TB·HIV

EVIDENCE FOR ACTION TECHNICAL PAPERS

POLICY GUIDELINES FOR COLLABORATIVE TB AND HIV SERVICES FOR INJECTING AND OTHER DRUG USERS

AN INTEGRATED APPROACH

World Health Organization

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POLICY GUIDELINES FOR COLLABORATIVE TB AND HIV SERVICES FOR INJECTING AND OTHER DRUG USERS
AN INTEGRATED APPROACH

Geneva, 2008

The World Health Organization (WHO) developed these guidelines in collaboration with the United Nations Office on Drugs and Crime (UNODC) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) and in consultation with a group of technical experts. Igor Toskin and Alasdair Reid prepared the initial scoping and first draft. Kathrin Thomas, Christian Gunneberg and Annette Verster finalised the guidelines.

WHO will review whether the recommendations in these guidelines need to be updated by 2012 at the latest and will publish the conclusions of the review.

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Summary of declaration of interests of the members of the Guideline Group

All members of the Guideline Group were asked to complete a WHO declaration of interests form, and none reported any conf ict of interest.

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ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
DOTS	the internationally recommended strategy for TB control
HIV	human immunodeficiency virus
TB	tuberculosis: unless otherwise specified, in this publication "TB" refers to TB disease and not TB infection with *Mycobacterium tuberculosis*
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

EXECUTIVE SUMMARY

In many settings, the epidemic of drug use has become intertwined with the HIV and the TB epidemics. Health systems have often responded with separate policies and structures, to the detriment of the individual user and their communities.

These guidelines are intended for professionals dealing with the drug users who have the most problematic patterns of use and who have the greatest risk of HIV and TB, especially those who inject drugs.

Drug users have high rates of HIV infection, mainly due to unsafe injecting behaviour. Drug users also have increased rates of TB infection, whether living with HIV or not. HIV infection greatly increases the risk of transition from TB infection to TB disease.

Globally, about 2.5 million injecting drug users are estimated to be living with HIV, although estimates for HIV prevalence among all drug users are not available. There is an overlap between countries where the HIV epidemic is mainly driven by injecting drug use and countries with some of the highest rates of multidrug-resistant tuberculosis.

Drug users tend to be a marginalized group with complex needs and have poorer access to life-saving interventions. Services should have a more coordinated response to drug users' needs to provide universal access to prevention, treatment and care services at all entry points. This requires collaborative planning between HIV and TB services, specialist drug services and the criminal justice system.

In particular, health services should provide treatment adherence support for drug users. Comorbidity, such as hepatitis infection, should not be a barrier to obtaining TB and HIV treatment services. Prisoners with HIV, TB or drug dependence need to have the same access to treatment and care as the civilian (general, non-incarcerated) population, as should drug users who are migrants, homeless or otherwise marginalized. In addition, continuity of care on transfer in and out of places of detention is essential.

The main recommendations are as follows.

Joint planning

1. There should be multisectoral coordination at the local and national levels to plan, implement and monitor TB and HIV activities for drug users. This should be done through existing mechanisms if possible.
2. The national strategic plans for TB, HIV and substance misuse should clearly define the roles and responsibilities of all service providers delivering services for drug users and should ensure the monitoring and evaluation of TB and HIV activities for drug users, including treatment outcomes.
3. Human resource planning should ensure that there are adequate numbers of personnel and that education and training programmes aim to build sustainable effective teams so that all personnel who have contact with drug users have the appropriate level of skill in dealing with TB and HIV and drug users.
4. All stakeholders for collaborative TB/HIV services for drug users should support and encourage TB/HIV operational research to develop the evidence base for efficient and effective implementation of collaborative TB/HIV activities.

Key interventions

5. All congregate settings in the health, drug service and criminal justice sectors should have a TB infection control plan supported by all stakeholders that includes administrative, environmental and personal protection measures to reduce the transmission of TB.
6. All services dealing with drug users should have a case-finding protocol for TB and HIV so that personnel are aware of the symptoms of TB and HIV and can ensure that drug users have access to appropriate TB and HIV testing and counselling, preferably at the service where they initially present.
7. TB and HIV services and services for drug users should ensure access to appropriate treatment for drug users by using global, regional and national clinical guidelines and should work in collaboration to ensure treatment supervision and to simplify the delivery of treatment.
8. All health services should ensure access to isoniazid preventive therapy for drug users living with HIV once active TB is reasonably excluded.
9. All personnel working with TB suspects and patients, people living with HIV and drug users should be able to assess risk factors for HIV infection and transmission and should provide comprehensive HIV prevention information and services to their clients to minimize these risks. Personnel should also be aware of how to protect themselves from occupational exposure to HIV and TB.

Overcoming barriers

10. All services dealing with drug users should collaborate locally with key partners to ensure universal access to comprehensive TB and HIV prevention, treatment and care as well as drug treatment services for drug users in a holistic person-centred way that maximizes access and adherence: in one setting, if possible.
11. Medical examination upon entry and any time thereafter, conforming to internationally accepted standards of medical confidentiality and care, should be available for all prisoners. Prisoners should obtain care equivalent to that provided for the civilian population, and care should be continuous on transfer in and out of places of detention.
12. There should be specific adherence support measures for drug users to ensure the best possible treatment outcomes for TB and HIV infection and to reduce the risk of development of drug resistance and the risk of transmission to other people.
13. Comorbidity, including viral hepatitis infection (such as hepatitis B and C), should not contraindicate HIV or TB treatment for drug users. Alcohol dependence, active drug use and mental health problems should not be used as reasons to withhold treatment.

PURPOSE

Aim

The aim of these guidelines is to provide a strategic approach to reducing morbidity and mortality related to TB and HIV among at-risk drug users and their communities in a way that promotes holistic and person-centered services.

Target population

The target population is people who use opiates, cocaine or amphetamine-type stimulants in a dependent or harmful way, especially those who inject drugs.

Target audience

The target audience is:

- health policy-makers and decision-makers (in the health care and the criminal justice systems) at the national and subnational levels;
- managers (in the health care and the criminal justice systems) of TB and HIV prevention and control programmes at the national and subnational levels;
- managers of programmes and drug treatment services for drug users and general health care services (in the health care and the criminal justice systems);
- drug users and the organizations representing them;
- advocacy and communication experts working with drug users or in TB and HIV prevention and control programmes;
- development agencies, donors, nongovernmental organizations and community-based organizations working with drug users; and
- people involved in all forms of research, particularly operational research, on TB, HIV and TB/HIV.

INTRODUCTION

Population of interest

These guidelines are intended for professionals dealing with the drug users who have the most problematic patterns of use and who have the greatest risk of HIV and TB, especially those who inject.

Problematic drug use is defined here in accordance with the 10th revision of the International Classification of Diseases *(1)* (see Annex 1 for full definitions).

These guidelines focus particularly on people who are:

- using opioid or stimulant drugs, such as cocaine or amphetamine-type stimulants, which are illegal to buy or supply (unless prescribed) in almost all countries;
- using the drugs in a way that is harmful to their physical or mental health; and
- using the drugs in a dependent way, defined as a cluster of behavioural, cognitive and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drugs, difficulty in controlling use, persisting in use despite harmful effects, giving higher priority to drug use than to other activities and obligations, increased tolerance and sometimes a physical withdrawal state.

The term "drug user" includes injecting and non-injecting users, unless specified.

For the purposes of these guidelines, alcohol, cannabinoids and tobacco dependence were specifically excluded from the original scope, although it is recognized that their use often coexists with opiate or amphetamine use. This was done because they have a low risk of producing dependence (such as cannabis), are rarely injected or are less associated with the risks of HIV or TB. This also enabled a focus on the most vulnerable and excluded populations.

Injecting behaviour

The main focus is on injecting drug users, the population group with the highest incidence of HIV *(2)*. Although non-opioid drug dependence, such as cocaine and amphetamine-type stimulants, carries an increased risk of HIV infection, particularly when the drugs are used by injection *(3)*, the risk is most established for injecting opioids. The risk is not linked with any particular drug but with unsafe practices using shared injecting equipment.

Drug users, whether injecting or not, are often among the most vulnerable and socially excluded people in any society and are therefore exposed to many other risk factors for TB such as poverty, homelessness, overcrowding and imprisonment.

Services for drug users

"Service for drug users" means any service that is intended primarily to offer voluntary help to address the drug use of the people it reaches, statutory or nongovernmental, and takes a harm reduction approach. It includes drug treatment services, needle syringe programmes, detoxification centres and outreach services.

TB strategy

Effective and equitable access to health care interventions remains a challenge. WHO recommends approaches based on strengthening health systems *(4)* with strategic planning and financing. This has become an increasingly important approach for tacking TB globally.

The DOTS strategy for controlling TB has been widely used since the early 1990s, with five components: political commitment; case detection with quality-assured bacteriology; standardized treatment with supervision and support of the people with TB; an effective drug supply and management system; and a monitoring and evaluation system and impact measurement.

In response to the increasing complexity of the epidemic and the widespread recognition that this required cross-cutting solutions, the 2006 Stop TB strategy *(5)* now has six components: pursue high-quality DOTS expansion and enhancement; address TB/HIV, multidrug-resistant TB and other special challenges; contribute to strengthening health systems; engage all care providers; empower people with TB and communities; and enable and promote research.

The main background policy for these guidelines is the WHO interim policy on collaborative TB/HIV activities *(6)*, which recommends a set of activities to reduce the burden of TB among people living with HIV and the burden of HIV among people with TB (Box 1). However, the policy also does not address the specific challenges of delivering comprehensive TB and HIV prevention, treatment and care services to drug users. These guidelines aim to highlight this gap and address the particular complex needs of drug users.

Box 1. Recommended collaborative TB/HIV activities

A. Establish the mechanisms for collaboration
- Set up a coordinating body for TB/HIV activities effective at all levels
- Conduct surveillance of HIV prevalence among people with TB
- Carry out joint TB/HIV planning
- Conduct monitoring and evaluation

B. Decrease the burden of TB among people living with HIV
- Establish intensified TB case-finding
- Introduce isoniazid preventive therapy
- Ensure TB infection control in health care and congregate settings

C. Decrease the burden of HIV among people with TB
- Provide HIV testing and counselling
- Introduce HIV prevention methods
- Introduce co-trimoxazole preventive therapy
- Ensure HIV care and support
- Introduce antiretroviral therapy

Source: adapted from *Interim policy on collaborative TB/HIV activities (6).*

METHODS

Annex 2 outlines the methods and search strategies.

Steering Group

WHO established the Steering Group in 2005 and expanded it in 2007 to include representatives from all the relevant departments. It also included representatives from the partner organizations within the United Nations: UNAIDS and UNODC.

Scoping

The WHO Steering Group produced an initial discussion document on injecting drug use and TB/HIV in June 2005. This document was circulated for comments to a small Reference Group, which included the members of the TB/HIV working group of the Stop TB Partnership, WHO staff and experts in drug use, TB and HIV.

Guideline Group

The Guideline Group included the members of the Steering Group and external experts. The Steering Group selected the external experts based on the advice of TB, HIV and drug use specialists within WHO, UNODC and UNAIDS regional offices and colleagues from other organizations. The selection took into account regional representation, gender balance, areas of expertise (service delivery, research and policy development), topics of expertise (substance misuse, HIV and TB) and representatives of potential stakeholders and civil society.

Guiding principles

The Guideline Group developed and used guiding principles when formulating the recommendations.

Equity

Drug users should have equitable access to the full range of TB and HIV prevention, treatment and care services without threat of arrest, harassment or abuse. These principles are reinforced by the International Standards for Tuberculosis Care *(7)* and the Patients' Charter for Tuberculosis Care *(8)*, which state the right to treatment without stigma, prejudice, or discrimination by health providers and authorities.

Access

Services should be person-centred to increase accessibility and integration and reduce unnecessary cross-referral. They could, for example, be at one site ("one-stop shopping"). They should be free of user charges. Services should also be designed in a way that minimizes stigma.

Health as a public good

Providing access to good TB and HIV prevention and treatment services for drug users also affects their families and communities. On public health grounds, addressing their health needs may prevent harm to those around them, for example in allowing them to care for their family, reducing the risk of HIV and TB transmission and possibly reducing the risk of drug-resistant TB in communities.

Harm reduction

The definition used here is that of the International Harm Reduction Association *(9)*: "policies and programmes which attempt primarily to reduce the adverse health, social and economic consequences of all psychoactive substances to individual drug users, their families and their communities".

It is a public health approach and includes policies (such as providing a supportive legislative and service provision environment) and practices, such as:

- information and education, especially about reducing risk through outreach;
- needle and syringe programmes;
- drug dependence treatment, especially opioid substitution therapy;
- voluntary, confidential counselling and testing for HIV infection;
- provision of HIV care and treatment, including antiretroviral therapy;
- prevention of sexual transmission, including treatment of sexually transmitted infections and condom programming; and
- primary health care including diagnosis, treatment and, where relevant, vaccination for hepatitis B and C, overdose management and wound care.

Evidence retrieval, assessment and summarizing

The following methods were used (Annex 2 documents the methods in full).

- a literature search of published literature (PubMed);
- this literature search of published materials was repeated in October 2007;
- a search of the grey literature and relevant web sites;

- the expert opinion of WHO Steering Group members through having worked in this field;
- evidence from regional and country WHO offices; and
- a systematic literature search on one question (adherence and drug users) carried out by Frederick Altice in March 2008.

Development of the recommendations

The Guideline Group considered this evidence at a meeting in November 2007 at which draft recommendations were presented and discussed. One gap was identified in the evidence, and the Guideline Group requested a further literature search on adherence. The Guideline Group subsequently agreed on a recommendation on adherence support by electronic communication.

The recommendations are not new but are based on the recommendations of key existing WHO, UNODC and UNAIDS guidelines for TB and HIV prevention, care and treatment. They have been placed in context for this population, taking into account the most important issues.

The development of the guidelines followed the WHO minimum standards for guidelines development applicable in 2007.

All the members of the Guideline Group were asked to declare any conf icts of interest.

Peer review

The draft guidelines were finalized based on the advice from the Guideline Group and agreed by them. This was then circulated for review to the Reference Group, which by this stage had become wider to include more of the interested and relevant organizations.

Stakeholder consultation

The final draft guidelines were circulated by e-mail to more than 500 individuals and organizations, with a large proportion from civil society organizations.

Layout of the guidelines

The guidelines are structured as follows for each section:

- background: the explanation of why this area is important;
- key issues: the main issues to be addressed in the recommendations;
- findings: the summary of the evidence considered when drawing up the recommendations; and
- recommendation(s): the recommendation(s) concluded with the advice of the Guideline Group by considering the evidence and making a judgement based on values and costs and preferences.

EPIDEMIOLOGY

Drug use

The UNODC states that the main problem drugs at the global level continue to be the opiates (notably heroin) followed by cocaine *(10)*.

Injecting drug use

Worldwide, it is estimated that there are more than 13 million injecting drug users, and most (about 80%) live in low- and middle-income countries (eastern Europe and central Asia, 3.1 million; south and south-east Asia, 3.3 million; east Asia and the Pacific, 2.3 million) *(11)*. Of these, an estimated 10 million injecting drug users are dependent on opioids, mainly heroin, and are concentrated in Europe, North America, central and south Asia and Australia. In South America and east and south-east Asia, injecting drug users predominantly inject cocaine and amphetamine-type stimulants.

HIV epidemic in drug users

The UNAIDS/WHO *AIDS epidemic update 2007 (2)* states the following.

Examination of global and regional trends suggests the [HIV] pandemic has formed two broad patterns:

- generalized epidemics sustained in the general populations of many sub-Saharan African countries, especially in the southern part of the continent; and
- epidemics in the rest of the world that are primarily concentrated among populations most at risk, such as men who have sex with men, injecting drug users, sex workers and their sexual partners.

Injecting drug use is a major mode of HIV transmission in several regions and is emerging as a concern in Africa. It is estimated that maybe as much as 10% of all new HIV infections are attributable to injecting drug use, and approximately 2.5 million past and current injecting drug users are living with HIV *(12,13)*.

In eastern Europe and central Asia, injecting drug use has accounted for between 60% and 80% of all HIV transmission *(14,15)*.

In many countries of east Asia and the Pacific, injecting drug users constitute a large proportion of people living with HIV, ranging between 38% and 77% *(11,16)*.

Injecting drug use is thus a major mode of HIV transmission in several regions and is emerging as a concern in Africa *(12)*. WHO estimates that 15% of the people with TB/HIV are living outside sub-Saharan Africa *(17)*. Many of these are associated with injecting drug use.

Among all the estimated 33.2 million [30.6 million – 36.1 million] *(2)* people living with HIV, TB is one of the commonest AIDS-defining conditions and the leading cause of death.

TB in drug users

The estimated number of new TB cases in the general population varies between countries (Fig. 1).

Fig. 1. Estimated number of new TB cases in the general population, 2006

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Source: *Global tuberculosis control: surveillance, planning, financing – WHO report 2008 (17).*

Drug use is associated with increased rates of TB disease and TB infection. Infection refers to evidence of the presence of TB bacilli, but the large majority of infected people do not become ill. TB can lie dormant for years, although the risk of developing disease is greatest in the first year. Infection with HIV dramatically increases progression to TB disease. People who have TB infection without HIV coinfection have a 5–10% lifetime risk of developing TB disease, whereas people living with HIV have a 5–10% annual risk of developing TB disease *(18)*.

TB disease rates among drug users in New York City in the early 1970s were already more than 10 times higher than those in the general population, before the emergence of HIV *(19)*. Injecting drug users show higher TB infection rates than the general population *(20)*. One study has shown that the risk of TB infection among crack cocaine users is equal to that of injecting drug users *(21)*. HIV-positive and HIV-negative injecting drug users had similar rates of TB infection in a two-year prospective study, and even HIV-negative drug users had a much higher rate of development of TB than did the general population *(18)*.

Increased TB disease rates among drug users are likely to be due to other risk factors for TB disease such as incarceration, homelessness and poverty. For example, the rates of TB disease in prisons can be more than 30 times higher than that outside prisons, and the prevalence of multidrug-resistant TB can be up to 10 times higher *(22)*.

TB is a leading cause of mortality among injecting drug users living with HIV. Both all-cause and TB-associated mortality rates are several times higher among drug users living with HIV than among other people living with HIV *(23,24)*.

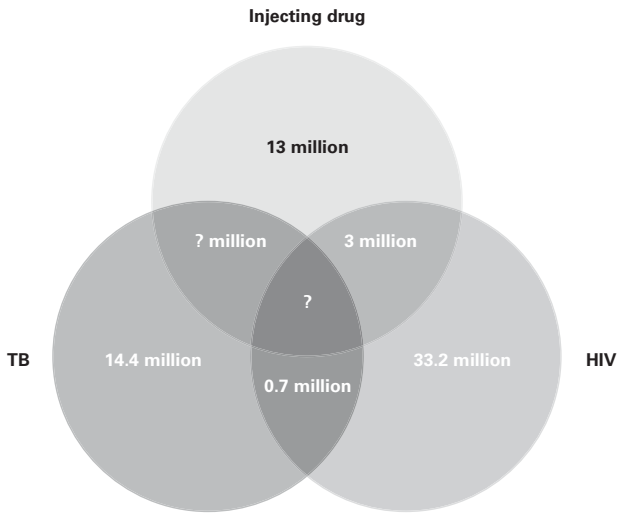
Extrapulmonary TB has been found to be more common among injecting drug users than in the general population in Latvia, Malaysia, Thailand and the United States of America *(25–28)*.

Multidrug-resistant TB poses a threat to TB control, with evidence of increases in some countries. Countries in the Commonwealth of Independent States and in south-east Asia have the highest rates. For example, in the two countries with the greatest TB burden, China and India, 8% and 5% of TB cases are estimated to have multidrug-resistant TB and will probably not respond to the treatment they currently receive. In eastern Europe, an estimated 1 in 5 cases are multidrug-resistant TB *(29)*.

These are the same areas where many of the HIV epidemics are centred on drug use. Surveillance data to inform the epidemiology are lacking, primarily because of lack of high-quality second-line drug resistance testing facilities. However, signs are emerging that people living with HIV may have a higher risk of multidrug-resistant TB. For instance, data available from Latvia and from Donetsk Oblast, Ukraine indicate a significant association between HIV and multidrug-resistant TB *(29)*.

The links between multidrug-resistant TB and HIV in drug users are of particular concern (Fig. 2). Drug use is associated with lower rates of TB treatment completion (which is a major risk for developing resistance), and drug users are also more likely to be exposed to multidrug-resistant TB in places of detention, where multidrug-resistant TB rates are often higher *(29)*.

Fig. 2. The overlap between TB, HIV and injecting drug use



TB = prevalence 2006 (new, retreatment, chronic cases) (13).

HIV = point prevalence in the 2007 UNAIDS report (2).

Injecting drug users = point prevalence of injecting users according to UNODC (10).

Gender and drug use

Although there are fewer women than men among drug users, women tend to suffer greater health and social effects. The links with sex work can put women at greater risk of HIV and hence HIV-related TB. They are at great risk of marginalization and violence. Women also have specific needs related to pregnancy and child-rearing, including contraception or maternal and child health care.

Prisons

About 8 million to 10 million people are imprisoned globally. Since many are detained for short periods, the actual number passing through prisons each year is potentially 4–6 times higher. Prisoners are often housed in overcrowded facilities with inadequate ventilation, hygiene and sanitation. The food that is provided can be unappealing and nutritionally inadequate. Health services may be weak or absent. Illegal behaviour such as the use of alcohol, drugs or sexual activities (with or without consent) may continue unchecked. Such conditions are ripe for the outbreak of epidemic diseases, including TB and HIV.

In many countries, drug users are at high risk of being imprisoned. Studies show that the proportion of prisoners who have a history of injecting drug use before incarceration ranged from 11% to 64% *(30)*. Injecting drug behaviour occurs in prisons. Since it is clandestine, it is more likely to be carried out with unsafe shared equipment *(30)*. In south-east Asia, data from India, Indonesia and Thailand suggest that between one tenth and two thirds of prisoners may be incarcerated on drug-related charges *(31)*.

HIV infection is a serious problem in prison systems. Rates of up to 50% have been documented. Where this has been studied, rates of infection are many times higher than in the community outside prisons. In many systems this is primarily attributable to HIV infection among injecting drug users, many of whom spend time in prison, and some of whom continue to inject while incarcerated. In these countries, high rates of HIV (and hepatitis C and hepatitis B) infection are related primarily to sharing injecting equipment outside and inside prison. The rate of HIV infection can also be high in prison because of high rates of HIV in the general population, as is primarily the case in Africa.

Much higher levels of active TB disease, up to 100 times more, are reported in prisoner populations compared with that reported in the civilian population. Some prison programmes have shown high levels of drug-resistant TB. Rates up to one third of all cases have been found *(32)*. A study from the Samara region of the Russian Federation showed rates of 37% in prison, twice as high as in the civilian population *(33)*. High rates of TB are made worse by late diagnosis and treatment of infectious cases, HIV infection and intravenous drug use, overcrowding, poor ventilation, high transfer rates of prisoners, poor nutritional status and stress.

Prison health is often forgotten or given low priority. The problems of TB, HIV and the poor health of prisoners will not stay confined to prisons. Society must be concerned about prison health for the purposes of enlightened self-interest and fulfilling fundamental human rights by coordinating health systems to ensure the continuity and equivalence of care.

JOINT PLANNING

Background

Most countries have separate strategic plans and implementation mechanisms for tackling substance misuse and for TB and HIV prevention, diagnosis and treatment. Although there are some excellent examples of joint planning, service provision in each of these areas can be very separate with a lack of understanding of the full needs of a drug user, who may require all these services at the same time. In particular, drug treatment services are often not planned together with harm reduction services.

Key issues

Service delivery is likely to be successful when people have access to the right intervention at the right time from the right service. For a drug user, this may entail using drug treatment, TB and HIV services while simultaneously coping with imprisonment or homelessness and poverty. Services therefore need to be planned to meet these complex needs, including by actively reaching out to drug users and designing services that will reduce stigma and encourage take-up of services.

The main barriers to service delivery for drug users are often the stigmatization of illegal drug use and a low level of political commitment. This can lead to a lack of adequate national policy and an environment of harassment and abuse.

Summary of findings

The WHO interim policy on collaborative TB/HIV activities *(6)* gathered evidence from operational research and expert opinion, which showed that having TB/HIV coordinating bodies operating at all levels is feasible and ensures commitment and ownership.

Rapid and effective responses to the TB and HIV epidemics among drug users depend on the awareness of the personnel in the service a drug user initially contacts. This often includes diverse settings such as an emergency service or primary care or in the criminal justice setting. The TB and HIV specialist services therefore depend on other services to identify and refer the right people at the right time.

High-quality monitoring and evaluation activities facilitate information for action and are critical to improving performance. WHO developed *A guide to monitoring and evaluating collaborative TB/HIV activities (34)* to facilitate assessment of joint TB/HIV activities in different settings. Some of the proposed indicators, especially those for HIV prevention activities and HIV counselling and testing, are consistent with the indicators used by harm reduction programmes.

Recommendation 1

There should be multisectoral coordination at the local and national levels to plan, implement and monitor TB and HIV activities for drug users. This should be done through existing mechanisms if possible.

Existing TB, HIV or drug users service coordination mechanisms should take up TB and HIV issues for drug users specifically, inviting some representation from the other groups, and should ensure that membership is broad. The sectors involved in the multisectoral coordinating body should include health, criminal justice and civil society and could include:

- representatives of the TB control programme;
- representatives of the national HIV control programme;
- representatives of services for drug users and harm reduction services;
- representatives of the criminal justice system;
- representatives of social care and psychological services;
- representatives of health care services, such as emergency and primary care; and
- representatives of drug user groups.

The multisectoral coordinating body should take a lead in advocacy and communication.

Goals should include *(35)*:

- creating a favourable environment for implementing drug services as a main channel for delivering integrated TB and HIV prevention, care and treatment for drug users;
- advocating for change in local legislation on drug use if the national laws conflict with human rights, evidence-informed practice and the principles of harm reduction;
- advocating for change in regulations or practices of health care provision that conflict with human rights, evidence-informed practice or the principles of harm reduction;
- reducing stigma against drug users at the level of decision-makers and policy-makers, health care providers, law enforcement officials and in the general population;
- empowering drug users with information on HIV, TB, harm reduction and drug dependence treatment;
- advocating for the removal of explicit or implicit prohibitions on treatment for drug users, including for HIV, TB and drug dependence;
- ensuring an approach that recognizes and addresses the special needs of the population, including for women and children, migrants and young people;
- ensuring equivalent access to health care, especially HIV and TB services, for drug users in prison settings.

Recommendation 2

The national strategic plans for TB, HIV and substance misuse should clearly define the roles and responsibilities of all service providers delivering services for drug users and should ensure the monitoring and evaluation of TB and HIV activities for drug users, including treatment outcomes.

This should involve either a joint TB/HIV plan for drug users or introducing TB/HIV activities into relevant national plans for TB, HIV, substance misuse, prison health care and legal frameworks.

The roles and responsibilities of each programme in implementing specific TB/HIV activities at the national and district levels must be clearly defined.

The plan should ref ect:

- joint needs assessment of the burden of TB and HIV in drug users;
- joint mobilization of the resources needed to implement or expand collaborative TB/HIV activities as part of all services for drug users;
- joint human resource development and training plans to ensure coherence between all service providers;
- joint assessment of the national regulatory barriers to enable reforms to allow maximum delivery of care;
- joint supervision and/or inclusion of drug use experts on supervision teams in heavily affected areas; and
- joint accountability for providing equity of access to universal prevention, treatment and care services for people in prisons or other places of detention.

The coordinating body should:

- attempt to establish the denominator populations of drug users, people with TB and people living with HIV as accurately as possible, to enable adequate monitoring;

- carry out surveillance that is representative of the population of people with TB, to ensure that drug users, if present in the population of people with TB, should be included;
- ensure that monitoring of TB/HIV activities is integrated into existing systems as much as possible, using existing indicators, with treatment outcome data of cohorts of drug users being assessed to compare with overall population treatment outcomes, which may involve more detailed analysis and special studies;
- engage with drug user representative groups and/or advocacy groups on their experience in seeking care and receiving treatment as well as the barriers they face, to improve the success of monitoring and evaluation; and
- engage in meaningful community participation in planning integrated services and in collecting accurate surveillance data.

Recommendation 3

Human resource planning should ensure that there are adequate numbers of personnel and that education and training programmes aim to build sustainable effective teams so that all personnel who have contact with drug users have the appropriate level of skill in dealing with TB and HIV and drug users.

Provision of comprehensive TB/HIV services for drug users requires adequate numbers of personnel and appropriate training.

Training should include personnel in TB and HIV services and services for drug users and personnel in low-threshold services or other health services in frequent contact with drug users. Personnel should have basic knowledge of HIV and TB, and personnel in HIV, TB and general health services should have basic awareness of the health problems associated with drug use.

This should include:

- awareness of the possibility that personnel and the users of services may be drug users;
- non-discriminatory identification of drug users, the drug being used and the route of administration;
- how to communicate with drug users in neutral, non-discriminatory ways;
- how to ensure appropriate referral for comprehensive care measures for the prevention, treatment and care of TB and HIV;
- provision of testing for hepatitis B and hepatitis C infection, with referral for positive cases and provision of vaccination for hepatitis B in negative cases;
- understanding of the polices and principles of harm reduction; and
- education on TB, HIV and drug dependence treatment and understanding how to improve adherence to all medicines used.

Recommendation 4

All stakeholders for collaborative TB/HIV services for drug users should support and encourage TB/HIV operational research to develop the evidence base for efficient and effective implementation of collaborative TB/HIV activities.

The Guideline Group developed an outline of areas in which research would strengthen the evidence base for the development of these guidelines in the future (Annex 3).

KEY INTERVENTIONS

Preventing TB transmission by controlling infection

Background

TB is a contagious disease that is transmitted through airborne infectious particles from person to person. Reducing the risk of transmission by measures to control infection is an underutilized and neglected area.

Key issues

Drug users are especially at risk for the transmission of infectious agents through poor living conditions and the congregate settings that are often part of drug treatment service and the criminal justice system. Prisons and other non–health care settings are generally not familiar with basic TB and HIV infection control measures, which can be implemented simply and at relatively low cost.

Summary of findings

The source of TB infection is people with TB affecting the lungs (pulmonary TB) or larynx who produce infected particles through coughing, sneezing, talking or singing. The risk of transmission depends on the time exposed and is usually assumed to be greatest for people sharing an enclosed space for prolonged or repeated periods. People who are infectious have not been diagnosed and treated or have not received enough treatment to become non-infectious. This normally takes about two weeks and is confirmed with two negative sputum-smear tests *(36)*. Left untreated, each person with pulmonary TB will infect on average between 10 and 15 people per year *(37)*.

Infection refers to the presence of TB bacilli, but the large majority of infected people do not become ill. TB can lie dormant for years, although the risk of developing disease is greatest in the first year. This is called latent TB infection. However, a weakened immune system most commonly caused by HIV infection can lead to TB infection becoming active and causing the disease *(36)*. People living with HIV are at higher risk of progressing to TB disease but are no more infectious than other people with TB. This can often happen before they are even aware that they have HIV. Similarly, health care workers and other personnel are also at risk, particularly those also living with HIV.

Direct sunlight can kill *Mycobacterium tuberculosis* within five minutes, but they can survive much longer in the dark and can remain suspended in the air for a long time *(36)*.

WHO is currently developing guidance on TB infection control. Specific guidance is available for settings with high HIV prevalence and resource-limited health care *(38)*.

Simple measures are:

- cough hygiene: covering mouth and nose with cloth or tissue when coughing or sneezing;
- using natural ventilation: open windows and outdoor clinics;
- separating people suspected of having TB when they are likely to be contagious from other people, especially those who may be most vulnerable, such as children and people living with HIV; and
- diagnosing and starting TB treatment quickly, to reduce the time a person is infectious to others.

Recommendation 5

All congregate settings in the health, drug service and criminal justice sectors should have a TB infection control plan supported by all stakeholders that includes administrative, environmental and personal protection measures to reduce the risk of transmission of TB.

An infection control strategy for TB should be based on the following.

- Administrative control measures

  These include implementing infection control plans for ensuring measures to protect personnel and the potential contacts of people with possible or confirmed TB.

- Environmental control measures

  These include measures such as ventilation, air cleaners and ultraviolet germicidal irradiation.

- Personal protective equipment, such as the use of surgical masks for patients and respirators for health care workers in respiratory protection.

In particular, all personnel should be aware of the symptoms of TB and ensure that someone who is known or suspected to have infectious TB is separated from other people until adequately treated and shown to be non-infectious.

This should apply in all congregate settings, including countries with high and low TB prevalence.

Annex 4 outlines the essential TB infection control actions recommended by the working group on TB/HIV of the Stop TB Partnership.

Intensified case-finding for TB and testing for HIV

Background

Given the multiple obstacles drug users face in accessing health services, HIV and TB are much more likely to be diagnosed at a late stage among drug users.

Key issues

Early identification of TB and HIV infection can reduce transmission and improve health outcomes. As many drug users may be seen first in low-threshold or non–health care settings, these may present opportunities for improved case-finding of HIV and TB, with further opportunities for partner testing and contact tracing.

Summary of findings

TB case-finding

The most important symptoms raising suspicion of pulmonary TB are a cough for more than two or three weeks, sputum production and loss of weight. Greater weight loss, diarrhoea and skin disease are more common among people living with HIV than among people who are HIV-negative *(36)*.

Intensified case-finding and treatment of TB among people living with HIV reduces mortality and interrupts disease transmission from people who are infected (in the household and hospital or clinic settings) and offers the opportunity to provide TB preventive therapy to people living with HIV *(35)*.

At a minimum, trained counsellors or other lay health workers can administer a brief questionnaire on TB symptoms to screen for active TB. The feasibility of screening for TB at a syringe exchange programme in the United States of America has been demonstrated *(39,40)*. However, the frequency of screening or the most cost-effective methods have not yet been established.

People living with HIV have a 24–61% higher chance of having smear-negative pulmonary TB and a 4–40% higher chance of having smear-negative extrapulmonary TB, so that alternative methods of diagnosis must be used *(41)*. Other methods of diagnosis depend on local guidance and policies and include chest X-ray and clinical assessment *(36,42)*. The people at highest risk of TB are those who have been in close contact with a known case of infectious TB. Close contact is defined as sharing an enclosed space for prolonged and/or repeated periods.

TB diagnosis

When a person is suspected of having TB, the first and most cost-effective test is sputum smear microscopy *(36)* (and culture, if available). For maximum identification, this requires collecting and transporting at least two sputum samples on two separate occasions, which can be done in most health care settings with simple infection control precautions.

HIV testing and counselling

The right to know one's HIV status is fundamental to accessing life-saving prevention, care and treatment services. HIV testing and counselling is now available in many non–health care settings. WHO, UNAIDS and UNODC are developing specific guidance on HIV testing and counselling for drug users and for prisons. However, in the meantime, global guidance on voluntary testing and counselling *(43,44)* and guidance on provider-initiated testing in health care facilities *(45)* are available. Neither of these is specific to drug users.

Recommendation 6

All services dealing with drug users should have a case-finding protocol for TB and HIV so that personnel are aware of the symptoms of TB and HIV and can ensure that drug users have access to appropriate TB and HIV testing and counselling, preferably at the service where they initially present.

The need for greater awareness should be met by adequately training and developing these personnel. The key aspect is to have a package of health care services available to provide a good reason to be tested.

Services should use the local tools in use to identify people who may have TB, which can be adapted for settings where drug users access help, such as low-threshold or drug treatment services that are not in the health sector. At a minimum, these should include a simple set of questions on the symptoms and signs of TB.

Sputum sampling for TB and blood testing for HIV can be offered safely in many non–health care settings if personnel are trained in counselling and carrying out the procedures. They should have access to safe laboratory services and the appropriate TB or HIV specialist service to which they can refer people if necessary. Personnel in all services should ensure that screening for TB is offered to the close household contacts of anyone known to have infectious TB.

In particular, personnel in all services should be aware that the prevalence of HIV among drug users is likely to be high and should offer voluntary HIV testing to any drug user, especially if they have any history of injecting.

Countries should expand access to HIV testing and counselling, while ensuring that:

- people who use drugs are able to give informed and truly voluntary consent to HIV testing;
- people receive adequate pretest information and post-test counselling; and
- the confidentiality of test results and of the fact of seeking the test is guaranteed.

Treatment

Background

TB is a curable disease when appropriate antimicrobial drugs are available and properly administered. With the introduction of highly active antiretroviral therapy, HIV infection is in the process of transforming from a progressive and usually fatal disease to a chronic manageable infection.

Key issues

There is often reluctance to start pharmaceutical treatment for drug users because of concerns about adherence as well as concerns about medication interactions and adverse effects especially linked to viral hepatitis. Low treatment completion rates are a concern because this is a risk factor in promoting drug resistance.

Summary of findings

Illicit drug use may mask or alter the significant side effect profile of the HIV and TB therapies. However, the use of illicit drugs does not influence the selection of therapy for TB or HIV infection.

Drug users should be a priority for prevention, care and treatment interventions since they are at greater risk individually and have a potentially greater impact from a public health perspective.

Treatment for TB

Among people living with HIV who are at risk of TB, the priority is to save lives and prevent illness by preventing and treating TB. The second priority is to stop TB transmission. Standard TB therapy consists of an initial phase of two months of treatment with four different antimicrobial drugs given daily under observation and a continuation phase of four to six months of at least two antimicrobial drugs, under as close supervision as possible (DOTS) *(36)*. The choice of antibiotic is recommended by the country TB programme based on international

recommendations but may need to be adjusted according to individual comorbidity. Regimens do not differ between people living with HIV and people who are HIV negative (except the need to use rifampicin and to avoid intermittent use).

Multidrug-resistant TB is much more difficult to treat, requiring injectable drugs. Treatment should be designed in accordance with WHO guidelines *(46)* and can last up to two years.

Treatment for HIV

WHO recommends a standardized public health approach to antiretroviral therapy regimens for HIV infection *(47,48)*. HIV treatment services should select a single first-line regimen and a limited number of second-line regimens. Combining TB treatment and antiretroviral therapy can cause problems with drug interactions (especially rifampicin with protease inhibitors and with non-nucleoside reverse transcriptase inhibitors or isoniazid with nucleoside reverse transcriptase inhibitors). There is also a risk of an exacerbation of symptoms and signs of TB when initiating combined treatment (immune reconstitution syndrome) *(36)*.

Multiple treatment regimens

In some cases, simultaneous medication may be needed for multiple conditions including TB, HIV, hepatitis B and hepatitis C, other infections and conditions related to drug dependence as well as drug dependence itself *(49)*. Most of the treatments require relatively long-term administration. Each prescribed drug may have side effects.

Drug users may indeed have specific needs in choosing the treatments that are the most appropriate and most effective and have the least adverse effects.

The following are specific findings regarding TB and/or HIV infection in drug users *(50)*.

- Drug users tend to present at a later stage of HIV infection and hence have more severe disease.
- Drug users are more likely to have other blood-borne viruses, such as hepatitis B and C infection, with a higher risk of hepatotoxicity due to comorbidity and drug interactions.
- They are more likely to have opportunistic infections, such as *Candida*, herpes simplex and *Pneumocystis* pneumonia as well as TB.
- Drug users are more likely to have mental health problems, such as depression and alcohol dependence.
- There are potential drug interactions between anti-TB drugs, antiretroviral therapy, alcohol, methadone and buprenorphine, some illicit drugs and drugs for other infections such as hepatitis C.
- Adherence is reduced by the delivery of multiple medication regimens in multiple settings, by homelessness, by continued illicit drug use and by lack of readiness to engage.

As many women who use drugs are young, considering family planning options is particularly important. Women living with HIV have the right to get pregnant but should be provided with options to avoid pregnancy if they desire this. Early diagnosis and providing antiretroviral therapy can reduce the risk of mother-to-child transmission of HIV *(51)*.
Comprehensive guidance is available on managing HIV and TB and also HIV-related TB among adults and children. These include sections on managing each condition among injecting drug users *(49,50,52,53)*, although none as yet are specifically for TB/HIV in drug users (please see the web links to policies, guidelines and manuals).

Despite these challenges, none of the treatment issues above absolutely contraindicates standard TB/HIV treatment regimens and treatment for associated morbidity in drug users.

Recommendation 7

TB and HIV services and services for drug users should ensure access to appropriate treatment for drug users by using global, regional and national clinical guidelines and should work in collaboration to ensure treatment supervision and to simplify the delivery of treatment.

TB and HIV care and treatment should be coordinated with all services and should be provided in one setting if possible rather than cross-referring clients.

TB treatment, especially when directly observed therapy is used, should be combined with HIV care and treatment interventions (such as co-trimoxazole), opioid substitution therapy and other medication regimens in a package that is easily accessible, so that the drug user is not required to attend multiple sites at multiple times.

Training of health care workers treating conditions related to drug dependence, including TB/HIV, needs to include drug interactions and side effects when several treatments are given concurrently.

The TB/HIV care to be considered for drug users should be according to their needs and at least equivalent to that offered to any other person.

Preventing TB through isoniazid preventive therapy

Background

Isoniazid preventive therapy is the use of this single anti-TB drug for six to nine months to prevent TB infection from progressing to TB disease among people who have been infected, especially people living with HIV.

Key issues

Although isoniazid preventive therapy has significant potential to reduce the burden of TB disease among people living with HIV, it is currently thought to be underutilized for preventing TB, especially among drug users.

Summary of findings

In countries with high TB prevalence, between 2.4% and 7.5% of adults living with HIV may develop active TB each year. Among the adults living with HIV with a positive purified protein derivative (tuberculin) skin test, the rate rises to between 3.4% and 10% per year *(54)*. Isoniazid preventive therapy is effective for preventing active TB in among people infected with TB who are also living with HIV and has been shown to be effective in injecting drug users living with HIV in settings with low levels of isoniazid resistance *(55–57)*.

Systematic reviews *(58–60)* have shown that isoniazid is effective in reducing the incidence of TB disease by about 60%. WHO/UNAIDS recommends isoniazid for people living with HIV *(54)*. The WHO policy on collaborative TB/HIV activities recommends providing isoniazid preventive therapy as part of the package of care for people living with HIV once TB has been reasonably excluded. A literature review of the benefits of screening for latent *Mycobacterium tuberculosis* infection *(61)* also identified injecting drug users as one of the groups with the lowest number needed to screen and treat to prevent cases (between 21 and 439) and deaths (between 103 and 4650).

Isoniazid may be given as daily, self-administered therapy for six to nine months at a dose of 5 mg/kg to a maximum of 300 mg. These individuals should be seen monthly and given a one-month supply of medication at each visit. Adherence may be improved by giving an additional two-week emergency buffer supply to be used if the individual has to defer his or her monthly review.

Isoniazid will not be effective among people who have been infected with a strain of TB that is resistant to isoniazid (such as multidrug-resistant TB).
Antiretroviral therapy reduces the incidence of TB by as much as 80%, so that providing antiretroviral therapy to drug users with HIV is also effective for preventing active TB, and this effect is also additive when used with isoniazid *(62)*.

Recommendation 8

All health services should ensure access to isoniazid preventive therapy for drug users living with HIV once active TB is reasonably excluded.

Isoniazid preventive therapy should be used under the following conditions.

- Isoniazid preventive therapy should be used in settings where the prevalence of TB infection in the general population is greater that 30% or in other populations at greater risk of TB such as health care workers, household contacts of people with TB, prisoners, miners or other selected groups at high risk of acquiring or transmitting TB *(63)*.
- Isoniazid preventive therapy should be considered to prevent TB among drug users living with HIV.
- Clinical and laboratory examinations to reasonably exclude active TB should be carried out according to national policies before any decision to provide isoniazid preventive therapy is taken.
- Completion of isoniazid preventive therapy should be ensured by providing adherence support measures, including directly observed therapy.
- Isoniazid preventive therapy should be dispensed with other treatments, such as opioid substitution therapy, in settings where this is implemented.

Preventing HIV

Background

Drug users are at increased risk for HIV transmission through injecting practices and high-risk sexual behaviour.

Key issues

HIV infection is the major risk factor among drug users for subsequent development of TB disease.

Summary of findings

Drug users with TB infection without HIV coinfection have a 5–10% lifetime risk of developing TB disease, and those living with HIV have a 5–10% annual risk of developing TB disease *(18)*. Preventing HIV infection therefore reduces the incidence of TB.

Sharing injecting equipment in an unsafe way is the greatest risk factor for HIV. There may be some confounders, since injecting drug use is associated with more chaotic lifestyles and hence the presence of other independent risk factors for TB such as poverty, imprisonment and overcrowding.

Sex is also a route of transmission for HIV among prisoners, sex workers who inject drugs and drug users who may also exchange sex for drugs or money *(64,65)*.

Advocacy and communication activities designed to provide decision-makers with adequate reliable information on harm reduction principles and their benefits are important and effective at all levels *(65–69)*.

Recommendation 9

All personnel working with TB suspects and patients, people living with HIV and drug users should be able to assess risk factors for HIV infection and transmission and should provide comprehensive HIV prevention information and services to their clients to minimize these risks. Personnel should also be aware of how to protect themselves from occupational exposure to HIV and TB.

There is extensive global, regional and national guidance on HIV prevention. UNAIDS, WHO and UNODC *(65,70,71)* recommend a package of HIV prevention for injecting drug users that includes:

- needle and syringe programmes;
- opioid substitution therapy;
- voluntary HIV counselling and testing;
- antiretroviral treatment and care services including post exposure prophylaxis for sexual partners of drug users
- preventing and treating sexually transmitted infections;
- male and female condom programming for injecting drug users and their partners;
- targeted information, education and communication for injecting drug users and their sexual partners;
- hepatitis diagnosis, treatment (hepatitis A, B and C) and vaccination (hepatitis A and B); and
- TB prevention, diagnosis and treatment.
- Create safe non stigmatizing environment where drug users can access information and services without fear of harassment or legal intervention.
- Targeted reproductive health and prevention of mother to child transmission services focused on appealing to the needs of women drug users and women partners of drug users.

OVERCOMING BARRIERS

Health outcomes for drug users can be much worse than those among the general population. Treatment programmes can help address this gap in health outcomes when organized properly. Conversely, substandard treatment and neglect of this group promotes the persistence of infection reservoirs that can contribute to the failure of HIV or TB control strategies and may promote the emergence of drug resistance.

Drug users tend to have very poor access to health care in general and are less likely than non-users to receive antiretroviral therapy if they are living with HIV. In some settings, there may be a reluctance even to record drug users in the District TB Register and to treat drug users with active TB. Both better case detection and adherence in drug users are feasible and a necessity for TB and HIV control programmes.

Models of service delivery

Background

Health services, especially TB and HIV services, are likely to encounter a proportion of people who are drug users. Similarly, services dealing with drug users and the criminal justice system will encounter a proportion of people who have become infected with HIV and/or TB.

The need to attend multiple services acts as a barrier to treatment in drug users. Currently TB and HIV services and services for drug users in many countries are likely to be organized very separately and are not as integrated as they could be.

Key issues

Policies and strategies for delivering HIV services to injecting drug users are well established in many countries. This is not the case for TB services, since the emerging problem of the double burden of TB/HIV among drug users was recognized relatively recently.

However, research and strategies for addressing problem drug use other than injecting behaviour are less well established.

Because of the intertwined nature of these conditions, the service delivery response needs to be flexible and integrated. A useful definition of integrated care is "an organizational process of coordination which seeks to achieve seamless and continuous care, tailored to the patients' needs and based on a holistic view of the patient" *(72)*.

Summary of findings

The many social and health service barriers to accessing prevention and care services for drug users may result in lengthy delays in seeking health care. Successful outcomes to care are further complicated by lower levels of adherence to prescribed treatments.

Daily drug use, alcohol dependence and depression are associated factors that can complicate care and treatment. Stigma against drug users among health workers, law enforcement personnel and social service workers also contributes to poor outcomes *(73)*, such as the forced registration of drug users within mandatory drug treatment programmes in many countries. Women who inject drugs are much more likely to delay approaching health facilities than men who inject *(74)*. Studies in the United States of America indicate that injecting drug users may have lower and suboptimal access to HIV care and may be less likely to receive antiretroviral therapy than other populations *(74–76)*.

Evidence for combining TB and HIV treatment services in settings with high HIV prevalence is backed up by policy *(6)* and practice *(77)*. The advantages of integrated co-located TB/HIV services, especially for injecting drug users, have been reviewed *(23)*.

A UNAIDS study *(78)* of HIV prevention activities in seven low- and medium-income settings that had achieved successfully high coverage among injecting drug users showed that common features included:

- using harm reduction principles to develop local programmes;
- advocacy efforts need to be given priority, adequately staffed and funded;
- the role of law enforcement services is crucial for success;
- there could be differences in each setting resulting in different services and approaches to attract injecting drug users to a programme;
- a single programme can be replicated to address the needs of injecting drug users in other districts, cities and provinces;
- convenience of access; and
- involvement of injecting drug users.

Table 1 shows the suggested TB/HIV activities that could be provided at each entry point into the services that drug users may access.

Table 1. Treatment delivery should be ensured in the setting that is the most accessible, non-stigmatising and convenient for the drug user and most likely to promote adherence

	General health services (prison, hospitals, primary care, sexually transmitted infection services)	TB service	HIV service	Service for drug users
	Ensure treatment delivery in the setting that is the most accessible and convenient for the drug user and most likely to promote adherence.			
Prevention	Identify harmful or dependent drug use Basic drug and HIV information	Identify harmful or dependent drug use Basic drug and HIV information	Identify harmful or dependent drug use Basic drug and HIV information	Drug information and counselling
	Needle and syringe programme Male and female condoms	Needle and syringe programme Male and female condoms	Needle and syringe programme Male and female condoms	Needle and syringe programme Male and female condoms
	TB infection control measures Ventilation Separate people suspected of having TB	TB infection control measures Ventilation Separate people suspected of having TB	TB infection control measures Ventilation Separate people suspected of having TB	TB infection control measures Ventilation Separate people suspected of having TB
	Ensure access to Post exposure prophylaxis & prevention of mother to child transmission services as indicated	Ensure access to Post exposure prophylaxis & prevention of mother to child transmission services as indicated	Ensure access to Post exposure prophylaxis & prevention of mother to child transmission services as indicated	Ensure access to Post exposure prophylaxis & prevention of mother to child transmission services as indicated
Care	HIV testing and counselling TB case-finding	Maintain the TB registry TB diagnosis confirmation HIV testing and counselling	TB case-finding HIV diagnosis confirmation	HIV testing and counselling TB case-finding
	Ensure access to HIV and TB treatment and manage comorbidity	Ensure HIV treatment and manage comorbidity	Ensure TB treatment and manage comorbidity	Ensure access to HIV and TB treatment

	General health services (prison, hospitals, primary care, sexually transmitted infection services)	TB service	HIV service	Service for drug users
Treatment	Adherence support measures	Initiate and supervise TB treatment Supervise HIV treatment	Initiate and supervise HIV treatment TB treatment	Initiate and supervise opioid substitution therapy or detoxification
	Supervise TB and HIV treatment	Initiate and supervise isoniazid preventive therapy and co-trimoxazole preventive therapy	Initiate and supervise co-trimoxazole preventive therapy	Adherence support measures
	Opioid substitution therapy	Opioid substitution therapy	Opioid substitution therapy	

Recommendation 10

All services dealing with drug users should collaborate locally with key partners to ensure universal access to comprehensive TB and HIV prevention, treatment and care as well as drug treatment services for drug users in a holistic person-centred way that maximizes access and adherence: in one setting, if possible.

Since stigma is a barrier to seeking health care and to adherence, personnel must be sensitive to the need to adopt appropriate neutral non-discriminatory attitudes towards people who use drugs.

Many drug users do not present to the TB and HIV services, and initial screening and subsequent investigation and treatment for TB and HIV should be integrated as much as possible with the point of first contact.

All services should be provided where possible in one setting rather than cross-referring clients.

When drug users are receiving regular health care, services should collaborate to support adherence through such measures as dispensing medication and monitoring at one site.

TB services

TB services may be a primary point of contact for people living with HIV or drug users. These programmes should implement the relevant recommendations of the WHO interim policy on collaborative TB/HIV activities *(35)*, including the following.

- TB control programmes should develop and implement comprehensive HIV prevention strategies targeting sexual, parenteral or mother-to-child transmission or should establish a referral linkage with HIV programmes to do so.
- Everyone attending TB clinics should be screened for sexually transmitted infections using a simple questionnaire or other recommended approaches. Those with symptoms of sexually transmitted infections should be treated or referred to the relevant treatment providers.

- TB control programmes should be equipped to identify and manage people with TB who use and/or inject drugs or should establish a referral linkage with services for drug users to do so.
- TB control programmes should ensure that mother-to-child transmission is prevented by referring pregnant women living with HIV to providers of services for preventing mother-to-child transmission.

The TB services should promote continuity of care in a drug user's care package, including HIV treatment and drug treatment, such as opioid substitution therapy.

HIV services

HIV services should:

- consider methods of reaching drug users living with HIV who may not currently be using their services;
- be equipped to identify and manage people living with HIV who use and/or inject drugs or should establish a referral link with services for drug users to do so;
- carry out intensified TB case-finding, especially among drug users with HIV who are at particular risk of TB;
- test for TB among all drug users living with HIV and consider isoniazid preventive therapy for all those without active TB (see the section on preventing TB through isoniazid preventive therapy);
- implement an infection control plan for all service settings to reduce the risks of TB infection among people living with HIV and personnel; and
- promote continuity of care in a drug user's care package, including TB treatment and drug treatment, such as opioid substitution therapy.

Services for drug users and all other first access services

Services for drug users and all other first-access services should:

- be aware of the risk factors for HIV and TB in drug users and how to reduce these, such as providing access to needle and syringe programmes and cough hygiene;
- be aware of the symptoms of HIV and TB and how to investigate them;
- be aware of their local health services and promote all means to achieve equity of access for drug users to the required health services;
- implement an infection control plan for all service settings to reduce the risks of TB infection among people living with HIV and personnel (Annex 4); and
- actively promote ways to improve adherence to HIV or TB treatment among drug users.

Prisons and other places of detention

Background

Drug users are very likely to experience prison or other places of detention including compulsory detoxification and rehabilitation centres since non-prescribed opiates and amphetamine-type stimulants are illegal in almost all countries and criminal behaviour is linked with obtaining illicit drugs.

Key issues

Prisons and other places of detention are congregate settings where some of the most vulnerable drug users are exposed to some of the highest risks for TB and HIV coinfection while often having the least access to health care and the fewest resources in terms of political commitment and investment.

Summary of findings

Prisoners have a high risk of transmission of TB and HIV infections and a high rate of dual TB/HIV infection *(22,79,80)* for reasons such as the following *(22,32,80–82)*.

- They receive people who are more likely to already have TB and/or HIV infection.
- Prisoners are more likely to be infected by TB because of overcrowding, lack of natural ventilation, poor nutrition and poor infection control.
- Prisoners are less likely to have access to health care services for prevention and treatment.
- Prisons are a high-risk environment for becoming infected with HIV through injecting practices and sexual behaviour.

Multiple links between prisoners and general communities include high turnover and release of prisoners, millions of family visits per year and the movement of prison staff. Infection can therefore be transmitted in either direction. Treatment risks being discontinued on transfer into, out of and between places of detention. However, prison can also be an important site for initiating and providing effective antiretroviral therapy *(83)*.

Multidrug-resistant TB may be more common in prison settings in some countries, particularly in the countries in the Commonwealth of Independent States, where rates of multidrug-resistant TB are among the highest in the world and are higher among prisoners *(22)*.

Several WHO guidelines and manuals have recommendations for preventing and treating both TB *(32)* and HIV *(30)* among prisoners.

Recommendation 11

Medical examination upon entry and any time thereafter, conforming to internationally accepted standards of medical confidentiality and care, should be available for all prisoners. Prisoners should obtain health care equivalent to that provided for the civilian population, and care should be continuous on transfer in and out of places of detention.

Health service providers should be aware of the ongoing risk of HIV and TB in the context of drug use and mental health problems among prisoners and should offer regular screening and health services to address these.

The existing guidelines on HIV and TB in prisons should be implemented for all drug users in prison, with special consideration that drug users are likely to be at even higher risk than other prisoners.

Infection control is particularly important, and all places of detention should have an infection control plan, including policies for ventilation, screening and separating prisoners with infectious TB.

Prison health care should be considered as part of the public health care system.

There should be mechanisms in place to ensure equivalence and continuity of care on transfer into, out of and between places of detention and the civilian health care sector.

National TB and HIV control programmes should cover prison settings. In particular, access to national drug treatment protocols and national prevention strategies should be fully integrated into the prison health system *(84)*.

Prison health should be integrated into wider community health structures, and responsibility for managing and providing prison health services should be assigned to the same ministries, departments and agencies providing health services to the general population. If this cannot be achieved in the short term, action should be taken to significantly improve cooperation and collaboration between prison health services.

Adherence

Background

Treatment for TB and HIV is highly effective, but drug users have not derived the most benefit. This loss of benefit is related to lifestyle issues and the reluctance of physicians to initiate therapy based on their prediction of poor adherence. Evidence increasingly indicates that adherence interventions targeting drug users can result in treatment completion rates as good as those for other people. Poor adherence leads to the development of drug resistance, and this may soon be seen as a failure not primarily of the drug user but of the health system to provide appropriate adherence interventions.

Key issues

There is a common perception that drug users do not adhere to therapy, but active drug use is not a valid reason for denying access to treatment and care. Nevertheless, programmes must be available to support drug users. For example, sometimes drug users cannot enter drug rehabilitation unless they can prove they do not have TB. At the same time, people with TB may not be allowed to use drugs (and are often not offered health care assistance for withdrawal) in TB hospitals, threatening treatment adherence (Open Society Institute, New York, USA, personal communication in response to guideline consultation, May 2008).

Summary of findings

A literature search was carried out to identify studies that examined adherence to pharmaceutical therapy for HIV, TB and opiate substitution therapy among drug users (see Annex 2 for search strategy).

Injecting drug users, in particular, have increased risks of morbidity, mortality and antiretroviral drug resistance *(23,84)*, poor access to health care and poor adherence to antiretroviral therapy *(85)* and to TB treatment *(86)*.

Drug users engaged in stable care with experienced personnel and adequate support can adhere to long-term treatment and can have clinical outcomes comparable to those of people who do not use drugs.

Barriers to adherence vary between settings, so services should consult with users and their representatives first to find the most effective ways to overcome them and the best local solutions. Evidence indicates effectiveness for adherence reminders, adherence counselling, contingency management, supervised therapy, opioid substitution therapy and ancillary services.

Adherence reminders are usually inexpensive and include beepers, alarms, timers and watches, blister packs, pill boxes and calendars. They may be useful for people for whom a major reason for missed doses is "forgetting", but they have little impact.

Evidence is mixed for the effect and persistence of the benefits of adherence counselling. One reason is that interventions are heterogeneous, ranging from high-cost cognitive behavioural interventions delivered by professionals to peer-led support *(87–90)*.

Contingency management means that participants are rewarded for positive health behaviour and sanctions are imposed for negative health behaviour. Such interventions may take the form of direct financial compensation, token economy systems such as vouchers, positive reinforcing medications (most commonly methadone) and material incentives (such as bus tokens or electronic items). Community-based directly observed isoniazid preventive therapy with cash incentives showed 89% completion rates *(91)*. The use of financial incentives in the United States of America and Canada has substantially increased compliance with TB screening and adherence to TB treatment among injecting drug users *(92,93)*, although questions of ethics (using payments to buy drugs) and sustainability are associated with this approach. Costs are usually high and the effect can be short-lived *(94,95)*.

Supervised therapy: the introduction of directly observed therapy for isoniazid preventive therapy in injecting drug users led to a reduction in the incidence of latent TB in a prospective observational study *(96)*. A randomized trial in the United States of America showed that supervised care for isoniazid preventive therapy had 80% completion rates *(97)*. Opioid substitution therapy in voluntary settings has been shown to improve relapse to opioid use, decrease recidivism, improve adherence to antiretroviral therapy for people living with HIV and decrease HIV risk-taking behaviour *(89,98,99)*.

Providing methadone with directly observed therapy for latent TB infection, with or without counselling, was associated with a four-fold improvement of isoniazid treatment completion *(55)*, and providing isoniazid preventive therapy for TB infection and directly observed therapy in methadone maintenance clinics has been shown to be a cost-effective approach to preventing TB *(100,101)*.

Ancillary services: complex factors such as social stability, education, housing situation and socioeconomic status can impact adherence. Services may include provision of primary care, social services or general friendship and social support that help to provide some level of lifestyle stability and may improve adherence. Co-location of multiple services, particularly for drug users, has been shown to result in improved health outcomes in the United States of America *(57,102)*. Social support has been associated with improved outcomes in directly observed therapy programmes for treating TB in Thailand and New York City *(103,104)*.

Recommendation 12

There should be specific adherence support measures for drug users to ensure the best possible treatment outcomes for TB and HIV infection and to reduce the risk of development of drug resistance and the risk of transmission to other people.

Common types of comorbidity

Background

The stigma against drug users in a sometimes abusive and criminalizing environment may encourage health care services to cite comorbidity as an excuse not to provide life-saving treatments to drug users. These treatments may also prevent infections from being transmitted to other people.

Key issues

There are particular concerns about hepatitis C infection leading to reluctance to start treatment for drug users.

Summary of findings

Many studies have demonstrated the high prevalence of comorbidity, especially viral hepatitis B and viral hepatitis C among injecting drug users. The prevalence of hepatitis C among injecting drug users in many countries, such as Brazil, Canada, China and the United States of America, approaches 100% *(105–108)*.

Although there are few data on the prevalence of coinfection of HIV and TB with hepatitis B or hepatitis C in drug users, this can be expected to occur in a significant proportion, particularly injecting drug users. Some studies have started to address the potential challenges of comorbidity. For example, a study of isoniazid-associated hepatotoxicity among people coinfected with hepatitis C virus showed no increased risk of transaminase elevation or drug discontinuation *(109)*.

Neither medication for TB nor antiretroviral therapy are contraindicated among drug users who have hepatitis B or hepatitis C *(36,50,53,110)*. Existing WHO guidelines provide recommendations on treatment modifications and monitoring in the presence of acute and chronic hepatitis infection *(50,110)*.

Recommendation 13

Comorbidity, including viral hepatitis infection (such as hepatitis B and C), should not contraindicate HIV or TB treatment for drug users. Alcohol dependence, active drug use and mental health problems should not be used as reasons to withhold treatment.

Many types of comorbidity such as mental health problems, hepatitis and ongoing illicit drug use may require increased health care supervision, and global, regional or national clinical guidelines should be followed in managing comorbidity.

WEB LINKS TO POLICIES, GUIDELINES AND MANUALS

Title	Web link
WHO: *The Stop TB Strategy*	http://www.who.int/tb/strategy/stop_tb_strategy/en/index.html
WHO: *Treatment of tuberculosis: guidelines for national programmes*	http://www.who.int/tb/publications/cds_tb_2003_313/en
WHO: *Interim policy on collaborative TB/HIV activities*	http://www.who.int/hiv/pub/tb/tbhiv/en
WHO: *A guide to monitoring and evaluation for collaborative TB/HIV activities: field test version*	http://www.who.int/hiv/pub/prev_care/tb_hiv/en
WHO: *Management of collaborative TB/HIV activities: training for managers at the national and subnational levels*	http://www.who.int/tb/publications/who_htm_tb_2005_359/en/index.html
WHO: *Guidelines for the prevention of tuberculosis in health care facilities in resource-limited settings*	http://www.who.int/tb/publications/who_tb_99_269/en/index.html
WHO and United States Centers for Disease Control and Prevention: *Tuberculosis infection control in the era of expanding HIV care and treatment. Addendum to WHO* Guidelines for the prevention of tuberculosis in health care facilities in resource-limited settings	http://www.who.int/tb/publications/who_tb_99_269/en/index.html
TB/HIV Working Group of the Global Partnership to Stop TB and UNAIDS/WHO Working Group on Global HIV/AIDS/STI Surveillance: *Guidelines for HIV surveillance among tuberculosis patients*	http://www.who.int/hiv/pub/tb/guidelines/en/index.html
WHO and the International Committee of the Red Cross*: Tuberculosis control in prisons: a manual for programme managers*	http://whqlibdoc.who.int/hq/2000/WHO_CDS_TB_2000.281.pdf
WHO Health in Prisons Project (WHO Regional Office for Europe*)* WHO Regional Office for Europe: *Status paper on prisons and tuberculosis*	http://www.euro.who.int/prisons http://www.euro.who.int/prisons/publications/20050610_1
WHO: HIV and prisons web site	http://www.who.int/hiv/topics/idu/prisons/en/index.html
WHO: *Tuberculosis care with TB-HIV co-management*	http://www.who.int/hiv/capacity/TBHIV/en/index.html
WHO: *Guidelines for the programmatic management of drug-resistant tuberculosis*	http://www.who.int/tb/publications/2006/who_htm_tb_2006_361/en/index.html
WHO guidance on the management of substance abuse	http://www.who.int/substance_abuse/en/index.html
WHO: *Policy and programming guide for HIV/AIDS prevention and care among injecting drug users*	http://www.who.int/hiv/pub/idu/iduguide/en

Title	Web link
WHO: *Antiretroviral therapy for HIV infection in adults and adolescents in resource-limited settings: towards universal access. Recommendations for a public health approach*	http://www.who.int/hiv/pub/guidelines/adult/en/index.html
WHO: *Antiretroviral therapy of HIV infection in infants and children: towards universal access. Recommendations for a public health approach*	http://www.who.int/hiv/pub/guidelines/art/en
WHO and UNAIDS: *Guidelines for provider-initiated HIV testing and counselling in health facilities*	http://www.who.int/hiv/pub/guidelines/pitc2007/en/index.html
WHO: Evidence for Action Series on HIV/AIDS and injecting drug use – five policy briefs and seven technical papers	http://www.who.int/hiv/pub/idu/idupolicybriefs/en/index.html
WHO web page on HIV prevention, treatment and care for injecting drug use and prisons	http://www.who.int/hiv/topics/idu/en/index.html
WHO: *Scaling-up HIV testing and counselling services: a toolkit for programme managers*	http://www.who.int/hiv/topics/vct/toolkit/en
Eramova I, Matic S, Munz M, eds. (WHO Regional Office for Europe): *HIV/AIDS treatment and care: clinical protocols for the WHO European Region* 13 protocols, including *Management of tuberculosis and HIV coinfection, HIV/AIDS treatment and care for injecting drug users* and *Management of hepatitis C and HIV coinfection*	http://www.euro.who.int/InformationSources/Publications/Catalogue/20071121_1
UNAIDS: *Practical guidelines for intensifying HIV prevention: towards universal access*	http://data.unaids.org/pub/Manual/2007/20070306_Prevention_Guidelines_Towards_Universal_Access_en.pdf
Preventing HIV infection among injecting drug users in high-risk countries an assessment of the evidence	by Institute of Medicine (U.S.). Committee on the Prevention of HIV Infection Among Injecting Drug Users in High-Risk Countries.; National Academies Press (U.S.)

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ANNEX 1

DEFINITIONS OF DRUG USE ACCORDING TO THE 10TH REVISION OF THE INTERNATIONAL CLASSIFICATION OF DISEASES

F.11 Harmful use A pattern of psychoactive substance use that is causing damage to health. The damage may be physical (as in cases of hepatitis from the self-administration of injected psychoactive substances) or mental (e.g. episodes of depressive disorder secondary to heavy consumption of alcohol).

F.12 Dependence syndrome A cluster of behavioural, cognitive and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance and sometimes a physical withdrawal state.

The dependence syndrome may be present for a specific psychoactive substance (e.g. tobacco, alcohol or diazepam), for a class of substances (e.g. opioid drugs) or for a wider range of pharmacologically different psychoactive substances.

Chronic alcoholism

Dipsomania

Drug addiction

Both of these definitions have subgroups, of which the following were included:

- Mental and behavioural disorders due to use of opioids
- Mental and behavioural disorders due to use of cocaine
- Mental and behavioural disorders due to use of hallucinogens
- Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

  This category should be used when two or more psychoactive substances are known to be involved, but it is impossible to assess which substance is contributing most to the disorders. It should also be used when the exact identity of some or even all the psychoactive substances being used is uncertain or unknown, since many multiple drug users themselves often do not know the details of what they are taking.

  Includes: misuse of drugs NOS [not otherwise specified]

ANNEX 2

METHODS

Steering Group

WHO established the Steering Group in 2005 and expanded it in 2007 to include representatives from all the relevant departments. It also included representatives from the partner organizations within the United Nations: UNAIDS and UNODC.

Scoping

The Steering Group produced an initial discussion document on injecting drug use and TB/HIV, reviewing all of the abstracts identified by the initial literature search (as described below) and selecting the articles they considered to be most relevant. This document was circulated for comments to a Reference Group, which included the members of the working group on TB/HIV of the Stop TB Partnership, WHO staff and experts in the fields of drug use, tuberculosis and HIV. The Steering Group identified the members through existing networks.

An initial literature search was carried out using PubMed with the following key words: "**tuberculosis** OR **TB** AND **injecting drug users** OR **IDUs**", "**HIV** OR **HIV/AIDS** OR **AIDS** AND **injecting drug users** OR **IDUs**", "**tuberculosis** OR **TB** AND **HIV** OR **HIV/AIDS** OR **HIV** AND **injecting drug users OR IDUs**". The main scope of the search and further classification of all literature found was summarized in the following themes that ref ected the initial outlines of the draft document, which were developed and agreed on through a series of consultations with teams from the WHO Stop TB Department and Department of HIV/AIDS. The themes were:

(1) epidemiology of HIV/AIDS, TB and TB/HIV in injecting drug users:
- HIV epidemic in injecting drug users
- TB epidemic in injecting drug users
- TB/HIV epidemic in injecting drug users
- associated risk factors for HIV, TB and TB/HIV in injecting drug users;

(2) pathogenesis and clinical picture of TB/HIV in injecting drug users: main patterns and particularities;

(3) existing evidence on specialized services (prevention, treatment and care) delivery in:
- injecting drug users
- TB
- HIV
- TB/HIV; and

(4) areas of particular concern:
- multidrug-resistant TB in injecting drug users
- TB preventive therapy in injecting drug users
- hepatitis C and B and TB in injecting drug users
- congregating settings and TB and HIV in injecting drug users
- adherence to TB and HIV treatment in injecting drug users.

Based on the feedback from the Reference Group, the membership of the Steering Group was expanded and the scope revised to update and expand on the original scope. The Steering Group then reviewed the abstracts, selecting and obtaining the full articles of the studies considered to be the most relevant.

Question posed:
What is needed to achieve adherence to and successful outcomes in intravenous (injecting) drug users treated with TB/isoniazid preventive therapy/highly active antiretroviral therapy (antiretroviral therapy). (Note: areas we know about include incentives, directly observed therapy, co-location of services and combining with substitution therapy.)

Sent on: Tue Oct 23 08:09:35 2007

("Isoniazid"(Mesh) OR "Isonicotinic"(All Fields) OR "Isonex "(All Fields) OR "Phthivazide "(All Fields) OR (("isoniazid"(TIAB) NOT Medline (SB)) OR "isoniazid"(MeSH Terms)) OR "Tubazide"(All Fields)) AND "Tuberculosis/prevention and control"(Mesh) OR ("Tuberculosis/diet therapy"(Mesh) OR "Tuberculosis/drug therapy"(Mesh) OR "Tuberculosis/radiotherapy"(Mesh) OR "Tuberculosis/rehabilitation"(Mesh) OR "Tuberculosis/therapy"(Mesh)) AND ("Substance Abuse, Intravenous"(Mesh) OR "Intravenous Substance Abuse "(All Fields) OR "Parenteral Drug Abuse"(All Fields) OR "Intravenous Drug Abuse "(All Fields) OR "IV Drug Users"(All Fields) OR "heroin users"(All Fields)) AND "humans"(MeSH Terms)

96 references found.

What is the evidence that provision of isoniazid preventive therapy has reduced the incidence of TB disease in intravenous (injecting) drug users overall and in subgroups (HIV positive, anergic, tuberculin positive and tuberculin negative)?

Sent on: Tue Oct 23 07:59:24 2007

("Substance Abuse, Intravenous"(Mesh) OR "Intravenous Substance Abuse" OR "Parenteral Drug Abuse" OR "Intravenous Drug Abuse" OR "IV Drug Users" OR "heroin users") AND (("Morbidity"(Mesh) AND "tuberculosis" (Mesh)) OR "Tuberculosis/epidemiology"(Mesh)) AND ("Isoniazid"(Mesh) OR "Acid Hydrazide Isonicotinic" OR "Isonex" OR "Phthivazide " OR "Ftivazide" OR "Tubazide")

17 references found.

Further evidence was then retrieved as follows:

1. a search of the grey literature and relevant web sites;
2. the expert opinion of WHO Steering Group members through having worked in this field;
3. evidence from WHO regional and country offices;
4. Frederick Altice carried out a literature search for adherence and drug users in March 2008:
   a. PubMed, Google Scholar, PsychInfo, OVID, and Scopus databases were searched;
   b. studies about adherence to pharmaceutical therapy for HIV, TB and opiate dependence among drug users;
   c. search terms included, in various permutations: drug users, adherence, compliance, substance use, substance users, drug use, drug users, illicit drug use, injection drug use, injection drug users, HIV, tuberculosis, opiate dependence, opiate use;
   d. these searches were supplemented by reviews of pertinent additional articles found, official documents and government sites that were obtained during the research phase.
   e. inclusion criteria included the following, described in the PICOT (population, intervention, comparison, outcome and type of study) framework: 1) a population consisting of any study globally consisting solely of drug users who met the definition of harmful use of an illicit substance in the 10th revision of the International Classification of Diseases; 2) interventions defined by some programme or strategy aimed at modifying adherence to pharmaceutical therapy for HIV, TB or opiate dependence; 3) a control group comprising a similarly defined population of drug users who received some other or no intervention (randomized controlled trials, nonrandomized controlled trials and longitudinal cohort studies); 4) outcomes consisting of at least one objective measure of adherence or a pertinent biological outcome; and 5) a time period defined at least through three months subsequent to the start of the intervention. In addition, the study had to have at least 20 subjects in the intervention arm and had to be published in English in a peer-reviewed journal.

After further revisions incorporating feedback from the Reference Group and an updated review of the published literature, the Steering Group produced draft recommendations.

Guideline Group

The Guideline Group included the members of the Steering Group and external experts. The Steering Group selected the experts on the advice of TB, HIV and drug use specialists within WHO, UNODC and UNAIDS regional offices and colleagues from other organizations. The selection took into account regional representation, gender balance, areas of expertise (service delivery, research and policy development), topics of expertise (substance misuse, HIV and TB) and representatives of potential stakeholders and civil society.

The Guideline Group met in November 2007 in Copenhagen, Denmark.

Development of the recommendations

The Guideline Group considered the evidence retrieved and summarized at a meeting in November 2007 where draft recommendations were presented and discussed. Recommendations were explicitly linked to the evidence for each section, with the supporting references provided.

The Guideline Group reviewed the draft recommendations and advised on:

- whether these recommendations addressed the policy needs;
- what additional questions should be addressed; and
- which important and/or controversial recommendations would benefit from further evidence retrieval and analysis.

One gap was identified in the evidence, and the Guideline Group requested a further literature search on adherence (as described above). The Guideline

Group subsequently agreed on the recommendation on adherence support measures by electronic communication.

Peer review

The draft guidelines were finalized in the light of the advice from the Guideline Group, which then agreed on them. They were then circulated for review to the Reference Group.

Stakeholder consultation

The final draft guidelines were circulated by e-mail to the individuals and organizations on the following mailing lists:

- WHO HIV Help Desk;
- UNAIDS country staff and personal networks;
- members of the TB/HIV working group of the Stop TB Partnership;
- the UNODC mailing list;
- a personal network of the WHO Substance Abuse Department;
- a personal network on harm reduction within the WHO Department of HIV/AIDS; and
- national TB control programme managers in all countries.

This was probably more than 500 individuals and organizations, although as the process included a cascade request, it is not possible to say how many were reached. A large proportion is in the civil society sector.

Responses were received from more than 30; Annex 5 provides a summary.

The Steering Group agreed on the final guidelines in June 2008, which are being distributed as a joint publication of UNODC, WHO and UNAIDS.

ANNEX 3

RESEARCH QUESTIONS IDENTIFIED TO STRENGTHEN THE EVIDENCE FOR THE UPDATE OF THESE GUIDELINES

Recognizing the need to generate new evidence in these areas, the Expert Consultation on TB/HIV Research Priorities in Resource-limited Settings on 14–15 February 2005[1] identified TB/HIV in injecting drug users as a special area for operational research and proposed the following research priorities:

- delivery of TB/HIV services within the context of a harm reduction programme, including substitution therapy;
- delivery of isoniazid preventive therapy for injecting drug users in settings with a high level of isoniazid primary resistance and a high prevalence of hepatitis B and hepatitis C;
- administration of antiretroviral therapy to injecting drug users living with HIV coinfected with TB;
- addressing the associated stigma in the context of injecting drug users coinfected with TB/HIV;
- delivery of TB/HIV health care and treatment to incarcerated injecting drug users;
- the complex interactions between anti-TB drugs, drugs for HIV treatment and illicit drugs and their substitutes, particularly within the context of hepatitis B and C coinfection, including the need to develop expertise in identifying and managing these drug reactions to optimize treatment in the target population;
- there are no data on antiretroviral therapy delivery in TB-infected injecting drug users or in injecting drug users with active TB who are also living with HIV, and evidence needs to be developed on the safe use of antiretroviral therapy among injecting drug users living with HIV who are also TB-infected and particularly among those who are coinfected with hepatitis B or C;
- isoniazid preventive therapy delivery in settings with high primary resistance to isoniazid: >10%;
- isoniazid preventive therapy delivery among injecting drug users coinfected with hepatitis B and/or C;
- using incentives to increase compliance with TB screening and adherence to treatment and impact on service provision to other groups of people; and
- stigma as a barrier to service delivery and methods of reducing it.

The Guideline Group also generated several questions for further research.

Epidemiology

What is the relative risk of TB among:

- non-injecting drug users?
- crack, cocaine and opiate smokers?
- all problematic users?
- people who are living with HIV and those who are HIV-negative?

What are the confounders:

- Homelessness? Poverty? Mental health problems?

What are the particular characteristics of different countries:

- India, Pakistan, Nepal; other large Asian countries with high prevalence TB/HIV and also growing injecting drug use?

What is the impact of TB in drug users on the general population?

Establish numbers for the denominator for injecting drug users:

- baseline population of drug users;
- baseline rates of injecting drug use; and
- TB and HIV rates in background population and in drug users.

Multidrug-resistant TB

- What are the rates of multidrug-resistant TB and extensively drug-resistant TB (resistance to isoniazid and rifampicin plus any fluoroquinolone and at least one of three injectable second-line drugs (capreomycin, kanamycin and amikacin)) among drug users relative to the background population?
- Do drug users have lower rates of adherence in settings with high rates of multidrug-resistant TB?
- Is there an association between drug use and multidrug-resistant TB?

1 *TB/HIV research priorities in resource-limited settings: report of an expert consultation, 14–15 February 2005*. Geneva, World Health Organization, 2005 (http://www.who.int/hiv/pub/tb/tb_hiv/en, accessed 27 June 2008).

- What proportions of the civilian population outside and drug users inside prison have multidrug-resistant TB?

Service delivery

What is the evidence for health care delivery models?

- What are specific barriers or issues for women drug users?
- In different delivery systems?
- In different settings, such as in the criminal justice systems?

What is the best way to deal with drug users released from prison who may disappear into the community?

Adherence

What are the effective and cost-effective methods to promote adherence?

- The evidence is currently from high-income countries; what has worked in other countries?

Transmission of TB

- What happens when there is ongoing repeated exposure in congregate settings?
- What are the risks and the effective solutions:
  - In health care settings?
  - In services for drug users?
- What is the additive effect of HIV, TB and drug use in the prison setting?
- What is the frequency of reinfection on re-exposure?
- Are there particular strains of TB that cause superinfection?
- What are the most effective ways to protect health care workers and other personnel in health care and criminal justice settings?

Old data and evidence exist from the early days of TB research:

- Can useful answers be found in these?

What are the most effective advocacy interventions?

What is best policy and practice for prisons?

- What proportion of drug users maintains treatment on entry to prison and on release or transfer?
- What is best practice in alternatives to custody for drug users with TB/HIV?
- What proportion is followed up and completes treatment and what are the treatment outcomes? (TB diagnosis is collected fairly reliably – is it underdiagnosed in prison?)
- What is the best prison release practice – how should it best be integrated with TB/HIV programmes and services for drug users?
- Good opportunity for treatment in prison, but how can continuity be ensured?
- What is the current practice if prisoners are terminally ill – is there an incentive for prisons to discharge if they are monitored on mortality rates?

ANNEX 4

INFECTION CONTROL ACTIONS

Stop TB Partnership TB HIV World Health Organization

Essential Actions for Effective TB Infection Control Safety without stigma*

Transmission of TB is a recognized risk in health care facilities and communities, especially in resource-limited settings where transmission is facilitated by inadequate TB infection control measures. The impact of the human immunodeficiency virus (HIV) epidemic, the increasing importance of multidrug-resistant tuberculosis (MDR) TB, and the emergence of extensively drug-resistant (XDR) TB have heightened concern about TB transmission and increased the urgency to focus on TB infection control. These 10 essential actions can be taken immediately to prevent TB transmission in health care facilities and in the community.

1.Include Patients and Community in Advocacy Campaigns
The community should be well-educated about TB infection, prevention and control. Patients should understand that they should know their TB status, may be eligible for isoniazid preventive therapy (IPT) and have a right to rapid TB diagnosis and treatment. They should know that TB can be spread by coughing and expect health care settings and community services to require persons coughing to cover their mouths when coughing. They should understand that health care workers (HCWs) may wear personal respiratory protection sometimes or that they may be asked to wear a mask to protect others. Safety without stigma should be the goal--a request to wear a mask or provide a sputum outside, or in a well ventilated room should not be stigmatizing but is part of a safer clinic for everyone. Patient and HCW safety may include receiving health care in the community to avoid unnecessary admissions to health care facilities. Information, education, and communication (IEC) campaigns should include themes such as "Our community is TB-Safe" or "Our health facilities are stopping TB."

2.Develop an Infection Control Plan
All facilities should have an infection control (IC) plan and a facility person or team responsible for IC. The plan identifies high risk areas for TB transmission and provides information on TB and HIV rates among health care workers and patients. The plan provides area-specific infection control recommendations for the facility including the laboratory which should have its own specialized standard safety procedures.

3. Ensure Safe Sputum Collection
Collecting and processing sputum are an essential part of the diagnosis of TB. Sputum collection can be potentially hazardous for health care workers and other patients-- HCWs should explain to patients that safety without stigma is the goal of good TB infection control and that sputum be collected outside (if feasible) or if necessary, in specially designed rooms with adequate ventilation.

4. Promote Cough Etiquette and Cough Hygiene
Every facility should have a poster on TB infection control and cough etiquette in at least the outpatient department waiting area, admissions area, and casualty department. Patients should be instructed to cover their mouths and nose when coughing, with hands, cloth such as handkerchief, clean rag, tissues, or paper masks. All staff are responsible for safety and should work together to help patients adhere to this practice.

5. Triage TB suspects for "fast-track" or separation
All patients should be screened upon arrival for chronic cough (i.e. >2-3 weeks), fever, weight loss, night sweats, haemoptysis, or contact with a person with TB. HCWs should explain to all clinic visitors that safety without stigma is the goal and that the screening is part of quality care. Patients should understand that they should know their HIV status, may be eligible for IPT and have a right to rapid TB diagnostic services and treatment. Persons suspected of having TB should be "fast-tracked" for rapid diagnosis and care services or should be asked to wait near an open window or in a comfortable area separate from the general waiting room (outside when possible).

Whenever possible, community-based treatment models should be encouraged. Where there are in-patient settings, TB suspects should be placed in a room or area separate from general wards. Patients with known or suspected drug-resistant TB should be separated from general ward patients and from other TB suspects.

6. Assure Rapid Diagnosis and Initiation of Treatment

Patients suspected of having TB should move to the front of the queue for all services and should undergo prompt evaluation for TB. Sputum collection should be done away from other people. Sputum specimens are sent to a quality-assured laboratory for AFB smear and culture (when possible). Turn-around time for sputum AFB (acid-fast bacillus) smear results should be no more than 24 hours. A patient-tracking system assures that TB suspects who are AFB smear-negative receive additional procedures (e.g. chest x-ray and referral visits) or treatment as quickly as possible. DOTS treatment for TB begins immediately when a diagnosis of TB is made, and a plan for assuring adherence with treatment is developed. All people with HIV who are not TB suspects should be eligible for initiating IPT.

7. Improve Room Air Ventilation

Patient waiting areas should be open and well-ventilated. Windows and doors should remain open when possible, to maximize cross ventilation. Appropriately placed simple fans can assist ventilation. Where weather permits, open-air shelters with a roof to protect patients from sun and rain are recommended. Patients should not wait for services in narrow, poorly ventilated corridors. Hospitals where patients with drug-resistant TB receive care should provide separate patient wards or rooms, preferably with good ventilation. New buildings and renovations should consider TB infection control as integral to the building plans.

8. Protect Health Care Workers

Health care workers should know the symptoms of TB and be given a health assessment including screening for TB and HIV, at least annually. All HCWs are encouraged to know their HIV status and those with HIV infection should be given the opportunity to minimize exposure to persons with TB, e.g. offered a change of duties. HIV-infected HCWs should be screened for isoniazid preventive therapy as part of basic HIV care and treatment. Health care workers working in high-risk settings for transmission of TB (e.g. bronchoscopy suites) should be provided with appropriate personal respiratory protection.

9. Capacity Building

Training on TB infection control practices should be incorporated into the broader infection control trainings at hospitals and facilities (e.g. hand washing, other respiratory, and bloodborne infection control trainings). Where no such trainings exist, trainings on airborne TB infection control practices should be developed. Infection control practices require a system-wide approach, and health care workers at all levels should receive training and be engaged in improving their own and patient safety.

10. Monitor infection control practices

Supervision of infection control practices should be a part of every supervisory visit. This should include a facility tour to check that IC is being implemented and that all essential supplies for IC are available. At the very least, facilities should have an IC plan. Where feasible, monitoring annual TB cases among HCWs can also provide useful information on transmission of TB in facilities. Surveillance of TB disease among HCWs is another means of evaluation. Additional on-site measures include examining medical records of a sample of TB patients looking at the time interval from admission to suspicion of TB, suspicion of TB to ordering sputum for AFB, time from ordering to collection of sputum, collection of sputum to reporting of results, to initiation of TB treatment and interviewing patients to discuss understanding of infection control, safety and stigma.

**These ten essential actions are based on current WHO policy and are issued to help facilities implement IC interventions while waiting for the revised WHO policy on TB IC which will be available by the end of 2008. See http://www.who.int/tb/en/ http://www.who.int/topics/hiv_aids/en/ or and http://www.stoptb.org/wg/tb_hiv/tbics.asp for more information.*

Developed by the TB Infection Control Subgroup of the Global TB/HIV Working Group in collaboration with the HIV/AIDS and Stop TB Departments at WHO.

ANNEX 5

STAKEHOLDER CONSULTATION

Two members of the Steering Group reviewed the responses from the consultation. The text of the guidelines was adjusted where suggestions for clarifications were made, and the Steering Group agreed on the final guideline in June 2008. None of the recommendations was altered. Each respondent was contacted to explain that suggestions would be helpful for the implementation process and would also be used in the review of the guideline in 2012 suggested by the WHO Guidelines Review Committee.

General comments

The guidelines address an important problem and are very much needed. They need still some improvement both in content and in language.
Useful and comprehensive guidelines. Guidelines concerning environmental aspects in prisons could be strengthened. Emphasis on prison health as part of public health, quality and continuity of care of TB/HIV patients after release from prison. The *Status paper on prisons and TB* of the WHO Health and Prisons Project should be used and mentioned as a resource.
This is an appropriate policy document at the right time to fill the gap in the care of injecting drug users.
Useful guidance for organizing activities reducing TB- and HIV-related outcomes among drug users.
Readable, well structured, good-quality document. Criminal justice and prison issues are well worked into the text.
This is well researched and captures areas that pertain to injecting drug users and TB/HIV.
1. Given the significance of prisons for TB and HIV and drug users, it is suggested that the topic be brought forward in the text from the last page and that prisons be profiled in the chapter on epidemiology. 2. As the primary diagnostic step for a TB-positive patient in HIV is testing, it is suggested that guidance on diagnosis on both HIV and TB be included, with HIV testing clearly profiled for HIV.
1. The College welcomes the opportunity to respond to the joint WHO, UNODC and UNAIDS consultation on draft policy guidelines for collaborative TB and HIV services for injecting and other drug users. 2. We are broadly supportive of this document but feel it may have greater relevance in other countries.

The reasoning for not covering certain drugs is not well documented or justified. Tobacco would have to be included, at least, as well as other drugs that do lead to dependence. If there is no evidence that dependence on certain drugs does not have a link with HIV/TB (such as cannabis, if that's the case), then there would be a justification to exclude them. It seems that the guide really wants to address injecting drug users, so it would be clearer to do just that, instead of trying to be inclusive but providing insufficient evidence to exclude certain drugs and modes of use. In addition, drug use is being mixed with drug use disorders, which I believe are more the scope of these guidelines. This needs to be clear and the term should be used whenever possible. Drug use is also not a diagnostic category and can lead to other misunderstandings in terms of the target group of these guidelines. It is not only a matter of scope; there are certain concepts that need to be clarified in this version. "Drug use" cannot be used to mean use in a dependent or harmful way only, as it is not compatible with all that WHO has been saying over the past 50 years. Actually, drug use per se is not a problem in the framework of WHO, so we can't use the same term to mean exactly the opposite extreme of consumption…

The guidelines will be useful for the aimed population. However, if we consider prison conditions, I think it is very important to make better cooperation between health centre in prison and health service in the community, and it should be done at the national level as well in accordance with the law. The guidelines can be useful also on the regional level. A plan for forming teams that would educate prison staff members about HIV and TB prevention would be very useful and also could be arranged on the regional level.

To my mind, it is fortunate that a document like this one will exist.

Providing some examples would be good. Also, the publication would be easier to read if there would be other titles than "Recommendation 1 to x" but more specific headlines.

It also would be fine if people or bodies that usually are responsible for an area (e.g. health planning in prison: health ministry, justice ministry) could be named, in order to at least mention those who should be addressed. Otherwise, the document would be a little bit vague.

Was there any reason to omit hepatitis B and C prevention? Is there any other guideline regarding viral hepatitis B and C?

(I thought WHO would be an institution capable to present an integrated, comprehensive approach.) In case there is already another document regarding hepatitis, a link should be provided.

Too general, with most of the recommendations already in place in many countries. Nothing new or specific that can make these guidelines used by countries. Difficult to see what specific or different you are proposing for injecting drug users from other drug users.

Thanks for involving us for feedback on these important and immensely helpful policy guidelines.
Greatly improved compared to previous version(s). There are still some areas that are not (yet) sufficiently addressed.

Reader friendly, reasonable volume, good coverage.

Thank you for the opportunity to provide feedback for the draft "Policy guidelines for collaborative TB and HIV services for injecting and other drug users".

The National Drug Research Institute (NDRI) acknowledges the need for policy guidelines such as those proposed in reducing the morbidity and mortality associated with combined HIV and TB infections among injecting and other drug users. We further agree that a coordinated response is needed to respond to the needs of injecting drug users to provide access to prevention, treatment and care services equal to those available to the general community.

Australia is fortunate in having one of the lowest TB notification rates in the world (4.4 cases per 100 000 population) as well as a low prevalence of HIV among the country's injecting drug users (<2%). Australia is also fortunate in having a well-developed TB surveillance scheme which monitors new and relapsed cases of TB including the identification of drug-resistant cases. While there are higher rates of TB infection among Indigenous Australians, most are diagnosed among those aged 50 years or older and are associated with poor living conditions, overcrowding and poor nutrition rather than injecting drug use.

We commend WHO, UNODC and UNAIDS on producing these guidelines and agree in principle to the recommendations contained within it. However, given the situation in Australia with low rates of TB infections and low rates of HIV among injecting drug users, it is not appropriate for NDRI to comment further.

This report is welcome and its recommendations sensible, pragmatic and based on evidence. I would like to have seen a recommendation on the widespread introduction of needle and syringe provision in custodial settings.
I would like to thank you for the colossal job you have done. They are really useful guidelines, especially for countries with low incomes and lack of preventive programmes (like Albania). I'm looking forward to keeping in touch soon. The draft guidelines are a strategic document, and it would very useful for health care providers and people involved in HIV/TB preventive programmes, with a main focus on injecting drug users.

Because I found your draft of extreme relevance for my work in Viet Nam, where most HIV (and subsequently most TB/HIV cases) occur in injecting drug users, I went carefully through all of it and noted my comments in track changes mode. My previous exposure to injecting drug users has been mainly as clinician in an infectious disease department in Italy. During my service in hospital I have also been the consultant for infectious diseases in the local state prisons, dealing mostly with young injecting drug users detained for drug-trafficking and affected mostly by hepatitis B and C, only a minority by HIV. My experience with TB dates back to 1995. I worked 4 years in Ethiopia in an Italian TB project covering approximately 4 million people. I joined WHO as Medical Officer/Tuberculosis in 2002 and worked 2 years in Afghanistan, then 28 months in Uganda and now, since January 2007, in Viet Nam. Thanks for your interesting initiative and for involving people on the front line in your endeavour.
This is a relevant paper. I find it helpful, particularly regarding the horizontal integration of health services.
Well-written easy-to-read compilation of information and recommendations.
A potentially useful document, a very good start and in fact an area which deserves further attention; however, the purpose needs to be clearer, with a more focused target audience. It is very difficult to develop a document useful for managers and drug users likewise. The heading "findings" is misleading. Are these based on experts' opinion, common sense or evidence referring to the literature review? This is not clear and should be mentioned in the "Methods" section. On the other hand, some recommendations are too general and applicable to any other TB and HIV risk group. Unfortunately, the document does not provide practical country experiences; however, it provides a good summary of what is not known in the field of TB/HIV prevention and control among drug users and injecting drug users. It is obviously easier to comment than to contribute; however, the document certainly deserves further work until it can be called guidelines.
I think these guidelines are essential for management of TB/HIV in countries with a high burden of injecting drug users.

It was quite a document to plough through and technically I know zilch about TB. However, from a more general perspective I have the following comments on the document:

1. It claims to be written from a holistic or person-centred approach, but this would really need to be spelled out as it is not clear how it does this – if at all. Certainly not from the perspective of the drug user.
2. The stated target audience is so wide it includes almost everybody, from policy-makers to drug users! Probably better to set priorities among the various groups it claims to target, as it will meet some needs much better than others. For example, obviously drug users need something short, precise, bold and more user friendly about the TB/HIV–drug use links.
3. Think there has been a bit of cutting and pasting going on. Problem drug use is used sometimes, then substance misuse. Personally I think that in these instances consistency is needed.
4. The implication of the document is that the real key issue is health care workers, particularly doctors, working in HIV and TB need training and guidance on how to work positively and constructively with chaotic drug users, especially injecting drug users. This could be made much clearer with more concrete proposals.
5. Big question – will it be translated? Into which languages? If not then part of the main target audience will be lost.
6. Bigger question – the document provides some very good positive constructive ideas, but how do you implement these in an under-resourced health care system as in Afghanistan, or indeed a large part of the developing world? I always feel these types of documents are not always cognizant of the daily practical problems faced in such situations. Some pointers for different types/underfunded health care systems might be useful.
7. Quite a few typos, needs editing, such as p.16: "implantation" should be "implementation".

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