasma or oral fluid. These tests, however, have slightly lower specificity and sensitivity than conventional fourth generation antibody enzyme immunoassay test. If such rapid tests are used, all positive results must be confirmed by serological tests.

When to refer: IDUs with a confirmed positive HIV test should be referred to a specialist clinic. The care provider and their specialist colleague should try to ensure that the client has an intake appointment within one to two weeks of 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.

The IgM antibody normally develops early in the infection and peaks about one to two weeks after the development of jaundice. It diminishes within a few weeks, followed by the development of the 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 cases 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 is not within the scope of these guidelines. It is recommended that a specialist is consulted where there is uncertainty about the test results. The window period is four to six months.

When to refer: IDUs diagnosed with acute or chronic hepatitis B (i.e. HBsAg can be detected in repeated samples for longer than six months) should be referred to a specialised clinic. Liver function status is important when evaluating 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 a 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 four to six months.

When to refer: All IDUs with a positive antibody test and a positive PCR should be followed up by a repeated test after three to six months, and if the test is still positive, should be considered 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 at national and European level (Hepatol, 1999). 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 (Hepatol, 1999; Reimer et al., 2005).

Hepatitis D

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

Syphilis

The diagnosis of syphilis in people 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 of one or the other, according to the particular objectives of screening. Various methods combined enable detection of 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 people who have previously contracted syphilis and been adequately treated.

Most laboratories now use specific enzyme-linked 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 detect specific antibodies and have high enough sensitivity and specificity to be used for either screening or confirmation, and also for monitoring the change in antibody levels following adequate therapy.

At the same time, providers often use one of the following tests:

- the VDRL test (venereal disease research laboratory test);
- the RPR test (rapid plasma reagin test);
- the FTA-abs test (fluorescent treponemal antibody absorption test) was 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.) enzyme-linked immunoassay (EIA) methods capable of detecting specific antibodies early on, from 10 to 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.

When to refer: Interpretation of serologic tests for syphilis may be difficult and it is not within the scope of these guidelines. Where test results are uncertain, a microbiologist or venereologist should be consulted and the patient should be referred to a STI centre.

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. A 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. Biopsy or needle aspirates are the specimen of choice for anaerobic culture, while anaerobic swabs are the least desirable. Generally, any specimen should not be stored for more than 24 hours. 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 that increases 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 haemoglobin. 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 or current TB disease depend on the epidemiological situation in the country/setting and among IDUs with regard to TB and HIV infection. In addition, screening methods depend on the presence of any symptoms of TB disease. Ideally, all IDUs should be screened for active TB disease or for latent TB infection.

Sputum smear microscopy, culture and chest X-ray should be used in all European countries and in IDUs with symptoms or signs of TB disease ([1]).

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

- *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 Mycobacterium 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 Mycobacterium 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 organised 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 five to seven 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 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

([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.

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

  The screening procedures in IDUs with no signs or symptoms of TB disease can be limited to screening for latent TB. The screening methods for latent TB in asymptomatic IDUs include the tuberculin skin test and blood tests.

- *The tuberculin skin test (TST)*
  This skin test has traditionally been used to diagnose latent infection with Mycobacterium tuberculosis. However, it has several limitations, particularly poor specificity because of cross-reactivity with the antigens of the Bacille Calmette Guérin (BCG) vaccine, as well as many of the nontuberculous mycobacteria. In addition, false-negative TST is more likely to occur among

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 TB together with signs and symptoms of the disease.

- *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 TB infection compared with traditional TSTs (Grimes et al., 2007). 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 findings consistent with suspected TB disease should immediately be referred to a TB clinic or other specialists for further examination, diagnosis and treatment.

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

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. The additional panel of tests recommended in provider-initiated routine medical examination are:

- serology for HTLV-infections;
- swab or urine testing for genital chlamydial infections;
- swab or urine testing for gonorrhoea.

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 (Sexton et al., 2005).

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. NAAT tests such as PCR are available for testing 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 samples could be used if available.

HTLV infection

HTLV infections are diagnosed using combined HTLV-I/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 latter being frequently positive in IDUs.

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 healthcare provider or other trained personnel, and ideally by the same healthcare provider who initiated testing and counselling. If for some reason the client does not show up to the follow-up consultation, the healthcare provider should make every reasonable attempt to ensure that they receive and understand the test results in a confidential manner. All available channels should be considered in trying to contact the client, with the involvement of social services. Written information about test results should never be sent to the client unless specifically agreed on prior to testing. Results of tests should not be given via any third party, including relatives or other clinical teams, unless the IDU has specifically agreed to this.

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 them 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 TB, 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 the follow-up services that are available in healthcare 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 testing and counselling of recent sexual partners or, if relevant, family members, and offer referral. 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, and shortly thereafter arrange for an appointment to be scheduled for the client with those services soon;
- briefly check that the key issues have been understood by asking the client to repeat the main points that have been discussed;

- give the client a clearly written (or pre-existing) memo with a summary of those points and any relevant contact details, and explain that they can re-contact you (the healthcare provider) if they have doubts or new questions.

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

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 realistic and counselling should therefore include information on how to reduce the risk of acquiring infections (see box).

Information for injecting drug users on the prevention of blood-borne and bacterial infections

- Always use a new (sterile) needle and syringe every single time you inject. Syringes and needles are not designed to be used more than once.
- Never share needles, syringes, water, cooker, filters or cotton with anyone.
- Never re-use needles, syringes, water, cooker, filters or cotton.
- If you are sometimes forced to re-use or share needles and syringes, clean them thoroughly each time. Follow these steps to clean a needle or syringe:

1. Clean the needle and syringe (twice) with cold running tap water to remove blood, blood clots, and other organic material.

2. Disinfect them with bleach (twice): 30 seconds' exposure to undiluted household bleach is the best way to eradicate viable HIV (Abdala et al., 2001).
3. Rinse them in clean running tap water (twice) to remove the bleach.

   Alternatively, clean the needle and syringe thoroughly under running tap water, then cook them for 10 minutes.

- If re-using 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. Use either:
  - water boiled for five minutes in a clean pan;
  - cold running tap water;
  - a newly opened bottle of mineral water or soda pop/fizzy drink.
- Improve safer injection practices:
  1. Wash hands before and after injecting (especially when helping others).
  2. Boil the drug if possible.
  3. Clean the skin before injecting with alcohol or any other disinfectant solution.
  4. Avoid the use of dangerous injection sites such as the neck and groin.
  5. Avoid injecting under the skin or directly into a muscle.
  6. Clean all materials used, including the table surface, with disinfectant.
- If available, use treatment facilities and harm reduction measures such as:
  - needle exchange programmes and other sources of sterile injecting materials (e.g. pharmacies) — ask for enough equipment to avoid having to re-use anything;
  - 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 your personal hygiene, especially oral hygiene.

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

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 on the results of tests carried out at the first consultation. Self-reported vaccination status is usually unreliable and the decision on what vaccines to offer should not be based on self-reporting. A plan should be made in consultation with the client for the provision of additional or booster doses. Recommended vaccines for IDUs are:

- hepatitis A and B combination vaccine (or separate hepatitis A and hepatitis B vaccines);
- diphtheria/tetanus vaccine (every 5 to 10 years);
- influenzae vaccine (seasonally);
- pneumococcal vaccine (especially if HIV positive and >50 years of age).

Hepatitis A and B combination vaccines or separate hepatitis B vaccine can be administered as a three-dose schedule at zero, one and six months or as a four-dose schedule administered on days zero, seven 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 those infected with HIV, than in the general population. It is therefore recommended to test for antibody to hepatitis B surface antigen (anti-HBs) one to two months after completing the third dose of the vaccine series. In cases of low antibody titre, additional booster dose(s) may be needed.

BCG vaccination against TB 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 for 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 allowing the decision to depend on serological results or self-report, and given the difficulty of maintaining contact with IDUs for follow-up vaccination (de la Fuente et al., 2007).

Vaccinations should in general be avoided during pregnancy.

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 that need specialist follow-up and care (such as HIV infection, TB, hepatitis and syphilis) should be referred to competent clinics or specialist services. Patient referral works best if the healthcare 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.

Frequency of examination and testing

The recommended frequency of routine medical examination, testing and counselling in IDUs depends on various factors, such as the local epidemiological situation of HIV infection or other infections, and the availability of human and financial resources. In addition, 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 who are ongoing injecting drug users or involved in 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 carriership after infection and thus the risk of infecting others. For practical reasons and taking into account these considerations, it is recommended that examination and testing is offered to IDUs at least once every six to 12 months.

Ethical considerations

(See also the section 'Pre-test counselling, informed consent and possibility to opt-out', page 28.)

The provider must ensure that the drug user's decision-making ability is not impaired by intoxication before they discuss and decide on 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 of the proposed tests without coercion.

Confidentiality must be strongly enforced with regard to test results and information obtained during the examination. However, this must not prevent the provider from documenting findings in the patient's medical record. It is recommended that the offer of an HIV test is recorded explicitly, and that informed consent and pre- and post-test counselling have taken place; where a client refuses a test, a note of the reasons for their refusal should be made in their records. Such medical records should only be accessible to those (other healthcare providers) who have a direct role in the ongoing management of the patient. Administrative personnel at institutions (e.g. prisons) should never have access to a patient's health records.

It is the healthcare 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 that provider initiated testing is refrained from, and voluntary counselling and testing is made available at the individual's request, while making sure that individuals are well aware of this possibility.

PART **TWO**

Background and implementation of the guidelines

CHAPTER THREE

Chapter 3
Background

Existing guidelines and the 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, 2007)*
  This document offers 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 (UNAIDS and WHO, 2004), although it states that for highly vulnerable populations, an opt-in approach may merit consideration. The guideline addresses the testing of IDUs at needle and syringe access points, and other harm reduction interventions including referral to opioid substitution therapy. It recommends testing higher risk individuals every 6 to 12 months, depending on the epidemic situation. However, the guidelines have no specific section on testing in IDUs.
- *Guidance on testing and counselling for HIV in settings attended by people who inject drugs (WHO and UNODC, 2009)*
  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 whose clinical presentation might result from underlying HIV infection and as a standard part of medical care for all patients attending specialised healthcare 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 healthcare settings (Centers for Disease Control and Prevention, 2006b)*
  The objective of these recommendations is to increase HIV screening of patients in healthcare settings, including substance abuse treatment clinics and correctional healthcare 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 healthcare settings following notification to the patient that the testing would be performed unless the patient declines (opt-out screening). It is recommended that people at high risk of 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 programmes in healthcare settings. Although these recommendations mentioned IDUs as a high-risk group who should be offered annual HIV testing, there is no specific information about testing IDUs.

- *Policy and programming guide for HIV/AIDS prevention and care among injecting drug users (WHO, 2005)*
  This guide concentrates on distilling the principles from policies and programmes that have worked well in responding to HIV/AIDS epidemics among IDUs. It emphasises 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 to help people in applying principles that have proven 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 emphasised, 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, 2008b)*
  WHO has, in cooperation with UNODC and UNAIDS, and in consultation with a group of technical experts, published policy guidelines for collaborative HIV and TB services for injecting users and other drug users in general. The aim of this guidance is to provide a strategic approach to reducing TB- 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 (Jürgens, 2008; Jürgens and Betteridge, 2007).

Similar to IDUs, men who have sex with men (MSM) are a population most at risk of acquiring HIV in addition to other sexually transmitted infections. In 2006, the Centers for Disease Control and Prevention published the document 'Sexually transmitted disease treatment guidelines 2006' (Centers for Disease Control and Prevention, 2006a). 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 in Norway (Blystad and Klouman, 2005). In the 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 healthcare settings in order to reduce the proportion of individuals with undiagnosed HIV infection. The guidelines stress 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 they support the use of opt-out testing in certain situations (British HIV Association, 2008).

IDUs have specific needs and encounter specific challenges for testing, care and treatment, warranting particular approaches for the group. Lack of testing uptake in IDUs may have serious consequences for the prevention of further spread of HIV and other infections, as well as for the early treatment and care of those infected, and the quality of diagnostic surveillance data regarding this group.

Efficient testing approaches need 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 is likely to lower the risk of secondary spread from infected individuals.

Recommendations at policy level to create and ensure the necessary conditions for provider-initiated testing for IDUs ([1])

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. needle and syringe programme, opioid substitution treatment, antiretroviral therapy, etc.) (WHO, UNODC and UNAIDS 2009).
- If antiretroviral therapy (ART) is not available there must be a reasonable expectation that it 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 and supervision should be provided for staff to enable them to uphold ethical standards.
- Additional discussion may be needed on the client's right to decline testing.
- Referral mechanisms should be reviewed and optimised.
- If conditions for provider-initiated approaches are not met, testing should instead be made available for highly vulnerable populations at the individual's request.
- Most at-risk populations or their representatives (e.g. non-governmental organisations) 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.

([1]) Adapted from Jürgens and Betteridge, 2007 and WHO, 2005.

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. in prisons or other closed settings), testing should be limited to making voluntary counselling and testing available at the individual's request.

Provider-initiated

Provider-initiated means that examination, testing and counselling is recommended by a healthcare provider as a standard component of medical care offered to people attending the facilities. The person involved may attend the facility for a variety of reasons, for instance specific medical or other health problems, rehabilitation, use of harm reduction services or through social and economic need. The objective of provider-initiated testing is to identify specific infections in people 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 testing injecting drug users for HIV. Ever since injecting drug users were recognised as a most-at-risk population for HIV in the early 1980s, national health authorities have actively promoted provider-initiated voluntary HIV testing in settings such as prisons, health or rehabilitation centres where IDUs are being contacted by health or social services, and through harm reduction programmes or different types of outreach. IDUs have for many years 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 programmes have resulted in considerable increases in HIV testing uptake in Europe and elsewhere, including the United States, the United Kingdom, Norway and Canada (Obermeyer and Osborn, in press).

Opt-out versus opt-in approaches

Different guidelines have taken different standpoints regarding opt-out or opt-in strategies. Published literature suggests that the testing uptake is increased where universal routine ('opt-out') strategies have been adopted (Simpson et al., 1998; Haukoos et al., 2008). An opt-out testing strategy stresses that testing is a standard part of medical care and that the individual must specifically decline testing for some or all infective agents following pre-test

counselling. It must be emphasised that in an opt-out approach no tests should be done against a person's wishes or without his/her knowledge. In an opt-in approach clients are offered testing, and if they agree, they must provide explicit consent once they have received pre-test information.

In these guidelines, we have chosen to refrain from using the terms 'opt-in' or 'opt-out', as it became clear that some confusion still surrounds these terms. In addition, it seems evident that an opt-out approach can be well coupled with informed consent and counselling and may not in practise differ much from an opt-in approach.

In a policy statement of HIV testing published by WHO and UNAIDS in 2004, four types of HIV testing were clearly distinguished (UNAIDS and WHO, 2004):

- voluntary counselling and testing based on a client's initiative;
- diagnostic HIV testing (when there are symptoms or following exposure);
- routine offer of HIV testing by healthcare providers;
- mandatory HIV testing.

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

Populations that are most at risk, such as IDUs, may be more susceptible to coercion and discrimination upon disclosure of their HIV status and their status regarding 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 TB 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 healthcare providers must follow the highest standards with regard to confidentiality and unauthorised disclosure of test results.

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.

HIV testing uptake by IDUs

One of the objectives of these guidelines is to increase the uptake of HIV testing by IDUs. Available data suggest that at the end of 2006 the transmission of HIV among IDUs was low in most countries of the European Union and Norway (Jürgens, 2008; Tefanova et al., 2006; Haukoos et al., 2008; ECDC and WHO, 2007). 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 programmes, although other factors, such as the decline 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 continued at relatively high rates.

Since the beginning of the HIV/AIDS epidemic in the early 1980s, HIV testing in populations most at risk has been regarded as a key 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 (Desenclos et al., 1993). In addition, since effective antiretroviral 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 (Uusküla et al., 2006). 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 (Health Protection Agency, 2007).

Summary of research findings regarding HIV testing and counselling in people who use drugs ([2])

It is not within the scope of this document to provide a review of research on HIV testing and counselling, so for more detail and references the reader is referred to Van den Hoek (1997), Centers for Disease Control and Prevention (2006b), 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 figure is likely to be higher for other infections such as hepatitis C.
- Reported rates of HIV testing vary widely in Europe.
- Drug users have inequitable access to highly active antiretroviral treatment 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 (needle and syringe programmes, opioid substitution treatment) and additional testing, such as for hepatitis C.
- IDUs are more likely to delay testing and fail to return for test results than other groups, but if they do return for results they may be more likely to enter treatment, if required.

([2]) Adapted from Jürgens and Betteridge, 2007 and WHO, 2005.

- Factors related to testing or returning for test results can work either in a positive or negative direction:
  - — Positive factors include: knowledge about HIV/AIDS; convenience of access to the testing site; risk perception; education; desire to protect oneself or others; support from others; monetary incentives; the perception that having HIV is a problem.
  - — Negative factors include: fear about possible positive results; fear of police, medical staff, employer or others; fear of needles and difficulty drawing blood; frequency of drug injecting; perceived lack of confidentiality; limited access to treatment; desire not to know one's status; drug use taking precedence over self-care; a negative test result by the sexual partner; recently having had a test; costs.
- Testing is often coercive in low- and middle-income countries and is often associated with serious confidentiality problems.
- There is little or mixed evidence of a reduction in risk behaviour in IDUs (sexual or injecting risk).
- Predictors for continued risk include poor health, lack of social support, low level of knowledge. Coping mechanisms may play an important role as well.
- There is little evidence on whether testing increases prevention and care uptake in IDUs, and delays in onward referrals are a significant 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 needle and syringe programmes and is readily used even if other testing sites are available.
- Combining voluntary counselling and testing with other services such as opioid substitution treatment 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.

CHAPTER FOUR

Chapter 4
Implementation

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 facilities most suitable for offering provider-initiated voluntary medical examination, testing and counselling for infectious diseases to IDUs are:

- primary healthcare, 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 healthcare facilities;
- rehabilitation centres and other drug treatment services;
- sexual health clinics;
- infectious diseases clinics;
- tuberculosis clinics (in countries with a 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 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 (Jürgens, 2008).

Yet it is important that such settings do provide ethically high standard healthcare 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) (Council of Europe, 2006). 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 is actually able to decline some or all the tests and that this does not result in any negative consequences for them. It is important to note that in settings where these conditions are unlikely to be met, or where it is not possible to ensure a 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 at the explicit request of the client.

Healthcare provider training

Training and ongoing supervision and monitoring of healthcare providers carrying out routine medical examination, testing and counselling with 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 facility 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 of declining testing for HIV or other infections;
- protecting the confidentiality and privacy of clients;

- avoiding stigmatisation and treating all clients with respect and without discrimination on the basis of their HIV status or risk behaviour;
- opposing negative attitudes among healthcare providers towards IDUs.

It is of particular importance that such training is provided to healthcare providers in prisons and other closed settings such as compulsory residential rehabilitation where IDUs may be more likely to experience coercion.

Adaptation of the guidelines

Success in the implementation of routine medical examination, testing and counselling in IDUs will depend on an assessment of a particular country with regard to the epidemiological situation, the healthcare system, and available financial and human resources. In addition, a country's social, policy and legal frameworks for protection against discrimination of people 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)
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)
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
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
VDRL	Venereal disease research laboratory test (syphilis test)
WHO	World Health Organization

Glossary

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

Provider-initiated examination, testing and counselling A healthcare provider recommends examination, testing and counselling to people attending facilities as a standard component of medical care. The person involved may have attended the facility for reasons such as 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 people 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 Cs' – informed consent, counselling and confidentiality – must be strictly observed.

Informed consent This involves a process of communication between client and provider that results in the patient agreeing to voluntarily undergo testing or any other specific medical intervention. Elements of informed consent typically include providing oral or written information to the client about the proposed procedure that stresses the voluntary aspect of taking the test or intervention.

Opt-in approach Clients are offered testing, and if they agree, they must provide explicit consent once they have received pre-test information.

Opt-out approach 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 to be tested. No tests are carried out against a person's wishes or without their knowledge.

Screening Screening involves carrying out a laboratory test for all the people in a defined population.

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

Client-centred prevention counselling Tailoring a discussion of risk reduction to the patient's individual situation.

European Monitoring Centre for Drugs and Drug Addiction

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The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is one of the European Union's decentralised agencies. Established in 1993 and based in Lisbon, it is the central source of comprehensive information on drugs and drug addiction in Europe.

The EMCDDA collects, analyses and disseminates factual, objective, reliable and comparable information on drugs and drug addiction. In doing so, it provides its audiences with an evidence-based picture of the drug phenomenon at European level.

The Centre's publications are the prime source of information for a wide range of audiences including policy-makers and their advisors; professionals and researchers working in the drugs field; and, more broadly, the media and general public.

The EMCDDA's Manuals are practical handbooks aimed at professionals and grassroot practitioners working in the drugs field.

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