World Health Organization

GUIDELINES

CONSOLIDATED GUIDELINES ON

HIV PREVENTION, DIAGNOSIS, TREATMENT AND CARE FOR KEY POPULATIONS

JULY 2014

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ABBREVIATIONS AND ACRONYMS

3TC	lamivudine
ART	antiretroviral therapy
ARV	antiretroviral (drug)
AZT	zudovudine
EFO	efavirenz
FTC	emtricitabine
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HIVST	HIV self-testing
HPV	human papillomavirus
HTC	HIV testing and counselling
IPT	isoniazid preventive treatment
LPV/r	lopinavir/ritonavir
M&E	monitoring and evaluation
MAT	medically assisted treatment
MMT	methadone maintenance treatment
NNRTI	non-nucleoside reverse transcriptase inhibitor
NSP	needle and syringe programme
OST	opioid substitution therapy
PEP	post-exposure prophylaxis
PEPFAR	United States President's Emergency Plan for AIDS Relief
PI	protease inhibitor
PITC	provider-initiated testing and counselling
PMTCT	prevention of mother-to-child transmission of HIV
PPT	periodic presumptive treatment
PrEP	pre-exposure prophylaxis
RTV	ritonavir
STI	sexually transmitted infection
TB	tuberculosis
TB-MDR	multi-drug resistant tuberculosis
TDF	tenofovir
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNODC	United Nations Office on Drugs and Crime
VMMC	voluntary medical male circumcision
WHO	World Health Organization

DEFINITIONS OF KEY TERMS

Definitions used in this guideline are aligned with current consensus definitions used in the Global Health Sector Strategy on HIV/AIDS 2011–2015 *(1)* and by the United Nations, as described in the Joint United Nations Programme on HIV/AIDS (UNAIDS) *"*Guidance note on HIV and sex work*"(2)* and other relevant World Health Organization (WHO) and other United Nations documents.

Key populations are defined groups who, due to specific higher-risk behaviours, are at increased risk of HIV *irrespective of the epidemic type or local context*. Also, they often have legal and social issues related to their behaviours that increase their vulnerability to HIV. These guidelines focus on five key populations: 1) men who have sex with men, 2) people who inject drugs, 3) people in prisons and other closed settings, 4) sex workers and 5) transgender people. People in prisons and other closed settings are included in these guidelines also because of the often high levels of incarceration of the other groups and the increased risk behaviours and lack of HIV services in these settings. The key populations are important to the dynamics of HIV transmission. They also are essential partners in an effective response to the epidemic *(1)*.

Vulnerable populations are groups of people who are particularly vulnerable to HIV infection *in certain situations or contexts*, such as adolescents (particularly adolescent girls in sub-Saharan Africa), orphans, street children, people with disabilities and migrant and mobile workers. These populations are not affected by HIV uniformly across all countries and epidemics. These guidelines do not specifically address vulnerable populations, but much of the guidance can apply to them.

Men who have sex with men refers to all men who engage in sexual and/or romantic relations with other men. The words "men" and "sex" are interpreted differently in diverse cultures and societies and by the individuals involved. Therefore, the term encompasses the large variety of settings and contexts in which male-to-male sex takes place, regardless of multiple motivations for engaging in sex, self-determined sexual and gender identities, and various identifications with any particular community or social group.

People who inject drugs refers to people who inject psychotropic (or psychoactive) substances for non-medical purposes. These drugs include, but are not limited to, opioids, amphetamine-type stimulants, cocaine, hypno-sedatives and hallucinogens. Injection may be through intravenous, intramuscular, subcutaneous or other injectable routes. People who self-inject medicines for medical purposes – referred to as "therapeutic injection" – are not included in this definition. The definition also does not include individuals who self-inject non-psychotropic substances, such as steroids or other hormones, for body shaping or improving athletic performance. While these guidelines focus on people who inject drugs because of their specific risk of HIV transmission due to the sharing of blood-contaminated injection equipment, much of this guidance is relevant also for people who inject other substances.

People in prisons and other closed settings: There are many different terms used to denote places of detention, which hold people who are awaiting trial, who have been convicted or who are subject to other conditions of security. Similarly, different terms are used for those who are detained. In this guidance document, the term "prisons and other closed settings" refers to all places of detention within a country, and the terms "prisoners" and "detainees" refer to all those detained in criminal justice and prison facilities, including adult and juvenile males and females, during the investigation of a crime, while awaiting trial, after conviction, before sentencing and after sentencing. This term does not formally include people detained for reasons relating to immigration or refugee status, those detained without charge, and those sentenced to compulsory treatment and to rehabilitation centres. Nonetheless, most of the considerations in these guidelines apply to these people as well *(3)*.

People who use drugs include people who use psychotropic substances through any route of administration, including injection, oral, inhalation, transmucosal (sublingual, rectal, intranasal) or transdermal. Often this definition does not include the use of such widely used substances as alcoholic and caffeine-containing beverages and foods.

Sex workers include female, male and transgender adults (18 years of age and above) who receive money or goods in exchange for sexual services, either regularly or occasionally. Sex work is consensual sex between adults, can take many forms, and varies between and within countries and communities. Sex work also varies in the degree to which it is more or less "formal", or organized *(4)*.

As defined in the Convention on the Rights of the Child (CRC), children and adolescents under the age of 18 who exchange sex for money, goods or favours are "sexually exploited" and not defined as sex workers *(5)*.

Many individuals will relate to more than one key population. For example, some men who have sex with men and some transgender people may also engage in sex work and/or inject drugs.

Transgender is an umbrella term for people whose gender identity and expression does not conform to the norms and expectations traditionally associated with the sex assigned to them at birth; it includes people who are transsexual, transgender or otherwise gender non-conforming *(6, 7)*. Transgender people may self-identify as transgender, female, male, transwoman or transman, trans-sexual or, in specific cultures, as *hijra* (India), *kathoey* (Thailand), *waria* (Indonesia) or one of many other transgender identities. They may express their genders in a variety of masculine, feminine and/or androgynous ways. The high vulnerability and specific health needs of transgender people necessitates a distinct and independent status in the global HIV response.

Sexual risk differs among different subgroups within the transgender community. For example, sexual risk may be higher among transgender women (male to female) or transgender men (female to male) who have receptive anal intercourse with men than among transgender men or transgender women who have sex only with women. The prevalence of HIV among transgender women in many countries is as high as or higher than among men who have sex with men. Owing to these differing sexual risk profiles, the focus of this consolidated guideline is on transgender women or transgender men who have sex with men rather than on transgender women and transgender men who have sex only with women *(8)*.

Children: According to Article 1 of the Convention on the Rights of the Child, "A child means every human being below the age of eighteen years unless, under the law applicable to the child, majority is attained earlier" *(5)*.

Adolescents: Individuals between the ages of 10 and 19 years old are generally considered adolescents. Adolescents are not a homogenous group; physical and emotional maturation comes with age, but its progress varies among individuals of the same age. Also, different social and cultural factors can affect their health, their ability to make important personal decisions and their ability to access services *(9)*.

This document primarily uses the term "adolescents". Other terms covering overlapping age groups include:

Youth: This term refers to individuals between the ages of 15 and 24 *(10)*.

Young people: This term refers to those between the ages of 10 and 24 *(10)*.

EXECUTIVE SUMMARY

Purpose

In this new consolidated guidelines document on HIV prevention, diagnosis, treatment and care for key populations, the World Health Organization (WHO) brings together all existing guidance relevant to five key populations – men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people – and updates selected guidance and recommendations. These guidelines aim to: provide a comprehensive package of evidence-based HIV-related recommendations for all key populations; increase awareness of the needs of and issues important to key populations; improve access, coverage and uptake of effective and acceptable services; and catalyze greater national and global commitment to adequate funding and services.

The risk behaviours and vulnerabilities of key populations result in their being disproportionately affected by HIV in all countries and settings. These disproportionate risks reflect both behaviour common among members of these populations and specific legal and social issues that increase their vulnerability. Yet HIV services for key populations remain largely inadequate. In many settings HIV incidence in key populations continues to increase, even as incidence stabilizes or declines in the general population.

To date, WHO has developed normative guidance separately for each of the five key populations, but, in general, guidance has not adequately addressed overarching issues relating to key populations. Similarly, the WHO global HIV guidance, including the 2013 consolidated ARV guidelines, did not specifically consider issues relating to key populations. These guidelines aim to address these gaps and limitations. Countries and other end-users have indicated the importance of consolidating WHO's key population guidance to aid national programme managers and service providers, including those from community-based and community-led programmes, in planning for and implementing services for these populations. Thus, this consolidated guidance addresses the issues and elements for effective HIV service delivery that are common to all key populations as well as those specific to one or more groups.

Format of the guidelines

The guidelines are presented in seven chapters:

Chapter 1: Background, context, rationale, guiding principles, objectives and the target audience.

Chapter 2: Methods and process for developing the guidelines.

Chapter 3: Comprehensive package of interventions.

Chapter 4: Clinical interventions for key populations.

Chapter 5: Critical enablers required for successful implementation.

Chapter 6: Service delivery issues and case studies.

Chapter 7: Guidance on prioritizing and planning services, monitoring and evaluation, target setting, indicators and costing tools.

Guidelines development methodology

In October 2013 an External Steering Group met and reviewed all relevant existing WHO guidance and identified recommendations requiring updating and new areas to be addressed. This group consisted of people from key population networks and organizations, academics, researchers, programme managers and implementers, United Nations partner organizations, supported by a WHO secretariat.

The External Steering Group proposed that the consolidated key populations guidelines provide recommendations along the continuum of HIV care – prevention, diagnosis, linkage, treatment and care – and include recommendations and guidance on the critical enablers that are essential to support provision of safe, effective and acceptable HIV services. New areas identified included re-reviewing evidence concerning the provision of pre-exposure prophylaxis of HIV (PrEP) for men who have sex with men and assessing evidence concerning PrEP for people who inject drugs, a group not considered in the previous guidance. The External Steering Group also prioritized development of recommendations on the community delivery of naloxone for treating opioid overdose and updating of recommendations for people in prisons and other closed settings.

Following the October 2013 meeting of the External Steering Group, a Guidelines Development Group was formed, comprising the majority of the External Steering Group members along with some additional expert members. Meeting in March 2014, the Guidelines Development Group unanimously supported a reworded PrEP recommendation for men who have sex with men; a majority vote determined the strength of the recommendation. In addition, the Guidelines Development Group reviewed and fully supported all other areas of the existing guidelines. In March 2014 a separate Guidelines Development Group reviewed proposed new guidance on community delivery of naloxone.

Following these meetings the draft consolidated key populations guidelines were reviewed by external peer reviewers, UN agency reviewers and WHO staff members from the Department of HIV and the Department of Mental Health and Substance Abuse, other WHO departments and regional teams.

Recommendations

The accompanying table summarizes the recommendations presented in this document.

All recommendations and guidance in the document derive from existing WHO guidance with the exception of the new recommendations on PrEP and community opioid overdose management. The new PrEP recommendation constitutes a change

from a conditional recommendation for PrEP use in demonstration projects to a strong recommendation endorsing PrEP as part of a package of prevention services for men who have sex with men. The Guidelines Development Group made no recommendation on PrEP use for people who inject drugs. (See Chapter 2 for methodology and Chapter 4 for the updated recommendation.) The new recommendation on opioid overdose management supports providing naloxone to people in the community who might witness an overdose and instructing them on its administration. The updated evidence reviews for the HIV recommendations for people in prisons and other closed settings reinforced the existing recommendations. For all other recommendations, the original guidance documents, which are referenced in this document, describe how that guidance was developed.

Implications for programming

Both public health and equity considerations underlie the need to prioritize and improve HIV services for key populations. These guidelines for key populations aim to support countries to provide more effective and acceptable comprehensive HIV services for key populations, to increase coverage and to address current inequities in access. Countries will need to assess their specific situations, taking into account current population sizes and reviewing current coverage levels and the quality of programmes. It is also important to assess and, where possible, to address social and legal barriers to access and to make progress as country-specific circumstances allow.

Further research

With partner organizations, the Department of HIV is developing a comprehensive HIV service implementation science framework, highlighting key research priorities, including those for key populations.

Summary of WHO recommendations concerning key populations

HEALTH SECTOR INTERVENTIONS	
HIV PREVENTION	
1	The correct and consistent use of condoms with **condom-compatible lubricants** is recommended for all key populations to prevent sexual transmission of HIV and sexually transmitted infections (STIs).
2	Among men who have sex with men, **pre-exposure prophylaxis (PrEP)** is recommended as an additional HIV prevention choice within a comprehensive HIV prevention package. NEW RECOMMENDATION
3	Where serodiscordant couples can be identified and where additional HIV prevention choices for them are needed, daily oral **PrEP** (specifically tenofovir or the combination of tenofovir and emtricitabine) may be considered as a possible additional intervention for the uninfected partner.
4	**Post-exposure prophylaxis (PEP)** should be available to all eligible people from key populations on a voluntary basis after possible exposure to HIV.
5	**Voluntary medical male circumcision (VMMC)** is recommended as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men, particularly in settings with hyperendemic and generalized HIV epidemics and low prevalence of male circumcision.

HARM REDUCTION FOR PEOPLE WHO USE DRUGS	
6	All people from key populations who inject drugs should have access to sterile injecting equipment through **needle and syringe programmes**.
7	All people from key populations who are dependent on opioids should be offered and have access to **opioid substitution therapy**.
8	All people from key populations with harmful alcohol or other substance use should have access to **evidence-based interventions**, including brief psychosocial interventions involving assessment, specific feedback and advice.
9	People likely to witness an opioid overdose should have **access to naloxone** and be instructed in its use for emergency management of suspected opioid overdose. NEW RECOMMENDATION
HIV TESTING AND COUNSELLING (HTC)	
10	**Voluntary HTC** should be routinely offered to all key populations both in the community and in clinical settings. **Community-based HIV testing and counselling for key populations**, linked to prevention, care and treatment services, is recommended, in addition to provider-initiated testing and counselling.
HIV TREATMENT AND CARE	
11	Key populations living with HIV should have the same access to **antiretroviral therapy (ART)** and to ART management as other populations.
12	All pregnant women from key populations should have the same access to services for **prevention of mother-to-child transmission (PMTCT)** and follow the same recommendations as women in other populations.
PREVENTION AND MANAGEMENT OF COINFECTIONS AND CO-MORBIDITIES	
13	Key populations should have the same access to **tuberculosis (TB) prevention, screening and treatment** services as other populations at risk of or living with HIV.
14	Key populations should have the same access to **hepatitis B and C prevention, screening and treatment** services as other populations at risk of or living with HIV.
15	Routine screening and management of **mental health** disorders (depression and psychosocial stress) should be provided for people from key populations living with HIV in order to optimize health outcomes and improve their adherence to ART. Management can range from co-counselling for HIV and depression to appropriate medical therapies.
SEXUAL AND REPRODUCTIVE HEALTH	
16	**Screening, diagnosis and treatment of sexually transmitted infections** should be offered routinely as part of comprehensive HIV prevention and care for key populations.
17	People from key pop**ulations, including those living with HIV, should be able to** experience full, pleasurable sex lives and have access to a range of **reproductive options**.
18	**Abortion laws and services** should protect the health and human rights of all women, including those from key populations.
19	It is important to offer **cervical cancer screening** to all women from key populations.
20	It is important that all women from key populations have the same support and access to services related to **conception and pregnancy care**, as women from other groups.

CRITICAL ENABLERS	
1	**Laws, policies and practices** should be **reviewed** and, where necessary, revised by policy-makers and government leaders, with meaningful engagement of stakeholders from key population groups, to allow and support the implementation and scale-up of health-care services for key populations.
2	Countries should work towards implementing and enforcing **antidiscrimination and protective laws**, derived from human rights standards, to eliminate stigma, discrimination and violence against people from key populations.
3	**Health services** should be made **available, accessible and acceptable** to key populations, based on the principles of medical ethics, avoidance of stigma, non-discrimination and the right to health.
4	Programmes should work toward implementing a package of interventions to **enhance community empowerment** among key populations.
5	**Violence** against people from key populations should be prevented and addressed in partnership with key population-led organizations. All violence against people from key populations should be monitored and reported, and redress mechanisms should be established to provide justice.

INTRODUCTION

1

1 INTRODUCTION

1.1 Key populations and vulnerable groups

Key populations. The risk behaviours and vulnerabilities of specific populations and their networks determine the dynamics of HIV epidemics. These guidelines focus on five key population groups, which in almost all settings are disproportionately affected by HIV:

- **men who have sex with men**
- **people in prisons and other closed settings**[1]
- **people who inject drugs**
- **sex workers** and
- **transgender people.**

Without addressing the needs of key populations, a sustainable response to HIV will not be achieved.

These disproportionate risks reflect both behaviour common among members of these populations and specific legal and social barriers that further increase their vulnerability. Key populations influence epidemic dynamics and play a key role in determining the nature and effectiveness of the response to HIV. People living with HIV are central to the response to HIV and, therefore, are also often considered as a key population. This document, however, does not discuss all people living with HIV as a separate population.

In most countries inadequate coverage and poor quality of services for key populations continue to undermine responses to HIV. All countries should consider the importance of reaching these key populations, understanding their needs and providing equitable, accessible and acceptable services. To accomplish this, it is essential to work with key population groups and networks as partners in developing and providing services *(1)*.

Vulnerable groups. In certain contexts other groups also are particularly vulnerable to HIV infection, for example, migrant workers, refugees, long-distance truck drivers, military personnel, miners, and, in southern Africa, young women. These populations are not uniformly vulnerable or equally affected across different countries and epidemic settings. Countries should also identify these additional populations specific to their settings and focus attention and develop and tailor services accordingly.

A focus on key populations. Overall, countries should prioritize their HIV responses to focus on the populations that are most vulnerable, experience the greatest burden of HIV and are currently underserved. These populations will include both specific vulnerable populations and, in all settings, key populations. These guidelines provide recommendations for the five key populations listed above (both adults and adolescents), while recognizing that countries will need to tailor their response to the

[1] UNAIDS currently defines "key populations" as men who have sex with men, sex workers, persons who inject drugs and transgender people, but recognizes that prisoners, too, are particularly vulnerable to HIV and frequently lack adequate access to services.

size of these populations and also address the needs of vulnerable populations (see box). Detailed guidance on treatment and care of people living with HIV is provided in the WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2)*.

Without addressing the needs of key populations, a sustainable HIV response will not be achieved. To date, however, in most countries with generalized HIV epidemics, the response has focused almost exclusively on the general population. Even countries recognizing that HIV epidemics are concentrated in key populations often are reluctant to implement adequate interventions that reach those most in need.

An effective response requires more than supporting services and programmes for key populations; it also requires systemic and environmental changes that only concerted action can bring about. For members of both key populations and vulnerable groups, many factors that influence a person's risk are largely outside that person's control. Particularly for key populations, social, legal, structural and other contextual factors both increase vulnerability to HIV and obstruct access to HIV services. Such factors include punitive legislation and policing practices, stigma and discrimination, poverty, violence and high levels of homelessness in some sub-populations. These factors affect how well individuals or populations can protect themselves from, and cope with, HIV infection; they can limit access to information, prevention services and commodities, and care and treatment. In addition, other health services specific to the needs of key populations are often scarce or non-existent – for example, gender affirming treatment for transgender people and harm reduction services for people who inject drugs. Geographic setting and social context also can affect a person's vulnerability.

Members of all key populations continue to experience intense stigma and discrimination, legal barriers and constraints to accessing services and often low prioritization by the public health system, including ministries of health. In many settings

Rationale for consolidated guidelines on key populations

World Health Organization (WHO) guidance exists on each of the five key populations, but it has not adequately addressed issues common to all these key populations nor has it addressed countries' needs for a coherent approach informed by situational analysis. This document seeks to bring together WHO and UN partners' guidelines on the five key population groups into one document. This document also makes reference to WHO tools and other documents on programme activities relevant to the health of key populations, such as strategic information/ monitoring and evaluation for key populations, along with publications from United Nations partners and new material to fill identified gaps.

These guidelines consider the elements common to all key populations as well as highlighting specific issues and risks unique to each group. This approach is meant to help countries to plan, develop and monitor, more effectively and efficiently, acceptable and appropriate programmes for key populations relevant to their particular epidemiological context. The guidelines discuss implementation issues that services must address to achieve equity and maximize impact.

community-based organizations provide important services for key populations. Better partnerships and linkages between community organizations and ministries of health are crucial. Equitable access to, and provision of, HIV and related health services to key populations are a high priority, requiring adequate domestic and external funding.

1.2 HIV in key populations

Key populations experience significant HIV burden, and they influence the dynamics of HIV epidemics.

There is a clear epidemiological rationale for HIV programmes to focus on key population groups. In many settings HIV incidence in the general population has stabilized or fallen. However, globally, key populations continue to experience significant HIV burden, and they influence the dynamics of HIV epidemics.

In general, health data, including HIV prevalence data, are less robust for key populations than for general populations due to complexities in sampling (and lack of size estimation data), legal concerns and issues of stigma and discrimination. Laws criminalizing the behaviour of key populations make it difficult to collect representative data. Under such circumstances people are reluctant to be counted as members of these populations.

1.2.1 Men who have sex with men

Epidemics of HIV in men who have sex with men continue to expand in most countries. In major urban areas HIV prevalence among men who have sex with men is on average 13 times greater than in the general population *(3)*. One reason for the high HIV prevalence among men who have sex with men may be that HIV transmission through anal intercourse without a condom is more efficient than through vaginal intercourse without a condom, and individual-level risks for HIV acquisition among men who have sex with men include unprotected receptive anal intercourse, high number of male partners, and concomitant injecting drug use *(4, 5, 6)*.

Globally, epidemics of HIV in men who have sex with men continue to expand.

By region, estimates of HIV prevalence among men who have sex with men range from 3.0% in the Middle East and North Africa to 25.4% in the Caribbean *(4)*. In Kenya, the only African country with HIV incidence data, an annual incidence of greater than 20% was reported recently in Mombasa *(4)*. Other countries in Africa report high prevalence, for example, Côte d'Ivoire, where the prevalence of HIV among men who have sex with men has been estimated at 18% *(7, 8)*. In other regions where HIV incidence among men who have sex with men is reported or modelled, there is no evidence of decrease. In fact, for example, China and Thailand report increasing incidence.

Discriminatory legislation, stigma (including by health workers) and homophobic violence in many countries pose major barriers to providing HIV services for men who have sex with men and limit their use of what services do exist. Many countries criminalize sex with the same gender (either male–male only or both male–male and female–female). As of December 2011 same-sex practices were criminalized in

38 of 53 countries in Africa *(9)*. In the Americas, Asia, Africa and the Middle East, 83 countries have laws that make sex between men illegal *(10)*. The range of legal sanctions and the extent to which criminal law is enforced differs among countries *(11)*.

1.2.2 People in prisons and other closed settings

There are more than 10 million men and women in prisons and other closed settings, with an annual turnover of around 30 million moving between prison and the community *(17)*. Globally, the prevalence of HIV, sexually transmitted infections, hepatitis B and C and tuberculosis in prison populations is estimated to be twice to ten times higher than in the general population *(18)*. Higher HIV prevalence and HIV risk are seen among both prisoners and those working in prisons and their families in many settings *(19)*.

In addition to HIV risk behaviours in prison (unsafe sexual activities, injecting drug use and tattooing), factors related to the prison infrastructure, prison management and the criminal justice system contribute to increased risk of HIV, hepatitis B and C and tuberculosis in prisons *(20)*. Due to the conditions of imprisonment, including overcrowding, sexual violence, drug use and lack of access to HIV prevention commodities such as condoms and lubricants, transmission risk is very high *(18)*.

In some settings HIV prevalence rates are higher among women in prisons than among men and much higher than among women in the general population. For example, in Moldova in 2005, HIV prevalence among female prisoners was 9.6% compared with male prisoners at 1.5–5% and women in the general populations at <0.5% *(21)*. In Canada in 2002 HIV prevalence was reported at 3.71% among female prisoners compared with 1.96% among male prisoners and <0.5% among women in the general population *(22)*.

1.2.3 People who inject drugs

Worldwide, 158 countries have reported injecting drug use, and 123 of these countries (78%) have reported HIV among people who inject drugs *(12, 13)*. Prevalence data on the extent of injecting drug use is not available for almost half of these countries, in particular in Africa, the Middle East and Latin America. The United Nations Office on Drugs and Crime (UNODC) jointly with WHO, UNAIDS and the World Bank estimated that in 2012 worldwide about 12.7 million (range: 8.9 million–22.4 million) people had recently injected drugs and that, of these, 1.7 million (range: 0.9 million–4.8 million) people (13.1%) were living with HIV.

Rates of HIV infection are high among people who inject drugs. For example, in Pakistan HIV prevalence among people who inject drugs is estimated at 37.8%, based on 2011 surveillance data, almost quadruple the rate in 2005 *(15)*. In Indonesia HIV prevalence among people who inject drugs is estimated to be 36.4% (compared with 0.4% in the general population ages 15–49 years); in Ukraine at least 20% (compared with 0.9%), and in Myanmar 18% (compared with 0.6%) *(16)*. Based on data from 49 countries, the risk of HIV infection averaged 22 times greater among people who inject drugs than among the general population. In 11 of these countries the risk was at least 50 times higher. In Eastern Europe an estimated 40% of new HIV infections occur among people who inject drugs and their sexual partners *(3)*.

Because of the illegality of sex work, drug use, and same-sex behaviour in many countries, many people from various key populations are incarcerated at some point in their lives. Since being held in detention is itself a risk factor for HIV, it further increases HIV risk for people from other key populations. Settings with forced gender segregation (e.g. prisons) are important contexts for male-to-male sexual activity not linked to homosexual identity.

Access to HIV testing and counselling and to HIV prevention, treatment, and care programmes is often poor in prisons and other closed settings. Few countries implement comprehensive HIV programmes in prisons *(18)*. Not only are such services needed in prison and other closed settings, but also they need linkages to HIV services in the community to maintain continuity after a person is released.

1.2.4 Sex workers

Globally, the average HIV prevalence among sex workers is estimated to be approximately 12%. There is large variation within regions in HIV prevalence and odds ratios for HIV infection. In 26 countries with medium and high HIV prevalence in the general population, 30.7% of sex workers were HIV-positive *(3, 23)*. For example, HIV prevalence among sex workers in Nigeria was estimated at 24.5% (compared with 3.7% among the general population ages 15–49 years), in Latvia at 22.2% (compared with 0.7% in the general population), and in Rwanda at 50.8% (compared with 2.9% in the general population) *(3)*.

Sex workers are at an increased risk due to exposure to multiple sexual partners and, sometimes, inconsistent condom use, often due to clients' unwillingness or coercion. Legal issues, stigma, discrimination and violence pose barriers to HIV services for sex workers.

1.2.5 Transgender people

A meta-analysis published in 2013 highlighted the particular vulnerability to HIV of transgender women. Data were available only for countries with male-predominant HIV epidemics, which included the United States of America, six Asia–Pacific countries, five in Latin America, and three in Europe. The pooled HIV prevalence was 19.1%. Among 7197 transgender women sampled in 10 low- and middle-income countries, HIV prevalence was 17.7%. Among 3869 transgender women sampled in five high-income countries, HIV prevalence was 21.6% *(24)*.

1.2.6 Overlapping vulnerabilities and differing risks

Many people from key populations engage in more than one high-risk behaviour (e.g. injecting drugs and sex work, or a man who has sex with other men who also injects drugs). Thus, they are likely to have higher HIV prevalence rates than those with only one type of risk.

Subgroups of key populations may have especially high risk for HIV infection *(25, 26)*. For example, a cross-sectional study of 1999 female sex workers in Viet Nam found that HIV prevalence was significantly greater among street-based sex workers than among

sex workers in entertainment establishments (3.8% versus 1.8%, p = 0.02) *(27)*. The subgroups with higher risk for HIV are not efficiently covered by current surveillance or intervention programmes.

1.2.7 Adolescents and young people from key populations

Adolescents and young people from key populations are at significant HIV risk, higher than that of their older peers in these populations. Studies are limited, but they consistently show that adolescents and young people from key populations are even more vulnerable than older cohorts to STIs, HIV and other sexual and reproductive health problems *(28)*. Rapid physical, emotional and mental development, complex psychosocial and socio-economic factors and poor access to and uptake of services increase their vulnerability and risk *(29)*. Particularly for those under age 18 years, policy and legal barriers related to age of consent often prevent access to a range of health services, including HIV testing and counselling (HTC), harm reduction and other services provided specifically for key populations *(30)*. Such barriers also limit adolescents' ability to exercise their right to informed and independent decision-making.

Adolescents from key populations may face stigma, discrimination and violence even greater than that faced by older people from key populations. Fearing discrimination and/or possible legal consequences, many adolescents from key populations are reluctant to attend diagnostic and treatment services. Consequently, they remain hidden from many essential health interventions, further perpetuating their exclusion *(31)*.

Reliable and representative epidemiological and behavioural data on adolescents and young people from key population groups remain limited *(32)*. Young people remain largely invisible in routine HIV surveillance and in research on HIV prevalence and risk. This lack of data often leads to neglect of their specific needs by policies and programmes designed for youth generally and by services for adults from key populations *(32)*.[1]

The specific needs of young people from key populations are neglected both by programmes designed for youth generally and by programmes for adults from key populations.

1.3 Addressing key populations: a wise investment

The recent move toward more strategic use of HIV resources *(33)* draws attention to the value of addressing HIV in key populations. In both concentrated and generalized epidemics, greater investment in a country's key populations is likely to improve the cost-effectiveness of the response to HIV.

To date, investments in most countries have focused on the general population. In concentrated epidemics, however, almost by definition the great majority of infections are in key populations and, sometimes, specific vulnerable groups. Even in generalized

[1] WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the United Nations Office on Drugs and Crime (UNODC) and key community networks have developed four technical briefs on young people from key populations. These policy briefs are based on reviews of epidemiological data, the literature on service delivery, a policy analysis, and qualitative research on the values and preferences of young people from key populations. These guidelines include key messages from this work. The technical briefs are available in Web Annex 6.

epidemics key populations often account for a large share of HIV prevalence, and incidence in certain key populations often has continued to rise even when rates in the general population have stabilized or declined.

Estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS) suggest that as many as 50% of all new HIV infections worldwide occur in people from key populations.[1] In countries in Asia and Eastern Europe and Central Asia, people from key populations account for more than half of new infections – from 53% to 62%. Even in the sub-Saharan African countries with generalized epidemics that have carried out modes of transmission (MOT) analyses, the proportion of new infections in key populations is substantial, although it varies greatly – for example, an estimated 10% in Uganda, 30% in Burkina Faso, 34% in Kenya, 37% in Nigeria, 43% in Ghana and 45% in Benin.

Estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS) suggest that as many as **50% of all new HIV infections worldwide occur in people from key populations.**

1.3.1 Key to the dynamics of epidemics

Another reason that investment in key populations is cost-effective is the central role of key populations in the dynamics of epidemics. People from key populations can also transmit HIV to other populations – for example, sex workers' clients and the sexual partners of people who inject drugs. Thus, infections in people from key populations can have a multiplier effect.

In an analysis of six countries in West Africa, for example, the proportion of new infections occurring in the sexual partners of people considered at "higher-risk" ranged from 20% in Burkina Faso and Nigeria to around 30% in Benin, Côte d'Ivoire, and Ghana and possibly as high as 49% in Senegal *(34)*. Meanwhile, the proportion of HIV prevention expenditures devoted specifically to programmes for sex workers, their clients, men who have sex with men and people who inject drugs was 1.7% in Burkina Faso, 0.4% in Côte d'Ivoire and 0.24% in Ghana, whereas the percentage of new infections estimated to occur in these population groups was 30%, 28% and 43%, respectively *(35)*.

1.3.2 Expanding coverage can make a difference

Projections suggest that the impacts of improved service coverage of key populations could range from averting a considerable number of new infections in countries with generalized epidemics to stabilizing or even turning around growing incidence rates in countries with concentrated epidemics.

For a country the impact of improved coverage for key populations could range from averting a considerable number of new infections to stabilizing or even turning around growing overall incidence rates.

For example, in Asia HIV transmission occurs primarily through unprotected commercial sex, injecting drug use, and unprotected sex between men. Increasing condom use by sex workers and their clients, due to effective condom promotion, is credited with

1 UNAIDS 2013 unpublished Spectrum estimates.

reversing the rising trend in prevalence in the mid-1990s. In recent years, however, annual incidence rates have changed little. Without further and well-focused investment, prevalence may start rising again *(36)*. According to a 2008 estimate, an expanded programme of HIV interventions focused on these higher-risk behaviours would avert five million new infections between 2007 and 2020 – a number about equal to the number living with HIV in the region in 2007. In addition, the number of HIV-related deaths would decrease by 40%, and in 2020 there would be 3.1 million fewer people living with HIV *(37)*.

In 2011 the World Bank projected that, if Peru did not increase the coverage of programming for men who have sex with men, the number of new infections per year in the general population would grow from about 14 000 in 2008 to about 20 000 in 2015. In contrast, expanding coverage of programmes specifically for men who have sex with men would at least stabilize the number of new infections per year in the general population or even start to decrease it.

Similarly, in Thailand full programme coverage for men who have sex with men would decrease the annual number of new infections in the general population from 22 500 in 2008 to 20 000 in 2015; otherwise, the number would rise to 27 200 *(38)*.

1.4 Scope of these key population guidelines

These guidelines outline a public health response to HIV for the five key populations. They present and discuss new recommendations and a range of recommendations and guidance from current WHO guidelines, including the 2013 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2)*. They summarize the components of a comprehensive package of interventions for key populations and consider implementation issues, challenges, and opportunities. The guidelines also provide help on prioritizing and planning services.

A number of case studies appear in Chapters 5 and 6. They include considerations for each key population group, describing a diversity of interventions and service delivery approaches across a range of country and regional programme experiences.

1.5 Using these guidelines

As in the consolidated ARV guidelines, these guidelines consider the need to support services across the cascade of HIV prevention, diagnosis, care and treatment (Fig. 1.1).

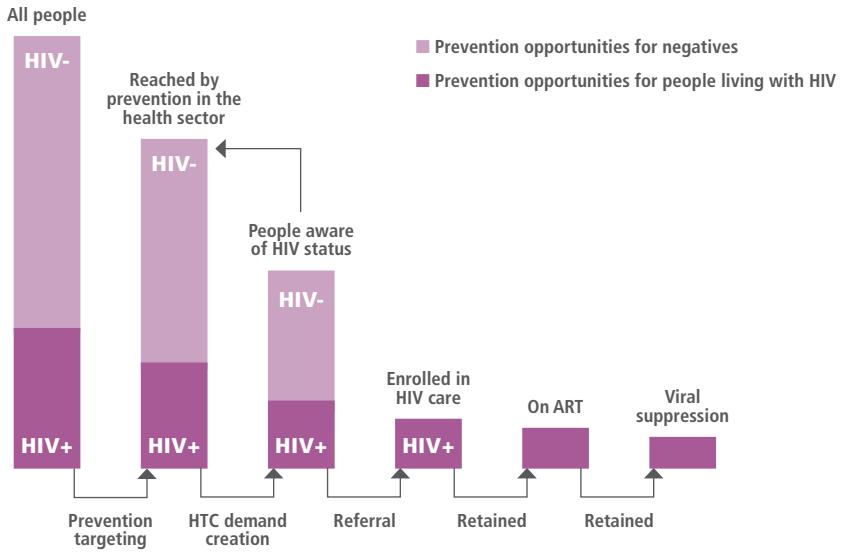
Symbols used throughout the document:

overarching WHO recommendations are in line with existing WHO recommendations and are shaded in blue (see below), and the source of the recommendation is provided for further reference,

NEW **new WHO recommendations** developed specifically for this guidance,

PIPELINE **recommendations under development** – key clinical areas where WHO is developing guidelines.

Fig. 1.1 Cascade of HIV prevention, diagnosis, care and treatment



Within these guidelines the heading "Good practice recommendations" indicates recommendations that may be helpful but do not need grading and are those in which it is sufficiently obvious that desirable effects outweigh undesirable effects. They often pertain to human rights principles reflected in a number of international agreements and to issues of equity and ethics.

Colour coding in this document:

All key population groups

Men who have sex with men

People in prisons and other closed settings

People who inject drugs

Sex workers

Transgender people

Adolescents from key populations

The background documents developed to support these guidelines include studies of the values and preferences of key populations and service providers. The systematic reviews and GRADE (Grading of Recommendations, Assessment, Development and Evaluation) tables for new recommendations appear in full in Web Annexes 1 and 2.

1.6 Goal and objectives

These guidelines seek to provide consolidated guidance to inform the development and implementation of HIV policies, programmes and services for key populations.

The guidelines have the following specific objectives:

- **consolidate guidance** for health sector interventions for HIV for each key population;
- **outline common HIV and related health service packages** that are beneficial and acceptable for all key populations and additional services needed for specific key population groups;
- **update guidance** for planning, delivering, monitoring and evaluating HIV prevention, diagnosis, care and treatment interventions for each key population;
- provide **gender- and age-specific guidance** for HIV interventions for members of key populations, including adolescents.

1.7 Target audience

These guidelines are addressed primarily to national HIV programme managers and other decision-makers within ministries of health and those responsible for health policies, programmes and services in prisons. In addition, the guidelines will be relevant for managers at national and sub-national levels responsible for services for TB, viral hepatitis, sexual and reproductive health, harm reduction and drug dependence, and mental health; community-led civil society organizations and implementing programmes; and development and funding agencies.

1.8 Guidelines principles

The framework for the development of these guidelines is based on human rights principles reflected in a number of international agreements *(39, 40)*.

- **Human rights:** Fundamental to development of these guidelines is the protection of human rights for all members of each key population. Legislators and other government authorities should establish and enforce antidiscrimination and protective laws, derived from international human rights standards, in order to eliminate stigma, discrimination and violence faced by key populations and to reduce their vulnerability to HIV *(40)*.

Guiding principles
- human rights
- access to quality health care
- access to justice
- acceptability of services
- health literacy
- integrated service provision.

- **Access to quality health care** is a human right. It includes the right of members of key populations to appropriate quality health care without discrimination. Health-care providers and institutions must serve people from key populations based on the principles of medical ethics and the right to health *(18)*. Health services should be accessible to key populations. This guidance can be effective only when services are acceptable and high quality and widely implemented. Poor quality and restricted access to services will limit the individual benefit and public health impact of the recommendations.
- **Access to justice** is a major priority for people from key populations, due to high rates of contact with law enforcement services and the current illegality of their behaviours in many countries. Access to justice includes freedom from arbitrary arrest and detention, the right to a fair trial, freedom from torture and cruel, inhuman and degrading treatment and the right, including in prisons and other closed settings, to the highest attainable standard of health *(41)*. The protection of human rights, including the rights to employment, housing and health care, for people from key populations requires collaboration between health-care and law enforcement agencies, including those that manage prisons and other closed institutions. Detainment in closed settings should not impede the right to maintain dignity and health *(18)*.
- **Acceptability of services is a key aspect of effectiveness.** Interventions to reduce the burden of HIV among people from key populations must be respectful, acceptable, appropriate and affordable to recipients in order to enlist their participation and ensure their retention in care. Services for members of key populations often employ appropriate models of service delivery but lack expertise in HIV. Conversely, people from key populations may not find specialized HIV services acceptable. There is a need to build service capacity on both fronts. Consultation with organizations of people from key populations and including peer workers in service delivery are effective ways to work towards this goal *(42)*. Mechanism of regular and ongoing feedback from beneficiaries to service providers will help inform and improve the acceptability of services to key populations.
- **Health literacy:** People from key populations often lack sufficient health and treatment literacy. This may hinder their decision-making on HIV risk behaviours and their health-seeking behaviour. Health services should regularly and routinely provide accurate health and treatment information to members of key populations. At the same time health services should strengthen providers' ability to prevent and to treat HIV in people from key populations, including adolescents *(42)*.
- **Integrated service provision:** People from key populations commonly have multiple co-morbidities and poor social situations. For example, HIV, viral hepatitis, tuberculosis, other infectious diseases and mental health conditions are common in key populations. Integrated services provide the opportunity for patient-centred prevention, care and treatment for the multitude of issues affecting key populations. In addition, integrated services facilitate better communication and care. Thus, wherever feasible, service delivery for key populations should be integrated. When this is not possible, strong links among health services working with key populations should be established and maintained *(43)*.

METHODOLOGY AND PROCESS FOR DEVELOPMENT OF THE GUIDELINES

2

2 METHODOLOGY AND PROCESS FOR DEVELOPMENT OF THE GUIDELINES

2.1 Overview

The WHO Department of HIV led development of these WHO consolidated key populations guidelines, following the WHO procedures and reporting standards laid out in the *WHO handbook for guideline development, 2012 (1)*.

These guidelines combine existing WHO recommendations, new recommendations and guidance published by WHO together with UN partners. Key recommendations from the WHO 2013 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2)* are included, with specific considerations for each of the key population groups highlighted.

2.2 Establishing guideline groups

The WHO HIV Department set up four groups to perform specific guideline development functions. Members of the groups were selected so as to ensure a range of expertise and experience, including appropriate geographical, gender and key population representation and expertise. The four groups and their functions were:

The **WHO Guideline Steering Group on HIV and Key Populations**, chaired by the WHO Department of HIV, led the guideline development process. It included participants from the WHO Department of Maternal, Newborn, Child and Adolescent Heath, the Department of Mental Health and Substance Abuse, the Department of Reproductive Health and Research, the Global Hepatitis Programme, and the Global TB Programme.

The **External Steering Group**, composed of a geographically and gender-balanced group of 25 academics, researchers, programme managers, implementers and people from key population networks and organizations, provided WHO with guidance on scope, content and new areas to be addressed.

The 26-member **Guidelines Development Group** consisted of the majority of the External Steering Group along with some additional expert members. This group was responsible for formulating new WHO recommendations, good practice guidance and consensus on the final content.

The **External Peer Review Group** was selected in consultation with the WHO regional offices to assure geographical and gender balance. In total 73 peer reviewers from academia, policy and research, implementing programmes and key population networks and organizations reviewed the guidelines. In general, reviewers made suggestions to improve the clarity of the document and provided minor additions and corrections to the narrative.

Involvement of key population groups and networks

Crucial to development of these guidelines has been the partnership with, and the engagement of, key population groups and networks at all stages of the process, both as members of the guidelines and peer review groups and as partners in developing the values and preferences investigation methodology and assessment, as described below.

Conflicts of interest

All External Steering Group participants, Guidelines Development Group participants and External Peer Review Group members submitted Declarations of Interest (DOI) to the WHO secretariat. The WHO secretariat and the Guidelines Development Group reviewed all declarations and found no conflicts of interest sufficient to preclude anyone from participating in the development of the guidelines. A full compilation of the declarations is available on request.

2.3 Defining the scope of the guidelines

To develop these guidelines, the WHO Guideline Steering Group mapped all existing WHO HIV guidance specifically concerned with the five key population groups; then it reviewed these and other materials to identify gaps, overlaps, inconsistencies and determine relevance. The outcome of the mapping exercise was presented to the External Steering Group at a scoping meeting in October 2013. The group reviewed the mapping and made recommendations on the scope of the guidelines (populations and range of interventions to be covered) and noted two areas needing new guidance: 1) **pre-exposure prophylaxis (PrEP)** and 2) **opioid overdose prevention and management**.

Other guidelines under development

The Department of HIV and other WHO departments currently are developing or updating a number of guidelines relevant to key populations. These include:

- **hepatitis C treatment** (completed by the global hepatitis team during the development of these guidelines and included here) and **hepatitis B treatment and hepatitis B and C screening** (to be completed during 2014–15);
- **contraception and HIV guidance** (completed by the Department of Reproductive Health and Research and included here);
- **post-exposure prophylaxis (PEP) guidance** (to be completed by late 2014 by the HIV Department and to be included in an updated version of this guidance);

- **STI guidance** (to be completed by early 2015 by the Department of Reproductive Health and Research and to be included in an updated version of this guidance).

Audience

The External Steering Group identified the audience for these guidelines. Health services in low-resource settings will benefit most from the guidance presented here, as they face the greatest challenges in providing services tailored to key populations. However, these guidelines are relevant for all HIV epidemic and economic settings and are, therefore, considered global guidance. Regions and countries can adapt these global recommendations to local needs, HIV epidemic contexts and existing services in order to facilitate their implementation.

2.4 Review of the evidence

These guidelines include both relevant existing recommendations and new recommendations. Development of the new recommendations began with systematic reviews of the evidence. The Guidelines Development Group recommended the commissioning of new literature reviews and appraisal of existing reviews and surveys investigating values and preferences, along with reviews of the costs and feasibility of implementation. Also, WHO commissioned new studies and reviewed existing studies of values and preferences related to existing recommendations to help ensure that the guidance appropriately reflects the concerns of key populations.

2.4.1 Information on prisons and other closed settings

In 2007 an extensive literature review was conducted to inform the development of the WHO publication *Effectiveness of interventions to address HIV in prisons (3, 4)*. In 2014 this work was updated for these guidelines, using an abbreviated literature review focusing on materials developed between 2007 and 2014. Results supported the 2007 review; no new evidence was found that would change the recommendations made in the 2007 guidelines. The Guideline Development Group and United Nations Office on Drugs and Crime (UNODC) reviewed, confirmed and accepted this conclusion. The 2014 review identified a need for further research in this area; Web Annex 4 includes potential research areas.

2.5 Development of the pre-exposure prophylaxis recommendations

To inform recommendations on PrEP, evidence questions were framed in the PICO format: Population, Intervention, Comparator, Outcome. External researchers used the PICO questions to develop search protocols and perform systematic reviews of the scientific evidence; Web Annexes 1 and 2 present details.

WHO convened the guideline development meeting in March 2014 to update recommendations regarding PrEP use among men who have sex with men *(5)* and to look at the evidence for formulating a new recommendation on PrEP use among people who inject drugs, as well as to review all sections of the consolidated guidelines. Individuals representing a broad range of stakeholders participated in the guideline development meeting as either Guideline Development Group members or expert observers.

Participants at this meeting assessed the evidence for both PICO questions concerning PrEP, along with the risks and benefits, values and preferences and cost-benefits/ feasibility associated with each possible intervention and made recommendations (see Section 4.1.5.1).

2.6 Evidence assessment

Under the WHO guideline development process, the guideline development group formulates the recommendations guided by the **quality** of available evidence. Other factors – values and preferences, costs and feasibility – are also taken into consideration when determining the **strength** of the recommendation.

2.6.1 How to interpret the quality of evidence

The higher the quality of scientific evidence, the more likely that a strong recommendation can be made. The GRADE approach to recommendation development, which WHO has adopted, defines the quality of evidence as the extent to which one can be confident that the reported estimates of effect (desirable or undesirable) available from the evidence are close to the actual effects of interest *(6, 7, 8)*. The GRADE approach specifies four levels of quality of evidence *(9)* (Table 2.1).

Table 2.1 Significance of the four GRADE levels of evidence

Quality of evidence	Rationale
High	Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on our confidence in the effect.
Low	Further research is very likely to have an important impact on the estimate of effect and is likely to change the estimate.
Very low	Any estimate of effect is very uncertain.

2.6.2 Determining the strength of a recommendation

The strength of a recommendation reflects the degree of confidence of the guidelines group that the desirable effects of the recommendation outweigh the undesirable effects (Table 2.2). Desirable effects (**potential benefits**) may include beneficial health outcomes (e.g. reduced incidence of HIV and reduced morbidity and mortality); reduction of burden on the individual and/or health services; and potential cost-savings for the individual, communities, programme and/or health system. Undesirable effects (**potential harms**) include those affecting individuals, families, communities or health services. Additional burdens considered include the resource use and cost implications of implementing the recommendations that programmes, care providers or patients would

have to bear; adverse clinical outcomes (e.g. drug resistance, drug toxicities); and legal ramifications where certain practices are criminalized.

The strength of a recommendation can be either strong or conditional.

A strong recommendation (for or against) is one for which there is confidence that the desirable effects of adherence to the recommendation clearly outweigh the undesirable effects.

A conditional recommendation (for or against) is one for which the quality of evidence may be low or may apply only to specific groups or settings; or the panel concludes that the desirable effects of adherence to the recommendation probably outweigh the undesirable effects or are closely balanced, but the panel is not confident about these trade-offs in all situations.

If implemented, a *conditional recommendation* should be monitored closely and evaluated rigorously. Further research will be required to address the uncertainties and is likely to provide new evidence that may change the calculation of the balance of trade-offs.

The **values and preferences** of the end users (key populations), **feasibility and cost** as well as consideration of potential benefits and harms contribute to determining the strength of a recommendation.

Table 2.2 Domains considered when assessing the strength of recommendations

Domain	Rationale
Benefits and risks	When a new recommendation is developed, desirable effects (benefits) need to be weighed against undesirable effects (risks), considering any previous recommendation or another alternative. The larger the gap or gradient in favour of the benefits over the risks, the more likely that a strong recommendation will be made.
Values and preferences (acceptability)	If the recommendation is likely to be widely accepted or valued highly, it is likely that a strong recommendation will be made. If there is a great deal of variability or strong reasons that the recommended course of action is unlikely to be accepted, it is more likely that a conditional recommendation will be made.
Costs/financial implications	Lower costs (monetary, infrastructure, equipment or human resources) or greater cost-effectiveness are more likely to support a strong recommendation.
Feasibility	If an intervention is achievable in a setting where the greatest impact is expected, a strong recommendation is appropriate.

Surveys, qualitative studies and literature reviews were commissioned and other available material was appraised to investigate the values and preferences of key populations and service providers and benefits, harms, cost and feasibility concerning new areas of guidance, existing recommendations and service provision issues. Specific attention was paid to the values and preferences of adolescents in key populations.[1]

Evidence on values and preferences included findings developed at workshops with members of key populations in a range of countries; a multi-regional, anonymous e-survey of men who have sex with men; in-depth key informant interviews with selected service providers and people who inject drugs; in-depth interviews with men who have sex with men; and a literature review of values and preference of key populations concerning PrEP. Web Annex 3 provides full reports and a table outlining the range of activities undertaken.

2.7 Review of service delivery, implementation approaches and case studies

A large-scale call for examples of good practices was undertaken to identify effective and acceptable delivery approaches for key populations. These case studies, presented in Chapters 5 and 6, offer insights into successful implementation of services for key population groups. Web Annex 5 presents more information on these case studies.

2.8 Producing the guidelines

Following the Guideline Development Group consultation, the full draft guidelines were revised and circulated electronically to both the Guidelines Development Group and the External Peer Review Group for comments and feedback. All responses were considered and, as appropriate, addressed in the final draft.

2.9 Plans for dissemination

The guidelines are being disseminated as a printed publication and electronically on the WHO web site including all Annexes.

2.10 Updating

The Department of HIV has committed to providing **regular updates** of consolidated key population guidelines when new or revised guidance becomes available, including relevant new guidance developed by other WHO departments.

[1] WHO, UNAIDS, the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP) and UNODC have developed four technical briefs on young people from key populations. These policy briefs are based on reviews of epidemiological data, the literature on service delivery, a policy analysis, and qualitative research on the values and preferences of young people from key populations. These guidelines include key messages from this work. See Web Annex 6.

COMPREHENSIVE PACKAGE OF INTERVENTIONS

3

3 COMPREHENSIVE PACKAGE OF INTERVENTIONS

3.1 Services for all key populations

A combination of interventions is required to respond effectively to HIV among key populations. The following comprehensive package of interventions is recommended to assist countries with programming for HIV prevention and treatment among key populations. While Chapters 4 and 5 describe the interventions in much more detail, here we summarize the overarching headings.

The package has two parts:

a) **Essential health sector interventions** (see Chapter 4 for detail)
   1. **comprehensive condom and lubricant programming**
   2. **harm reduction interventions for substance use**, in particular needle and syringe programmes[1] and opioid substitution therapy
   3. **behavioural interventions**
   4. **HIV testing and counselling**
   5. **HIV treatment and care**
   6. **prevention and management of co-infections and other co-morbidities**, including viral hepatitis, TB and mental health conditions
   7. **sexual and reproductive health interventions**.[2]

b) **Essential strategies for an enabling environment** (see Chapter 5 for detail)
   1. **supportive legislation, policy and financial commitment, including decriminalization of behaviours of key populations**
   2. **addressing stigma and discrimination**
   3. **community empowerment**
   4. **addressing violence against people from key populations.**

[1] Needle and syringe programmes are important for people who inject drugs and also for transgender people who require sterile injecting equipment to safely inject hormones for gender affirmation. Other important areas include for tattooing, piercing and other forms of skin penetration, which are particularly relevant in prisons and other closed settings.

[2] Including contraception, diagnosis and treatment of STIs, cervical screening, etc. (see Chapter 4).

The interventions and strategies included in this package are significantly interdependent.

The interventions and strategies in this package are significantly interdependent. The health sector interventions yield the most benefit when they are available in combination and when the necessary enabling environmental factors are in place. These health sector interventions should not be delayed because the enabling environmental factors are missing. The presence of the enabling factors will greatly increase their impact, however. Thus, while the enabling factors may be largely outside the control of the health sector, it is important for the health sector to address them jointly with other sectors.

In addition to the interventions listed, people from key populations need access to general medical, social welfare and legal services so that they can attain the highest possible standards of health and well-being.

3.2 Specific considerations

The comprehensive package outlined above is relevant for all people in key populations. Additional elements for specific key populations are summarized below and detailed in Chapters 4 and 5.

3.2.1 Prisons and other closed settings

The services for prevention and treatment of HIV in the community should also be provided to people in prison and other closed settings. The proven efficacy of these interventions in the community will not change when they are delivered in prisons and other closed settings. However, there may be some specific considerations as to *how best to deliver* these services in prisons and other closed settings to maximize their effectiveness. To improve the equity of health care in these settings, consideration should be given to assigning responsibility for prison health to the ministry of health rather than the ministry of justice or interior *(3)*.

In 2013 UNODC and partners agreed on a comprehensive package for effective HIV prevention and treatment in prisons and other closed settings. In addition to the recommended interventions for people in the community, interventions relevant to closed settings include:

- prevention of HIV transmission through medical and dental services
- prevention of transmission of HIV and other bloodborne diseases through tattooing, piercing and other forms of skin penetration
- protecting staff from occupational hazards.

Some other interventions are important and should not be overlooked, such as the distribution of toothbrushes and shavers in basic hygiene kits, adequate nutrition, intimate visit programmes, palliative care and compassionate release for terminal cases *(4)*.

3.2.2 People who inject drugs

This package is essentially the same as the comprehensive package for HIV prevention, treatment and care for people who inject drugs that has been widely endorsed at the highest political level and by major donor agencies *(1, 2)*. While the harm reduction interventions for substance use are part of this overall comprehensive package for key populations, it is important that countries where injecting drug use occurs **prioritize immediate implementation of needle and syringe programmes and opioid substitution therapy** (NSPs and OST). Implementation of these essential harm reduction services should facilitate and enhance access to HIV-specific services, such as HIV testing and counselling and antiretroviral therapy, and improve adherence to treatment. Harm reduction interventions for people who use drugs but who do not inject are also important. They should include evidence-based drug dependence treatment and provision of non-injecting drug use paraphernalia as appropriate to the local context and patterns of drug use.

3.2.3 Adolescents from key populations

The comprehensive package of interventions is also relevant for adolescents from key populations. Programming for adolescents should also include:

- HPV vaccination as part of national HPV programmes.

Countries are encouraged to:

- examine their current consent policies and consider revising them to reduce age-related barriers to access and uptake of HIV services.

Critical knowledge gaps remain, however, concerning how best to implement programmes that address adolescents' immediate needs *(5)*. However, it is essential that services are designed and delivered in a way that takes into account the multiple, overlapping vulnerabilities that confront adolescents from key populations, and their different needs based on their age, specific behaviours, the complexities of their social and legal environment and the epidemic setting.

HEALTH SECTOR INTERVENTIONS

4

4 HEALTH SECTOR INVERVENTIONS

4.1 Prevention

4.1.1 Comprehensive condom and lubricant programming

Background and rationale

Increasing the availability, accessibility, affordability and use of male and female condoms and condom-compatible lubricants among people from key populations through targeted distribution programmes is an essential component of the HIV response.

Consistent and correct use of male condoms reduces sexual transmission of HIV and other STIs by up to 94%.

Consistent and correct use of male condoms reduces sexual transmission of HIV and other STIs in both vaginal and anal sex by up to 94%. Use of water- or silicone-based lubricants (as opposed to petroleum-based) helps to prevent condoms from breaking and slipping *(1, 2, 3, 4)*. While fewer data are available on female condoms, evidence suggests that use of female condoms also prevents HIV and STIs *(4)*.

Effective condom programming is particularly important for key populations. Unprotected sex and other high-risk behaviours such as substance use often coincide for key populations, in particular adolescents from key populations *(5, 6, 7)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

The correct and consistent use of condoms with condom-compatible lubricants is recommended for all key populations to prevent sexual transmission of HIV and STIs *(strong recommendation, moderate quality of evidence) (3, 8, 9, 10)*.

Related recommendations and contextual issues for specific key population groups

MEN WHO HAVE SEX WITH MEN

- Condoms and condom-compatible lubricants are recommended for anal sex *(3)*.
- Adequate provision of lubricants needs to be emphasized.

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

Sexual activity takes place in prisons and other closed settings, but generally access to condoms there is limited. It is important to introduce, and expand to scale, condom and lubricant distribution programmes in prisons and other closed settings, without quantity restriction, with anonymity and in an easily accessible manner (e.g. condom vending machines) *(9, 11)*.

SEX WORKERS (AND CLIENTS OF SEX WORKERS)

- Correct and consistent use of condoms and condom-compatible lubricants is recommended for sex workers and their clients *(10)*.
- Sex workers, female or male, often face power imbalances that limit their ability to use condoms with clients. (See Chapter 5 on critical enablers.) Female sex workers who inject drugs may be particularly vulnerable to these power imbalances. The female condom has the advantages over the male condom that the woman can initiate its use and it can be inserted up to several hours before intercourse *(14)*. Peer-led and outreach approaches may help to increase knowledge, develop skills and empower sex workers to use condoms and lubricants consistently.

TRANSGENDER PEOPLE

- Condoms and condom-compatible lubricants are recommended for anal sex *(3)*.
- Adequate provision of lubricants for transgender women and transgender men who have sex with men needs emphasis.

ADOLESCENTS FROM KEY POPULATIONS

Adolescents' emotional, intellectual and social capacities are continuously evolving. Young people from key populations, perhaps more so than their peers in the general population, experience power imbalances in sexual relationships that limit their ability to use condoms *(5, 15, 16)*. Peer-led and outreach approaches may help to distribute condoms and lubricants, increase knowledge, develop skills and empower adolescents from key populations to use condoms and lubricants correctly and consistently *(17)*.

Implementation considerations

Legislation and law enforcement approaches need to support condom programming. Possession of condoms should not be used as evidence of criminal activity, and police should not harass those carrying condoms *(10)*.

Promote access. While condoms and lubricants may be widely sold in most countries, providing condoms with lubricants free to key populations removes any barrier that cost may pose (*17, 18)*. Condoms, both male and female condoms in various sizes, should be available through multiple outlets that reach all the different key populations and particularly young people in these populations. Condom promotion campaigns should increase awareness, promote the acceptability and benefits of condom use and help to overcome social and personal obstacles to their use *(10)*.

Lubricant. Condom-compatible lubricant should always be distributed along with male and female condoms. Lubricant decreases the risk of condom breakage and slippage and can reduce discomfort during penetrative sex *(10)*. Plenty of lubricant should always be used during anal sex *(19)*. Lubricants that are water- or silicone-based do not damage latex condoms; oil-based lubricants do and so should not be used with latex condoms.

Information and skills-building. Along with promotion and supply, programmes for key populations should offer information and skills-building in negotiating condom use *(10)*. In addition, behavioural interventions can encourage consistent condom use. All condom programmes should address the complex gender, religious and cultural factors that can impede condom use. Particularly, before introducing condom distribution programmes in prisons, education and information for both prisoners and prison staff should be carefully planned *(9)*.

Further reading

- *Condom programming for HIV prevention: a manual for service providers.* New York, UNFPA, 2005. http://www.unfpa.org/public/global/pid/1291
- *Comprehensive condom programming: a guide for resource mobilization and country programming.* New York, UNFPA, 2010. http://www.unfpa.org/webdav/site/global/shared/documents/publications/2011/CCP.pdf
- WHO, UNFPA, UNAIDS, NSWP, World Bank. *Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions. (Chapter 4).* Geneva, WHO, 2013. http://www.who.int/hiv/pub/sti/sex_worker_implementation/en/
- *Male latex condom specification, prequalification and guidelines for procurement.* Geneva, WHO, 2010. http://www.who.int/reproductivehealth/publications/family_planning/9789241599900/en/
- WHO, UNFPA, FHI360. *Use and procurement of additional lubricants with male and female condoms – advisory note.* Geneva, WHO, 2012. http://apps.who.int/iris/bitstream/10665/76580/1/WHO_RHR_12.33_eng.pdf

4.1.2 Harm reduction for people who inject drugs

Background and rationale

People who inject drugs are at risk of HIV and other bloodborne viral infections (such as hepatitis B and C) through the sharing of contaminated injecting equipment. In some settings drug use may be more prevalent among people from other key populations than in the general population.

The comprehensive package. A comprehensive package of evidence-based interventions to reduce harms associated with injecting drug use is outlined in the *WHO, UNAIDS, UNODC technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users (8)*. This publication and the package of interventions have been widely endorsed by the United Nations *(20, 21, 22, 23, 24)* and major international donors including the Global Fund to Fight AIDS, Tuberculosis and Malaria and the United States President's Emergency Plan for AIDS Relief (PEPFAR).

The comprehensive harm reduction package

1. Needle and syringe programmes (NSPs)
2. Opioid substitution therapy (OST) and other evidence-based drug dependence treatment
3. HIV testing and counselling
4. Antiretroviral therapy
5. Prevention and treatment of STIs
6. Condom programmes for people who inject drugs and their sexual partners
7. Targeted information, education and communication for people who inject drugs and their sexual partners
8. Prevention, vaccination, diagnosis and treatment for viral hepatitis
9. Prevention, diagnosis and treatment of TB.

Only the first two interventions, NSP and OST and other drug dependence treatment, are specific to drug use; they are discussed in this chapter.

Community-based outreach. Community-based outreach is not listed as a separate intervention in the package, but it is an effective method of reaching people, particularly those who face barriers to obtaining mainstream services, as is often the case for people from key populations. Outreach is a highly effective means of delivering HIV prevention interventions such as NSPs, condom programmes and targeted communication, as well as a useful access point for referral to OST and ART. Hence, outreach is an essential component of all HIV-related programmes *(25)*.

A number of other interventions are not included in the comprehensive harm reduction package because of insufficient evidence of their effectiveness for HIV prevention and treatment. However, one new recommendation on community distribution of naloxone is now included and described in detail at the end of this chapter.

Reducing harms related to injecting substances for gender affirmation. Distinct from injecting drug use as described above is the injection of substances by transgender people for gender affirmation. Where hormone therapy for gender affirmation is used, it is important for health care services to ensure that appropriate preparations are used, to avoid incorrect dosing, and to properly manage any adverse events, as well as to reduce sharing of injection equipment. As yet, there is no WHO guidance on hormone therapy for gender affirmation.

The injection of hormones is distinct from the injection of non-medical silicone preparations and other fillers for direct body modification *(26, 27)*. Injection of loose silicone and other fillers has been linked to such health harms as infection, disfigurement, migration of the injected substance within the body and systemic illness *(28, 29, 30)*. It is important for transgender people to be counselled about the health risks of these injections and afforded access to health-care services that provide safer methods for gender affirmation.

Adolescents who inject drugs.[1] Adolescents who inject drugs face additional risks and barriers to services due to multiple legal, developmental and environmental factors. Adolescents often have less knowledge of safer injecting practices and of services. In many countries age restrictions and/or parental consent requirements exclude adolescents from NSP and OST programmes. Adolescents and young people may require specific and more creative engagement strategies to promote uptake of services. Engaging parents of adolescents who inject drugs in harm reduction programmes may help to ensure adequate support to the adolescent. However, it is important to obtain the adolescent's consent before involving the parents.

4.1.2.1 Needle and syringe programmes

Background and rationale

NSPs substantially and cost-effectively reduce HIV transmission among people who inject drugs.

Once HIV is introduced in a population of people who inject drugs and commonly share syringes and injecting equipment, prevalence rates can reach epidemic proportions very quickly *(31)*. Distributing free or low-cost sterile injecting equipment to people who inject facilitates the use of clean needles and syringes and reduces the number of injections with used needles and syringes *(8, 32, 33, 34, 35, 36, 37)*.

NSPs substantially and cost-effectively reduce HIV transmission among people who inject drugs *(36)*. NSPs may also reduce transmission of other bloodborne viruses, such as viral hepatitis B and C, among people who inject drugs *(35, 36, 38, 39, 40)*. At the same time, needle and syringe programmes do not encourage drug use. There is no evidence of major unintended negative consequences of NSPs, such as initiation of

[1] See also Web Annex 6, briefs on young key populations.

injecting among people who have not injected previously or an increase in injecting at either the individual or societal level *(41, 42, 43, 44)*.

NSPs may serve as an important point of entry to other services. NSPs aim to engage their clients repeatedly on a regular basis. Thus, they have multiple opportunities to facilitate access to other health services such as OST and other drug dependence treatment, HTC, and treatment of HIV, TB and viral hepatitis *(45)*. Also, NSPs may offer basic health care and address other specific issues that commonly affect people who inject drugs, such as wound care and overdose prevention. Various models of needle and syringe distribution and service delivery can be employed, including distribution at fixed sites such as pharmacies, automatic dispensing machines or vending machines, and mobile and outreach services *(8, 36)*. Additionally, given the high incarceration rates of people who inject drugs, access to sterile injecting equipment and NSP are important components of prison health services *(4)*.

To prevent HIV transmission through injecting drug use, it is crucial to provide not only information on how to do so, through safer injecting and avoiding sharing injecting equipment, but also the means to do so, through distribution of free or low-cost sterile injecting equipment. Needle and syringe programmes also provide the opportunity for referral to other health and related services, including HTC and drug-dependence treatment.

Recommendations and guidance

ALL KEY POPULATION GROUPS

All individuals from key populations who inject drugs should have access to sterile injecting equipment through needle and syringe programmes *(strong recommendation, low quality of evidence)* *(8, 32, 36, 46)*.

Additional remarks

- It is suggested that needle and syringe programmes provide low dead-space syringes (LDSS) along with information about their preventive advantage over conventional syringes *(39)*.
- Injecting equipment should be appropriate to the local context, taking into account such factors as the type and preparation of drugs that are commonly injected *(8, 27)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- It is important to provide people in prisons and other closed settings with prevention measures, such as condoms and clean injecting equipment, and not just with information about avoiding risks. People in prisons and other closed settings should have easy, confidential access to NSPs *(9)*.
- Prison systems should pilot-test and evaluate safer tattooing initiatives to assess whether they reduce the sharing and re-use of tattooing equipment and, thereby, reduce infections *(9, 11)*.

TRANSGENDER PEOPLE

Transgender people who inject substances for gender affirmation should use sterile injecting equipment and practice safe injecting practices to reduce the risk of infection with bloodborne pathogens such as HIV, hepatitis B and hepatitis C *(3)*.

ADOLESCENTS FROM KEY POPULATIONS

WHO guidance does not specify age restrictions for needle and syringe programmes.

Implementation considerations

Structural change is needed to create a supportive policy, legal and social environment that facilitates equitable access to HIV prevention and treatment for all, including NSPs for people who inject drugs *(8)*.

Advocacy citing public health evidence is often required with various sectors, especially law enforcement agencies and the local community, to foster an environment that enables NSPs to function fully *(8, 36, 45, 47)*.

Criminalization counterproductive. If carrying used needles and syringes is a criminal offence or may be used as evidence of drug use, people who inject drugs may be reluctant to take used equipment to NSPs for disposal *(27, 36, 45)*.

Serving key populations. It is important that NSPs are sensitized to the health needs of each key population. Key population organizations can either provide these interventions themselves or have effective referral pathways to services that do *(32)*.

Other equipment. In addition to needles and syringes, other injecting-related equipment may also be provided, including alcohol swabs, ampoules of sterile water, filters, tourniquets, mixing vessels (e.g. spoons or "cookers") and acidifiers (e.g. ascorbic acid or citric acid powders) *(8, 27)*.

Safe disposal. NSPs should set up systems for safe disposal of injecting equipment and promote their use *(8, 27)*. There are various models for safe disposal systems, including distributing puncture-resistant one-way containers. Effective safe disposal reduces the amount of contaminated equipment in the community, thus reducing reuse and unintended needle-sticks and limiting negative reactions from the community. Information provided also can cover opportunities for reducing drug use in the longer term.

Information and education in prisons and other closed settings. Prisoners and prison staff should receive information about the programmes and participate in their design and implementation. Carefully evaluated pilot programmes of prison-based NSPs may be important to pave the way for ongoing full-scale programmes, but expansion of programmes should not wait for results from pilot programmes, particularly where injecting is common in prisons *(9)*.

Further reading

- WHO, UNODC, UNAIDS. *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision.* Geneva, WHO, 2012. http://www.who.int/hiv/pub/idu/targets_universal_access/en/
- WHO, UNAIDS, UNODC. *Guide to starting and managing needle and syringe programmes.* Geneva, WHO, 2007. http://whqlibdoc.who.int/publications/2007/9789241596275_eng.pdf
- *Effectiveness of sterile needle and syringe programming in reducing HIV/AIDS among injecting drug users.* Geneva, WHO, 2004. http://www.who.int/hiv/pub/idu/e4a-needle/en/
- *Best practices for injections and related procedures toolkit.* Geneva, WHO, 2010. http://whqlibdoc.who.int/publications/2010/9789241599252_eng.pdf

4.1.2.2 Opioid substitution therapy

Background and rationale

OST is highly effective in reducing injecting behaviours that put opioid-dependent people at risk for HIV.

Interventions that effectively treat drug dependence can reduce illicit drug use and, hence, the frequency of injection, as well as improve health and social functioning *(8)*. For people dependent on opioids, agonist opioid substitution therapy (OST) – sometimes referred to as medically assisted treatment (MAT) – is highly effective in reducing injecting behaviours that put opioid-dependent people at risk for HIV *(33, 34, 48, 49, 50)*. OST can reduce opioid use and improve retention in HIV treatment *(51, 52, 53)*. Access and adherence to OST can improve health outcomes *(4)*, reduce overdose and resulting mortality *(54)*, reduce criminal activity *(55)*, result in better psychosocial outcomes *(56)* and decrease risk to pregnant women dependent upon drugs and to their infants *(57)*.

Methadone and buprenorphine, both of which are on the WHO list of essential medicines, are the most commonly used opioid agonists *(58)*. Methadone is a synthetic

opioid used to treat heroin and other opioid dependence. It reduces opioid withdrawal symptoms and the euphoric effect when opioids are used. Methadone is taken orally on a daily basis; it is important to assure that the dose is sufficient (60–120 mg) and is given for sufficient duration *(8, 50)*. Buprenorphine is a partial agonist; its effectiveness in treating opioid dependence is similar to that of methadone. It is taken mainly in its sublingual form (8–24 mg/day). OST programmes should create supportive environments and relationships to facilitate coordinated treatment of co-morbid mental and physical health issues and address relevant psychosocial factors *(50)*.

- To achieve optimal coverage and treatment outcomes, opioid substitution therapy should be provided free of charge or covered by public health-care insurance and should be accessible to all those in need, including those in prison and other closed settings *(50).*
- OST should not be compulsory; patients must give informed consent for treatment *(8, 50)*.
- To be most effective, OST should be provided as maintenance treatment for sufficient duration and at adequate doses *(8, 50)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

All people from key populations who are dependent on opioids should be offered opioid substitution therapy in keeping with WHO guidance *(strong recommendation, low quality of evidence) (8, 32, 50)*, including those in prison and other closed settings *(9)*.

Additional remarks

- To maximize the safety and effectiveness of OST programmes, policies and regulations should encourage flexible dosing structures, without restricting dose levels or duration of treatment *(50)*. Usual methadone maintenance doses should be in the range of a minimum of 60–120 mg per day, and average buprenorphine maintenance doses should be at least 8 mg per day *(50)*. Take-home doses can be offered when the dose and social situation are stable and when there is little risk of diversion for illegitimate purposes *(50)*. OST is most effective as a maintenance treatment for longer periods of time (treatment for years may be necessary). Detoxification or opioid withdrawal (rather than maintenance treatment) results in poor outcomes in the long term. However, patients should be helped to withdraw from opioids if it is their informed choice to do so *(50)*.
- OST should be used for the treatment of opioid dependence in pregnancy rather than attempt opioid detoxification *(50, 59)*.

- Psychosocial support should be available to all opioid-dependent people, in association with pharmacological treatments of opioid dependence. At a minimum this support should include assessment of psychosocial needs, supportive counselling and links to family and community services *(50)*.
- For opioid-dependent people with TB, viral hepatitis B or C or HIV, opioid agonists should be administered in conjunction with medical treatment. There is no need to wait for abstinence from opioids to start treatment for these conditions *(50)*.
- Treatment services should offer hepatitis B vaccination to all opioid-dependent patients (whether or not they are participating in OST programmes) *(50)*.
- Care settings that provide OST should initiate and maintain ART for eligible people living with HIV *(4)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- Prison authorities in countries where OST is available in the community should urgently introduce OST programmes and expand them to scale as soon as possible *(9)*.
- Countries should affirm and strengthen the principle of providing treatment, education and rehabilitation as an alternative to conviction and punishment for drug-related offences *(8)*.
- Care should be taken to see that people on OST before entering prisons or other closed settings can continue OST without interruption while imprisoned and when transferred between settings *(9, 50)* and can be linked to community-based OST upon release *(60)*.
- Provision of OST before release can help reduce overdose-related mortality *(61)*.

TRANSGENDER PEOPLE

There is no evidence of drug interactions between opioid substitution therapy and medications used for gender affirmation; however, research is very limited.

ADOLESCENTS FROM KEY POPULATIONS

WHO guidance does not specify age restrictions for opioid substitution therapy.

Implementation considerations

Documented processes should be established to ensure the safe and legal procurement, storage, dispensing and dosing of medicines, particularly methadone and buprenorphine *(50)*.

Supervision. In the early phase of treatment, administration of methadone and buprenorphine doses should be directly supervised *(50)*.

Take-home doses can be recommended when the dose and social situation are stable and when there is a low risk of diversion for illegitimate purposes *(50)*.

Involuntary discharge from treatment is sometimes justified to ensure the safety of staff and other patients, but failure to follow programme rules alone should not generally be cause for involuntary discharge. Before involuntary discharge reasonable measures to improve the situation should be taken, including re-evaluation of the treatment approach *(50)*.

Further reading

- *Guidelines for psychosocially assisted pharmacotherapy for the management of opioid dependence.* Geneva, WHO, 2009. http://www.who.int/hiv/pub/idu/opioid/en/index.html
- *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision.* Geneva, WHO, 2012. http://www.who.int/hiv/pub/idu/targets_universal_access/en/
- *Operational guidelines for the management of opioid dependence in the South-East Asia Region.* New Delhi, WHO Regional Office for South-East Asia, 2008. http://www.who.int/hiv/pub/idu/op_guide_opioid_depend/en/index.html
- *Guidelines for identification and management of substance use and substance use disorders in pregnancy.* Geneva, WHO, 2014. http://www.who.int/substance_abuse/publications/pregnancy_guidelines/en/

4.1.2.3 Other drug dependence treatment

Background and rationale

The evidence on HIV prevention is not as strong as for NSP and OST. Still, other drug dependence interventions are strongly recommended where non-opioid drugs are widely used or OST remains unavailable.

The objective of drug dependence treatment is to achieve and maintain physical, psychological and social well-being by reducing the risk-taking associated with drug use, reducing levels of drug use, or completely abstaining from drug use. Because of the chronic, relapsing nature of drug dependence and the need to address social and psychological dimensions, achieving abstinence, if desired, is often a lengthy and difficult process. Providing "stepping stones" or "stabilizing strategies" – short-term, more achievable goals – can help to define and structure progress. It can also help to reduce drug-related harms, one of which is the transmission of bloodborne viruses such as HIV and hepatitis B and C *(62)*.

The available evidence on the impact of other forms of drug dependence treatment on HIV incidence is less compelling than that for OST *(8, 63)*. Still, these other interventions are recommended where non-opioid drugs such as amphetamine-type stimulants, cocaine, sedatives and hypnotics are widely used and also where OST remains unavailable *(8)*. Drug dependence treatment helps to prevent HIV by reducing injecting drug use, reducing the sharing of injecting equipment, reducing sexual risk behaviours and creating opportunities for HIV education and medical care *(64)*.

Treatment of drug dependence typically blends different treatment modalities, but approaches may be simply categorized as psychosocial (abstinence-based or behavioural interventions) or pharmacological. Pharmacological modalities can be further categorized as detoxification, relapse prevention and treatments to reduce drug craving and use *(62)*.

Detention is not treatment. In a number of countries, people who use or inject drugs are apprehended and confined to detention centres, ostensibly for the purpose of drug treatment and rehabilitation but without trial or clinical assessment of dependence, and clinical treatment outcomes rarely determine the duration of detention. Typically, these centres lack medical supervision of drug withdrawal, and evidence-based drug dependence treatment is not offered. Detainees may be forced to engage in unpaid labour or military-style drills and may be subject to physical punishment. Following release from these centres, many relapse to drug use, and the risk of overdose may be increased *(65)*.

These approaches infringe on human rights. Furthermore, there is no evidence that they effectively treat drug dependence or reduce HIV transmission. Hence, they cannot be considered drug dependence treatment *(8)*. For these reasons, WHO and other UN partners do not support these forms of detention and call on Member States to close compulsory drug detention and rehabilitation centres and to implement voluntary, evidence-informed and rights-based health and social services in the community *(66)*.

Containing the spread of HIV is more successful where there is a comprehensive and varied range of evidence-based services for drug dependence treatment *(62)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

All key populations with harmful alcohol or other substance use should have access to evidence-based interventions, including brief psychosocial interventions involving assessment, specific feedback and advice *(conditional recommendation, very low quality of evidence) (3, 46)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- People in prisons should have access to the same evidence-based treatment options for substance dependence as people in the community *(9, 60)*.
- To reduce over-incarceration and prison overcrowding, which increase the risk of HIV infection, it is important that countries review their laws and policies that criminalize people for their consumption of alcohol or drugs *(9, 60)*.

ADOLESCENTS FROM KEY POPULATIONS

Treatment should be provided in the best interests of the adolescent concerned and in consultation with her or him.

Implementation considerations

Psychosocial interventions should be part of comprehensive treatment for drug dependence *(39, 50)*.

Alternatives to criminalization. Countries should affirm and strengthen the principle of providing treatment, education and rehabilitation as an alternative to conviction and punishment for drug-related offences. Currently, many countries make major expenditures on imprisonment of drug dependent people, an approach associated with very high relapse rates soon after release. There is no evidence that such an approach is effective or cost-effective *(8)*.

Further reading

- *mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings.* Geneva, WHO, 2011. http://www.who.int/mental_health/publications/mhGAP_intervention_guide/en/index.htm
- *Technical briefs on amphetamine-type substances.* Manila, WHO Regional Office for the Western Pacific, 2011. http://www.who.int/hiv/pub/idu/ats_tech_brief/en/index.html
- *Basic principles for treatment and psychosocial support of drug dependent people living with HIV/ AIDS.* Geneva, WHO, 2006. http://www.who.int/substance_abuse/publications/basic_principles_drug_hiv.pdf

4.1.2.4 Opioid overdose prevention and management

Background and rationale

Worldwide, drug overdose is the leading cause of death among people who inject drugs and a common cause of non-HIV-related deaths among people with HIV. An estimated 69 000 people die from overdose each year *(67)*.

Opioid overdose is both preventable and, if witnessed, treatable.

Opioid overdose is both preventable and, if witnessed, treatable. OST provides the most effective prevention among people dependent on opioids *(50)*. Opioid overdose is treatable by respiratory support and via the short-acting opioid antagonist naloxone. Naloxone has a long clinical history of successful use for the treatment of opioid overdose. The medication has no effect if opioids are absent and has no potential for abuse. Naloxone is included on the WHO Model List of Essential Medicines *(68)*.

While naloxone has long been widely used by medical staff and in health-care facilities, a number of countries in several regions have recently started community-based distribution, i.e. allowing distribution and administration by people dependent on opioids and their peers and family members as well as by first-responders such as police and emergency services. Greater availability of naloxone through community-based distribution could help reduce the high rates of opioid overdose, particularly where access to essential health services is limited for people who inject drugs.

Recommendations and guidance

ALL KEY POPULATION GROUPS

- People likely to witness an opioid overdose should have access to naloxone and be instructed in its use for emergency management of suspected opioid overdose *(strong recommendation, very low quality of evidence) (69)*.
- Naloxone is effective when delivered by intramuscular, intranasal, intravenous and subcutaneous routes. Persons administering naloxone should select the route based on formulation available, skills in administration, setting and local context *(conditional recommendation, very low quality of evidence) (69)*.
- In suspected opioid overdose, first-responders should focus on maintaining an airway, assisting ventilation and giving naloxone *(strong recommendation, very low quality of evidence) (69)*.
- After successful resuscitation following administration of naloxone, the affected person's level of consciousness and breathing should be closely observed – where possible, until the person has fully recovered *(strong recommendation, very low quality of evidence) (69)*.

Related recommendations and contextual issues for specific key population groups

ADOLESCENTS FROM KEY POPULATIONS

WHO guidance does not specify age restrictions for overdose management.

Implementation considerations

Legal and policy issues. There may be both legal and policy barriers to the access and use of naloxone by lay first responders, which may need to be reviewed in order to implement this recommendation.

Dose. Where possible, efforts should be made to tailor the dose to avoid marked opioid withdrawal symptoms. The choice of initial dose will depend on formulation and context, however doses above 0.8mg IM/IV/SC are more likely to precipitate significant withdrawal symptoms.

Further reading

- *Community management of opioid overdose*. Geneva, WHO, forthcoming.
- *WHO model list of essential medicines, 18th list.* Geneva, WHO, 2013. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf
- UNODC, WHO. *Discussion paper. Opioid overdose: preventing and reducing opioid overdose mortality.* Vienna, United Nations, 2013. http://www.unodc.org/docs/treatment/overdose.pdf

4.1.3 Behavioural interventions

Background and rationale

Behavioural interventions help individuals support safer behaviours and sustain this positive change.

To reduce their risk of acquiring STIs or HIV, people must understand their risk and have the knowledge, skills and belief in their self-efficacy to reduce that risk. Behavioural interventions provide information, motivation, education and skills-building to help individuals reduce risky behaviours and sustain this positive change.

Behavioural interventions may address individuals or groups. One-on-one counselling may focus on awareness of personal risk and risk reduction strategies; for example, counsellors or community workers may discuss risk behaviours, relate a participant's activities directly to HIV risk, and consider strategies to reduce this risk. In contrast, peer-to-peer interventions and group sessions may focus more on awareness of risk overall, with group sessions offering the added benefit of group support for finding

workable risk-reduction strategies. Social marketing campaigns also may help by promoting testing, treatment and other services.

Behavioural change interventions can be delivered as part of the other interventions in the comprehensive package. They may take place face-to-face or through broadcast mass media and digital media such as the Internet. Choices of content and approach, as well as of the medium, should be based on good formative analysis of the local situation.

Although the logic of behavioural interventions is primarily based on individual awareness and decision-making about risk, such interventions also can operate at the community level. For example, interventions may involve training opinion leaders to communicate with their peers, thus changing perceptions of social norms about risk and risk avoidance.

Adolescents deserve specific consideration as at this stage the urge to explore and experiment normally develops ahead of decision-making ability *(70)*. Adolescents' evolving cognitive abilities are an important consideration in the design of behavioural interventions for them.

Recommendations and guidance

ALL KEY POPULATION GROUPS

A range of behavioural interventions can provide information and skills that support risk reduction, prevent HIV transmission and increase uptake of services among all key populations. There is insufficient evidence to make general recommendations for all key populations. However, specific behavioural approaches for particular key population groups have been assessed and can be recommended.

Related recommendations and contextual issues for specific key population groups

MEN WHO HAVE SEX WITH MEN

- The following strategies are recommended to increase safer sexual behaviours and increase uptake of HIV testing and counselling among men who have sex with men:
  - targeted Internet-based information
  - social marketing strategies
  - sex venue-based outreach *(3, 32)*.
- Implementing both individual-level behavioural interventions and community-level behavioural interventions is suggested *(3, 32)*.

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- A peer-based, comprehensive approach increases the effectiveness of prison-based HIV education efforts *(9)*.
- Information and education programmes about HIV and other infectious diseases are important for both prisoners and prison staff. Special attention should be paid to the needs of prisoners after release.

PEOPLE WHO INJECT DRUGS

- People who inject drugs and relevant community networks should participate in developing and delivering messages.
- Behavioural interventions for people who inject drugs need to address risk related to both drug use and sexual behaviour *(27)*.
- For people who inject drugs, peer interventions are particularly effective for the prevention of HIV and viral hepatitis *(39)*.
- Information and education about safe injecting and overdose prevention are also important.

SEX WORKERS

Condom promotion programmes, including community-led programmes, can increase condom use by sex workers and their clients. Through peer- and community-led interventions, these programmes can provide information and skills-building for condom use and information and create demand for HIV testing, STI screening, and HIV treatment and care *(71)*.

TRANSGENDER PEOPLE

The following strategies are recommended to increase safer sexual behaviours and increase uptake of HIV testing and counselling among transgender people:

- targeted Internet-based information
- social marketing strategies
- sex venue-based outreach *(3, 32)*

Implementing both individual-level behavioural interventions and community-level behavioural interventions is suggested *(3, 32)*.

ADOLESCENTS FROM KEY POPULATIONS

Skills-based interactive and participatory approaches for adolescents from key populations, including online, mobile health, peer and outreach approaches, have proved acceptable to adolescents and have shown promise in some contexts *(72, 73)*.

Further reading

- Kennedy CE et al. Behavioural interventions for HIV positive prevention in developing countries: a systematic review and meta-analysis. *Bulletin of the World Health Organization*, 2010, 88(8):615–623. http://www.who.int/bulletin/volumes/88/8/09-068213/en/
- *Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people.* Geneva, WHO, 2011. http://www.who.int/hiv/pub/guidelines/msm_guidelines2011/en/

4.1.4 Prevention of transmission in health-care settings

The essential elements for preventing HIV transmission in health-care settings include:

Primary prevention procedures

- blood safety (see http://www.who.int/bloodsafety/publications/en/);
- prevention of unsafe injections;
- emergency and essential surgical care that limit the need for blood transfusion;
- standard precautions to minimize the spread of infection associated with health care and to avoid direct and indirect contact with blood, body fluids, secretions and non-intact skin. These basic infection control precautions in health care involve hand hygiene, use of personal protective equipment to prevent exposures, safe disposal of sharps and waste, and safe cleaning and disinfection of the environment and equipment;
- identifying, eliminating and controlling exposure to hazards in the workplace and preventing needlestick injuries.

Secondary prevention – that is, post-exposure prophylaxis (PEP) – is applicable **in health-care settings** when primary prevention has failed or when a health-care worker or patient has been exposed to the risk of HIV transmission, whether accidentally or through unsafe procedures (see Section 4.1.5.2).

Further reading

- *Blood donor selection. Guidelines on assessing donor suitability for blood donation.* Geneva, WHO, 2012. http://www.who.int/bloodsafety/publications/bts_guideline_donor_suitability/en

4.1.5 ARV-related prevention

4.1.5.1 Pre-exposure prophylaxis

WHO has developed new guidance concerning pre-exposure prophylaxis (PrEP) for inclusion in this publication. Full discussion of the guidance and its rationale is presented here.

Background and rationale

Oral pre-exposure prophylaxis of HIV is the daily use of ARV drugs by HIV-uninfected people to block the acquisition of HIV. Studies have demonstrated the effectiveness of PrEP in reducing HIV transmission among serodiscordant heterosexual couples, men who have sex with men, transgender women, high-risk heterosexual couples, and people who inject drugs *(4, 74)*.

WHO encourages countries to undertake demonstration projects to gain experience in implementing PrEP safely and effectively *(74)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

Where serodiscordant couples can be identified and where additional HIV prevention choices for them are needed, daily oral PrEP (specifically tenofovir or the combination of tenofovir and emtricitabine) may be considered as a possible additional intervention for the uninfected partner *(conditional recommendation, high quality of evidence) (74)*.

Related recommendations and contextual issues for specific key population groups

MEN WHO HAVE SEX WITH MEN

NEW Among men who have sex with men, PrEP is recommended as an additional HIV prevention choice within a comprehensive HIV prevention package *(strong recommendation, high quality of evidence)*.

Background

The conditional recommendations of 2012 to offer PrEP to men who have sex with men, transgender people and the HIV-negative partner in serodiscordant relationships in the context of demonstration projects *(74)* was reconsidered in 2014 in the light of evolving evidence. In addition, continuing high rates of HIV incidence are increasingly reported in men who have sex with men in all regions, despite the availability of current prevention interventions, suggesting that additional prevention options could be important.

The systematic review that provided the evidence base for the 2012 WHO guidelines on PrEP *(74)* was updated in January 2014. This review examined the following PICO[1] question: "Should oral PrEP (containing tenofovir (TDF)) be used for HIV prevention among men who have sex with men?"

The review of values and preferences of men who have sex with men about PrEP also was updated in January 2014, through a review of published literature (see Web Annex 1 for the full report). Also, further values and preference research was undertaken by the Global Forum on MSM (MSMGF) (Web Annex 3).

Results

Combining results from the 2012 and 2014 searches for the systematic reviews yielded 764 citations and 139 conference abstracts. Following screening and review, four studies reported in five articles were deemed eligible for inclusion in the review. Of these, one was a Phase III efficacy trial, while three were smaller pilot feasibility/acceptability or extended safety studies. Given the differences in the studies' purposes, drug regimens/dosing schedule and size/statistical power (and, thus, in imprecision and quality, according to the GRADE framework), only results from the primary Phase III efficacy trial were included in the GRADE tables. These are the results presented below. For further information on the other four studies, see Web Annex 1.

The primary Phase III efficacy trial meeting all inclusion criteria was the iPrEx trial *(75)*. This was a randomized controlled trial to evaluate the safety and efficacy of once-daily oral tenofovir-emtricitabine (FTC-TDF) compared with placebo for the prevention of HIV acquisition among men who have sex with men and among transgender women. The trial involved 2499 participants in six countries: Brazil, Ecuador, Peru, South Africa, Thailand and the United States of America. All study participants were born male; 29 (1%) reported their current gender identity as female. The study measured all five key outcomes for this review: (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) condom use and (5) number of sexual partners.

HIV infection. Oral PrEP was associated with reduced risk of new HIV infection in both intention-to-treat analysis (HR: 0.53, 95% CI 0.36–0.78, p=0.001) and modified intention-to-treat analysis (HR: 0.56, 95% CI 0.37–0.85, p=0.005).

Adverse events. There were no significant differences in the rates of reported adverse events between the FTC-TDF and control arms for either any adverse event (RR: 0.99, 95% CI 0.94–1.04) for grade 3 and 4 adverse events (RR: 0.92, 95% CI 0.75–1.13).

Condom use and number of sexual partners. Both the FTC-TDF and control arms reported increases in condom use and a reduced number of receptive sexual intercourse partners from baseline to follow-up. There were no significant differences between study arms over time.

Quality of the evidence. The quality of evidence was high for all outcomes, without serious limitations.

Values and preferences. While the relevant literature has proliferated recently, the reported values and preferences on PrEP use of men who have sex with men and

[1] PICO stands for "patients, intervention, comparison and outcome".

transgender people have remained fairly consistent with findings of the systematic review conducted in 2011.

Globally, awareness of PrEP among men who have sex with men continues to be limited, although several studies suggest awareness has increased since the release of the iPrEx results. Willingness to use PrEP varies across studies, but the majority report that 40% to 70% of respondents are willing to use PrEP.

Main factors that would influence PrEP use include effectiveness, side-effects and cost. Respondents also mentioned concerns about accessibility, mistrust of health-care providers, stigma and risk compensation. All studies measuring potential risk compensation found that at least some participants anticipated changing their sexual behaviour as a result of PrEP. Providers generally expressed awareness and support of PrEP, although few had prescribed it. Providers' concerns included drug resistance, risk compensation, limited availability of ART (in Peru), poor adherence, lack of local guidelines and concern that PrEP does not fit well in current (US) models of care, which do not include frequent, regular clinic visits.

Feasibility. Oral PrEP for men who have sex with men has proved feasible in various trial settings and acceptability studies (including among young men who have sex with men). Implementation may prove challenging, however, where access to services and provision of alternative prevention tools are limited or lacking. Issues of criminalization, stigma and discrimination, and violence should be considered during implementation, especially where same-sex behaviour is illegal.

Additional considerations

In formulating the new recommendation, the Guidelines Development Group took into consideration the overall high quality of the evolving evidence base, with benefits clearly outweighing harms (see Web Annex 1). In addition, several new studies indicate no major variability in values and preferences, with men who have sex with men broadly in support of PrEP.

Data on the cost-effectiveness of PrEP vary widely, depending greatly on drug price. The Group noted that in low-income countries PrEP is considerably cheaper than in many middle- and high-income countries.

PrEP is best offered as one component of a comprehensive set of HIV prevention interventions. Comprehensive HIV prevention programmes should include unfettered availability of condoms and lubricants, routine HIV testing, risk-reduction counselling and adherence coaching if PrEP is offered. In the introduction of PrEP, it will be important to assess the barriers and facilitators to existing HIV prevention strategies in the specific community and context. This assessment should be undertaken in collaboration with local key population-led and community-based organizations, advocates, providers, and researchers who have cultural sensitivity, knowledge and the trust of men who have sex with men. This process should include an assessment at local levels of:

- sexual and HIV stigma
- stigma associated with receipt of a particular prevention intervention

- provider attitudes and knowledge about the sexual health needs of men who have sex with men
- availability, accessibility, quality and use of basic HIV services
- knowledge and acceptability of ART-based prevention strategies
- laws that criminalize sex between men
- personal safety and security
- privacy and confidentiality protections
- legal literacy among and legal protections and services for men who have sex with men and their service providers
- community engagement
- other concerns particular to the location (identified by local staff of community-based organizations and recipients of services).

Based on the assessment, and in collaboration with local community-based organizations, it will be helpful to develop a plan to:

- address identified barriers
- mitigate risk to confidentiality, privacy, personal safety and security
- support and enhance facilitators and enablers as needed
- assess changes over time.

PEOPLE WHO INJECT DRUGS

- No new recommendation was made for use of oral PrEP for people who inject drugs.
- The existing recommendation to offer daily oral PrEP as an additional HIV prevention choice for the negative partner in a serodiscordant relationship remains relevant for people who inject drugs and are in a serodiscordant relationship *(conditional recommendation, high quality of evidence) (74)*.

Background

In the scoping meeting of October 2013, the External Steering Group decided that the use of PrEP for people who inject drugs should be reviewed.

A systematic review included all studies published in peer-reviewed journals or presented as abstracts at scientific conferences between 1 January 1990 and 1 January 2014. This systematic review examined the following PICO question: "Should oral PrEP (containing tenofovir (TDF)) be used for people who inject drugs?" More detailed information on the systematic review is available in Web Annex 2.

Results

The search yielded 183 citations and 243 conference abstracts; following screening and review only one study (with data for PICO outcomes reported in one article and one conference abstract) was deemed eligible for inclusion in the review – the Bangkok Tenofovir Study *(76, 77)*. This was a randomized controlled trial to assess whether daily oral use of tenofovir disoproxil fumarate (tenofovir), compared with placebo, reduces HIV transmission in injecting drug users. Conducted in Bangkok, Thailand, the trial recruited 2413 participants from 17 drug treatment clinics. Participants' ages ranged from 20 to 59 years (mean=32.4), 80% were male, and 63% reported injecting drugs in the past 12 weeks. The study measured all seven key outcomes for this review: (1) HIV infection, (2) any adverse event, (3) any stage 3 or 4 adverse event, (4) condom use, (5) number of sexual partners, (6) injection frequency and (7) needle/syringe sharing.

HIV infection. Oral PrEP was associated with reduced risk of HIV in both intention-to-treat analysis (HR 0.53, 95% CI 0.36–0.78, p = 0.001) and modified intention-to-treat analysis (HR: 0.56, 95% CI 0.37–0.85, p = 0.005).

Adverse events. There were no significant differences in reported rates of adverse events between the TDF and placebo arms for any adverse event (91% versus 90%, p = 0.46) or for grade 3 and 4 adverse events (13% versus 13%, p = 0.89).

Injection frequency and needle/syringe sharing. Both the TDF and control arms reported reduced injection behaviour and less injecting with used needles over the course of the study. There were no significant differences between study arms over time or at 12-month follow-up (p = 0.520 for injection frequency and p = 0.874 for needle/syringe sharing).

Condom use and number of sexual partners. Both the TDF and placebo arms reported increased condom use with live-in partners and reduced numbers of sexual partners over the course of the study. There was no significant difference between study arms over time or at 12-month follow-up.

Quality of the evidence. The quality of evidence was moderate for all outcomes based on one RCT that was downgraded because of risk of bias due to a significant loss to follow-up (attrition bias).

Values and preferences. The systematic review described above identified one published study examining acceptability of PrEP and factors likely to influence uptake among people who inject drugs. This quantitative study involved 128 people in Ukraine. Most participants said that they would definitely (53%) or probably (32%) use PrEP if it became available. These results changed little when participants were prompted on potential side-effects, the need to continue condom use while taking PrEP and the need for regular HIV testing. Respondents considered route of administration the most important attribute influencing PrEP uptake; they preferred injections over pills.

Additionally, WHO commissioned a qualitative in-depth values and preferences survey. The survey interviewed 21 people who inject drugs as well as experts, service providers and activists from all geographic regions about their values and preferences regarding PrEP. Those interviewed gave qualified support to PrEP based on its potential usefulness for some people who inject drugs in countries where other harm reduction options are not available and that have good ART access. Reticence about PrEP as a useful HIV

prevention option for people who inject drugs was based on perceptions that investment should be made in other proven interventions that are already available (e.g. NSP, OST and hepatitis C screening, diagnosis and treatment), that PrEP is "not proven" for people who inject drugs, and that it is unethical to give PrEP when not all people living with HIV can get ART for treatment; and on concern about "hidden agendas". The Guidelines Development Group concluded: "A recommendation for the use of PrEP as a harm reduction intervention for people who inject drugs is not supported by the community at this time."

Feasibility. Groups of people who inject drugs *(78)* and some members of the Guidelines Development Group raised concerns about the operational feasibility of the Bangkok Tenofovir Study and whether it could be replicated in standard service delivery settings. In addition, members of the Guidelines Development Group commented that PrEP should not be seen as a substitute for NSP and other prevention programmes already proven to reduce the risk of HIV transmission among people who inject drugs. The Guidelines Development Group also stated that issues of criminalization, stigma and discrimination, and violence should be considered during implementation, especially where injection drug use is illegal.

Additional considerations

After reviewing all the available evidence, the Guidelines Development Group concluded that **no recommendation should be made on PrEP for people who inject drugs**. There was uncertainty regarding the benefits versus harms and about resource utilization and feasibility.

The Guidelines Development Group pointed out that existing acceptable, cost-effective methods of preventing HIV in people who inject drugs (such as NSP, OST) are not implemented in many settings. While the Group acknowledged that further effectiveness and safety studies are unlikely given the positive efficacy shown in the Bangkok trial, the Group considered that further research is needed into the values and preferences of injection drug users and to determine the feasibility of implementing PrEP in the context of these proven prevention strategies. Therefore, the Group concluded, it was premature to make a recommendation, but a recommendation could be reconsidered when further information becomes available.

SEX WORKERS

The existing recommendation to offer daily oral PrEP as an additional HIV prevention choice for the HIV-negative partner in a serodiscordant couple remains relevant for sex workers who are in serodiscordant couple relationships *(conditional recommendation, high quality of evidence) (74)*.

Summary of the Guidelines Development Group discussion and other considerations

In the scoping meeting of October 2013, the External Steering Group decided that the use of PrEP for sex workers should not be considered in this guidelines process as there were no studies of PrEP among sex workers and results from demonstration projects were not yet available. Furthermore, studies relating to the values and preferences of sex

workers regarding PrEP were underway, and results were not yet available. This decision was confirmed in the guidelines meeting. The Guidelines Development Group agreed that this question could be considered as a PICO question with subsequent systematic review and GRADE assessments for future guidelines and should be prioritized with a focus on high prevalence settings with good ART access. Additionally, concerns were raised that a recommendation to use PrEP could undermine current comprehensive condom programming efforts, which have high acceptability and uptake in many settings.

TRANSGENDER PEOPLE

Where HIV transmission occurs among transgender women who have sex with men and additional HIV prevention choices for them are needed, daily oral PrEP (specifically the combination of tenofovir and emtricitabine) may be considered as a possible additional intervention *(conditional recommendation, high quality of evidence) (74)*.

Summary of the Guidelines Development Group discussion and other considerations

In the scoping meeting of October 2013, the External Steering Group decided that the conditional recommendation of 2012 should not be reconsidered, as there was no new evidence relating to transgender women, and very few transgender women have been included in PrEP trials to date. This was confirmed in the guidelines meeting, endorsing no change to the 2012 WHO guidelines recommendation for the use of PrEP for transgender people in demonstration projects. The Guidelines Development Group recognized that a systematic review of values and preferences, resource utilization and feasibility had not been conducted in the specific population of transgender women. For this reason the 2012 recommendation would remain valid. The Guidelines Development Group agreed that this question could be considered as a PICO question with subsequent systematic review and GRADE assessments for future guidelines. Additionally, a concern was raised that potential drug interactions may exist between regular use of PrEP and hormone replacement therapy (see Section 4.4.3); any future assessment of PrEP for transgender women will need to consider this issue.

Implementation considerations

Issues of criminalization, stigma and discrimination, and violence should be considered during implementation.

Delivery. It is currently not possible to develop definitive guidance on how best to deliver daily oral PrEP; in many settings demonstration projects are needed *(74)*.

Demonstration projects. Countries that introduce oral PrEP should undertake demonstration projects to ascertain the most appropriate user groups and the best delivery approaches *(74)*.

Further reading

- Web Annexes 1, 2 and 3.
- *Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV: recommendations for use in the context of demonstration projects.* Geneva, WHO, 2012. http://apps.who.int/iris/bitstream/10665/75188/1/9789241503884_eng.pdf

4.1.5.2 Post-exposure prophylaxis (PEP)

Background and rationale

PEP is the only way to reduce risk of infection after exposure to HIV.

Post-exposure prophylaxis (PEP) is given to reduce the likelihood of acquiring HIV infection after possible exposure. Since the early 1990s antiretroviral medicines have been prescribed for PEP following occupational exposure to HIV. This practice has been extended to non-occupational situations, including sexual assault. Other non-occupational exposures include those arising from sharing of injection equipment among people who inject drugs and possible exposure through consensual sex *(79)*. PEP is currently the only way to reduce the risk of HIV infection in an individual who has been exposed to HIV. As such, it is widely considered an integral part of the overall prevention strategy *(79)*.

PIPELINE

WHO PEP guidelines will be updated in late 2014 for all populations. The current recommended duration of PEP is 28 days; the first dose should be taken as soon as possible and within 72 hours after exposure. There has been a progressive trend favouring the adoption of better tolerated PEP regimens, often composed by once daily triple ARV drug combinations including nucleotide analogues and heat stable boosted protease inhibitors. More recently, other alternative drug classes such as non-nucleside analogues and integrase inhibitors have been considered. The 2014 WHO PEP guidance will provide updated regimens for adults, adolescents and children.

Despite its short duration, reported completion rates for PEP are low. Therefore, counselling and other adherence support measures are recommended. PEP should not be considered 100% effective. It is, therefore, imperative that HIV post-exposure prophylaxis policies reinforce the importance of primary prevention and risk prevention counselling in all settings where HIV could be transmitted *(79)*.

Offering pre-exposure prophylaxis after completion of the 28 day PEP course could be considered for people who present with repeated high risk behaviour or for repeat courses of PEP.

PEP should be available to all eligible people from key populations on a voluntary basis after possible exposure to HIV.

Recommendations and guidance

ALL KEY POPULATION GROUPS

HIV post-exposure prophylaxis should be considered for people presenting within 72 hours of a sexual assault. Use shared decision-making with the survivor to determine whether HIV post-exposure prophylaxis is appropriate *(strong recommendation, very low quality of evidence) (80)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

PEP should be made accessible to all people in prisons and other closed settings who have possibly been exposed to HIV, just as in non-prison settings. Clear guidelines need to be developed and communicated to prisoners, health-care staff and other employees *(9, 11)*.

Implementation considerations

An HIV risk assessment and counselling specific to HIV and PEP should be part of the PEP intervention *(79)*.

Comprehensive ongoing services should be available for people following PEP, including treatment and care for people who seroconvert *(79)*.

Further reading

- *Guidelines on post-exposure prophylaxis (PEP) to prevent HIV infection*. Geneva, WHO and ILO, 2007. http://whqlibdoc.who.int/publications/2007/9789241596374_eng.pdf
- *Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines*. Geneva, WHO, 2013. http://apps.who.int/iris/bitstream/10665/85240/1/9789241548595_eng.pdf

4.1.5.3 Early initiation of ART/ART regardless of CD4 count

Background and rationale

Evidence supports early initiation of ART in individuals, irrespective of CD4 count, to prevent HIV transmission.

Viral load is the single greatest determinant of the risk of HIV transmission. When someone is virally suppressed (viral load is undetectable), the risk of HIV transmission is significantly reduced. There is increasing evidence of the potential of ART to reduce

HIV transmission by lowering viral load. This evidence supports early initiation of ART in individuals, irrespective of CD4 count, for prevention of HIV transmission *(4)*.

Current WHO ARV guidelines recommend initiation of ART regardless of CD4 count for the HIV-positive partner in serodiscordant couples for HIV prevention and for all pregnant and breastfeeding women living with HIV (option B+) *(4)*. Early ART initiation is also recommended for clinical reasons for people coinfected with HIV and hepatitis B virus with severe hepatic disease and/or active TB.

The 2013 WHO ARV consolidated guidelines recommend initiation of ART at a CD4 count of ≤500 cells/mm^3 in all populations, including people from key populations. WHO will periodically update this guidance and will reconsider this recommendation in 2015. At this time the guidelines group did not re-review the data or consider earlier or immediate ART for key populations, although some countries are considering or providing immediate or early ART to key populations for prevention.

The rationale for initiating ART regardless of CD4 count for people in key populations living with HIV is both operational (to increase access to ART in populations that currently have low access, poor linkage and high loss to follow-up following diagnosis) and for the public health benefits of decreasing HIV transmission. More research and implementation evidence are required to evaluate the posited longer-term individual health benefits. For its 2015 update WHO will draw on implementation evidence from pilot studies and programmes currently underway.

Although ART has a significant HIV prevention effect, it should be used in combination with other biomedical interventions that reduce HIV risk practices and/or reduce the probability of HIV transmission per contact event, including male and female condoms, needle and syringe programmes, opioid substitution therapy with methadone or buprenorphine and voluntary medical male circumcision *(4)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

ART should be initiated in all individuals with HIV regardless of WHO clinical stage or CD4 count in the following situations:

- Individuals with HIV and active TB disease *(strong recommendation, low quality of evidence)*.
- Individuals coinfected with HIV and hepatitis B virus (HBV) with evidence of severe chronic liver disease *(strong recommendation, low quality of evidence)*.
- For programmatic and operational reasons, particularly in generalized epidemics, all pregnant and breastfeeding women with HIV should initiate ART as lifelong treatment *(conditional recommendation, low quality of evidence) (4)*.
- Partners with HIV in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners *(strong recommendation, high quality of evidence) (4)*.

4.1.6 Voluntary medical male circumcision for HIV prevention

Background and rationale

Medical male circumcision reduces the risk of female-to-male sexual transmission of HIV by about 60%.

There is compelling evidence from three randomized controlled trials in Africa that medical male circumcision reduces the risk of female-to-male sexual transmission of HIV by approximately 60% *(81, 82, 83)*. Thus, WHO and UNAIDS recommend voluntary medical male circumcision (VMMC) as an additional efficacious intervention for prevention of heterosexually acquired HIV, particularly in settings with generalized HIV epidemics *(84)*. The most recent data from Uganda show that, in the five years since the Uganda trial was completed, high effectiveness has been maintained among the men who were circumcised, with a 73% protective effect against HIV infection *(85)*.

VMMC is safe when provided by well-trained health professionals in properly equipped settings. Health messages should be carefully tailored, culturally sensitive, draw on local language and symbols, and be appropriate to the particular level of education and understanding of the population groups that they address. Messages should address both men and women *(84)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

- VMMC is recommended as an additional, important strategy for the prevention of heterosexually acquired HIV infection in men, particularly in settings with hyperendemic and generalized HIV epidemics and low prevalence of male circumcision *(84)*.
- VMMC service provision should serve as an opportunity to address the sexual health needs of men; such services should actively counsel and promote safer sexual behaviour *(84)*.

Related recommendations and contextual issues for specific key population groups

MEN WHO HAVE SEX WITH MEN

- VMMC is not recommended to prevent HIV transmission in sex between men, as evidence is lacking that VMMC is protective during receptive anal intercourse *(3)*.
- Men who have sex with men may still benefit from VMMC if they also engage in vaginal sex. Men who have sex with men should not be excluded from VMMC services in countries in eastern and southern Africa where VMMC is offered for HIV prevention.

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

VMMC is **not** one of the recommended interventions in the prison package. If VMMC is offered to men in prisons in priority countries in eastern and southern Africa with generalized epidemics and low rates of male circumcision, it is crucial that it is provided with full adherence to medical ethics and human rights principles. Informed consent, confidentiality and absence of coercion should be assured.

SEX WORKERS (AND CLIENTS OF SEX WORKERS)

- Health messages and counselling should emphasize that resuming sexual relations before complete wound healing may increase the risk of HIV acquisition among recently circumcised HIV-negative men and may increase the risk of HIV transmission to female partners of recently circumcised HIV-positive men *(84)*.
- "Men's health services" offering VMMC to clients of sex workers or other men at higher risk (such as in serodiscordant couples) may be a promising approach in the high-priority countries of eastern and southern Africa to reach men at greater risk of HIV infection. This approach has not been systematically reviewed and evaluated, however.

TRANSGENDER PEOPLE

VMMC is not recommended for HIV prevention among transgender women *(3)*.

ADOLESCENTS FROM KEY POPULATIONS

Countries with hyperendemic and generalized HIV epidemics and low prevalence of male circumcision should increase access to male circumcision services as a priority for adolescents and young men *(84)*.

Implementation considerations

Partial protection. Male circumcision provides only partial protection against female-to-male HIV infection. Therefore, male circumcision services should not be delivered in isolation but rather as part of a recommended minimum package that also includes information about the risks and benefits of the procedure, counselling on safer sex practices, access to HIV testing, condom promotion and provision, and management of STIs *(84)*.

Opportunity to expand services. Introduction and expansion of VMMC services in high-priority countries of eastern and southern Africa should serve as an opportunity to expand HIV services to all males.

Further reading

- *Male circumcision for HIV prevention.* Geneva, WHO, 2014. http://www.who.int/hiv/topics/malecircumcision/en/
- *Clearinghouse on male circumcision for HIV prevention.* Research Triangle Park NC, USA, FHI360, 2014. http://www.malecircumcision.org/
- *New data on male circumcision and HIV prevention: policy and programme implications.* Geneva, WHO, 2007. http://libdoc.who.int/publications/2007/9789241595988_eng.pdf

4.2 HIV testing and counselling

Background and rationale

HIV testing and counselling (HTC) is the essential first step in enabling people with HIV to know their status and obtain HIV prevention, treatment and care services. For those who test negative, HTC is an important opportunity to put those at risk for HIV in contact with primary prevention programmes and to encourage later retesting *(4)*.

For key populations, especially those whose behaviour is criminalized, HTC services are sometimes used in punitive or coercive ways. To the contrary, HTC must always be voluntary and free from coercion, in particular by health-care providers, partners, family, clients of sex workers or within a prison or other closed setting *(4, 8, 9, 10, 86)*. Like all testing and counselling, HTC for key populations needs to emphasize the WHO 5 Cs of HTC: consent, confidentiality, counselling, correct results and linkage to care *(87)* – particularly consent and confidentiality.

HTC is the essential first step, but about half of people living with HIV do not know their HIV status.

Furthermore, HTC must be part of a comprehensive prevention, care and treatment programme *(4)*. It is important that there are clear and robust links between testing and HIV prevention, treatment and care services for those who test positive and with prevention services for those who test negative; poor linkages prevent people from acting on their test results. HIV testing among key populations should follow nationally validated testing algorithms, accord with WHO testing strategies and have appropriate quality assurance/quality improvement mechanisms in place *(88)*.

Unaware of HIV status. It is estimated that, globally, about half of the people currently living with HIV do not know their HIV status *(88)*. For people from key populations, access to HTC and, thus, knowledge of HIV status tend to be much less. People from key populations often test late and often fail to link from HTC to care and assessment for ART *(88)*. Thus, many start treatment when already significantly immunocompromised,

when poor health outcomes – and, for pregnant women presenting late in antenatal care or at delivery, vertical HIV transmission – are more likely *(4)*.

Counselling is an essential component of testing. Pre-test counselling must provide accurate information about the test and the implications of a positive or negative result in order to enable the person seeking testing to make an informed choice. Post-test counselling must offer, among much else, support concerning disclosure of HIV status. Also, HTC offers a valuable opportunity to provide accurate information about safer sex and harm reduction that is relevant to the person being tested, reflecting the test result. Behavioural change and risk reduction counselling may also have value.

Multiple settings. Rapid HIV testing enables health workers to provide clients with same-day results. Thus, HTC can be offered in a variety of settings, including primary care clinics (e.g. maternal, neonatal and child health clinics), and by a variety of providers, including outreach workers.

Community-based testing, linked to prevention, care and treatment, has the potential to reach greater numbers of people than clinic-based HTC – particularly those unlikely to go to a facility for testing and those who are asymptomatic *(89)*. It is important to have clear procedures in place, following national HIV testing strategies and algorithms, to confirm positive HIV test results and to link clients to treatment and care *(9)*.

Provider-initiated HIV testing and counselling (PITC), where HTC is offered routinely in health-care settings, aims to increase coverage of HTC. It is recommended so long as it is not compulsory, is not coercive and is linked to treatment and care, in line with WHO guidelines. Particular attention should go to providing accurate information; informed consent must always be obtained; and results should remain confidential.

All forms of HTC should be voluntary and adhere to the five Cs: consent, confidentiality, counselling, correct test results and connections to care, treatment and prevention services. Quality assurance of both testing and counselling is essential to all HTC approaches *(4, 90)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

- Voluntary HTC should be routinely offered to all key populations in both the community and clinical settings *(3, 4, 8, 10, 86, 91)*.
- Community-based HIV testing and counselling for key populations, with linkage to prevention, care and treatment services, is recommended, in addition to provider-initiated testing and counselling *(strong recommendation, low quality of evidence) (4)*.

Additional remark

Couples and partners should be offered voluntary HTC with support for mutual disclosure *(92)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

It is important to guard against negative consequences of testing in prisons – for example, segregation of prisoners – and to respect confidentiality. It is also important that people who test positive have access and are linked to HIV care and treatment services *(9, 93)*.

- HIV testing and counselling should be voluntary *(93)*.
- The use of HIV rapid testing can increase the likelihood of prisoners receiving their results *(93)*.
- Testing in conjunction with other risk-reduction services such as the provision of condoms with lubricants and STI screening can increase the benefits of testing and counselling *(93)*.

ADOLESCENTS FROM KEY POPULATIONS

In all epidemic settings accessible and acceptable HTC services must be available to adolescents and provided in ways that do not put them at risk *(86)*. Countries are encouraged to examine their current consent policies and consider revising them to reduce age-related barriers to access and uptake of HTC and to linkages to prevention, treatment and care following testing *(86)*. Young people should be able to obtain HTC without required parental or guardian consent or presence.

- HIV testing and counselling, with linkages to prevention, treatment and care, is recommended for adolescents from key populations in all settings (generalized, low and concentrated epidemics) *(strong recommendation, very low quality of evidence) (4, 86)*.
- Adolescents should be counselled about the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine when, how and to whom to disclose *(conditional recommendation, very low quality of evidence) (86)*.
- Children of school age should be told their HIV-positive status *(strong recommendation, low quality of evidence) (86)*.

Implementation considerations

Rapid tests. Rapid HIV diagnostic tests at point of care greatly facilitate access to testing, return of same-day results and appropriate referral and follow-up *(4)*.

Continuous supply. Mechanisms should be developed to provide a consistent supply of test kits and prevent stock-outs.

Quality of services determines the uptake of HTC. Therefore, it is critical to institute a quality assurance system at national, subnational, facility and community levels *(95)*.

Prison systems should be an integral part of national efforts to scale up access to HTC. Scaling up HIV HTC services in prisons should not be undertaken in isolation, but rather as part of a comprehensive HIV programme aimed at improving health care and achieving universal access to HIV prevention services in prisons and other closed settings *(93)*.

Couples HTC. There are many potential advantages to supporting couples to test together and mutually disclose their HIV status; together, they can make informed decisions about HIV prevention and offer each other support for obtaining and adhering to ART. HTC for couples or partners should be offered to anyone, regardless of how they define their relationships. The principle – and the policy – should be that providers support all people in a sexual relationship to receive testing as a couple or as partners, irrespective of their sexual orientation or the length or stability of their relationship.

Self-testing for HIV (HIVST) is a process whereby a person who wants to know his or her HIV status collects a specimen, performs a test and interprets the test result in private. HIVST is a screening test; it does not provide a diagnosis *(96)*, and so confirmatory testing is required if the initial result is positive. HIVST may increase the number of people who test, know their status and, if testing positive, link to treatment. To date, evidence on this potential is limited, however.

While HIV self-testing kits may have been approved for sale and use, many countries do not have formal regulations or policies on their use. WHO has not yet issued normative global guidance on HIVST. However, UNAIDS and WHO have issued a short technical update to inform stakeholders who are considering or already implementing HIVST *(97, 98)*.

Further reading

- *Guidance on provider-initiated HIV testing and counselling in health facilities.* Geneva, WHO, 2007. http://whqlibdoc.who.int/publications/2007/9789241595568_eng.pdf
- UNODC, WHO, UNAIDS. *HIV testing and counselling in prisons and other closed settings.* Vienna, UNODC, 2009. http://www.who.int/hiv/pub/idu/tc_prison_tech_paper.pdf
- *Delivering HIV test results and messages for re-testing and counselling in adults.* Geneva, WHO, 2010. http://whqlibdoc.who.int/publications/2010/9789241599115_eng.pdf
- *Service delivery approaches to HIV testing and counselling: a strategic policy framework.* Geneva, WHO, 2010. http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf
- *Guidance on couples HIV testing and counselling and antiretroviral therapy for treatment and prevention in serodiscordant couples.* Geneva, WHO, 2012. http://apps.who.int/iris/bitstream/10665/44646/1/9789241501972_eng.pdf
- *Report on the first International Symposium on Self-testing for HIV: the legal, ethical, gender, human rights and public health implications of HIV self-testing scale-up.* Geneva, WHO, 2013. www.who.int/iris/bitstream/10665/85267/1/9789241505628_eng.pdf
- *HIV and adolescents: guidance for HIV testing and counselling and care for adolescents living with HIV: recommendations for a public health approach and considerations for policy-makers and managers.* Geneva, WHO, 2013. http://www.who.int/iris/bitstream/10665/94334/1/9789241506168_eng.pdf

4.3 Linkage and enrolment in care

HTC is just the first step in the continuum of HIV care; a positive HIV diagnosis without linkage to HIV prevention, care and treatment confers limited benefit. Ensuring that people are linked to and enrolled in HIV clinical care is necessary to realize the full health and prevention benefits of ART. Unfortunately, substantial losses occur at every step of the HIV care continuum. These losses can be particularly great among people from key populations.

Psychological and social barriers. A number of psychological and social barriers hinder linkage to care for people newly diagnosed with HIV. The perceived stigma associated with attending an HIV clinic continues to be a barrier to early care enrolment. Lack of family support and fear of disclosure also hinder access. In addition, how people living with HIV perceive both their own health and the effectiveness of ART can affect their willingness to seek clinical care. People living with HIV who believe that alternative therapies will be effective, who fear the side-effects of ART, or who perceive that they are in good health are less likely to enrol in HIV care than those who do not have these perceptions *(99)*. Also, injecting drug use is associated with poor linkage to and retention in care *(100, 101)*.

Several interventions to address these psychosocial barriers have been evaluated. Intensified post-test counselling combined with follow-up counselling by community health workers significantly increases the proportion who enrol in HIV care *(102)*. People who inject drugs are more likely to start and stay in HIV treatment if they are participating in OST programmes *(103)*.

Economic constraints. Migration in search of employment opportunities *(104)* and an inability to miss work to attend clinical appointments *(105, 106)* may also inhibit enrolment in HIV clinical care.

Health system factors affecting linkage to care include reliance on passive referral as the only linkage strategy, inadequate staffing, long wait times, poor service offered in HIV clinics, and poor attitudes of health-care staff.

Key operational issues need to be considered and addressed in order to improve linkage to care, including better partnerships between community and clinical providers and increased efforts to improve the quality of services (see Chapter 6).

4.4 HIV treatment and care

4.4.1 Antiretroviral therapy

Background and rationale

The use of ART for HIV in key populations should follow the same general principles and recommendations as for all adults *(4)*. They should have the same access, as well. People in key populations may experience discrimination and marginalization that can impede their access to health care, including treatment for HIV. It is important to ensure that people from key populations have equitable access to HIV treatment and care.

Updated guidance. The 2013 revision of WHO ART guidelines includes new recommendations on when to initiate ART, what drug regimens to use for first-line, second-line and third-line treatment, and how to monitor people on ART. These guidelines *(4)* should be consulted for full details on ART management.

Key populations living with HIV should have the same access to ART and care and the same ART management as other populations.

Recommendations and guidance

ALL KEY POPULATION GROUPS

ART initiation

- As a priority ART should be initiated in all individuals with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 counts of ≤350 cells/mm^3 *(strong recommendation, moderate quality of evidence) (4)*.
- ART should be initiated in all individuals with HIV with CD4 counts between 350 and 500 cells/mm^3 regardless of WHO clinical stage *(strong recommendation, moderate quality of evidence) (4)*.
- ART should be initiated in all individuals with HIV, regardless of WHO clinical stage or CD4 count, in the following situations *(4)*:
  - individuals with HIV and active TB disease *(strong recommendation, low quality of evidence)*;
  - individuals co-infected with HIV and HBV with evidence of severe chronic liver disease *(strong recommendation, low quality of evidence)*;
  - partners with HIV in serodiscordant couples, to reduce HIV transmission to uninfected partners *(strong recommendation, high quality of evidence)*;
  - pregnant and breastfeeding women *(strong recommendation, moderate quality of evidence)*.

Additional remark

There are no special clinical ART recommendations specific to any key population. However, because of stigma, discrimination and marginalization, they frequently present late for treatment.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- HIV treatment adherence can be increased by addressing HIV stigma and discrimination, ensuring the confidentiality of a prisoner's HIV status, and allowing people in prisons and other closed settings access to care and treatment without discrimination by prison officials.
- If they are being transferred, people in prisons and other closed settings should be given a supply of ART to last until health care can be established at the new prison location or, if they are being released, until linkage can be made to community-based HIV care *(60, 107, 108, 109, 110, 111, 112, 113, 114)*.

PEOPLE WHO INJECT DRUGS

- Current WHO guidance on the use of ART for treatment of HIV infection in adults and adolescents applies to people living with HIV who inject drugs *(4)*.
- When ART is provided in a supportive environment, people who inject drugs have treatment outcomes similar to others' outcomes *(115)*.

ADOLESCENTS FROM KEY POPULATIONS

Community-based approaches can improve treatment adherence and retention in care of adolescents living with HIV *(86)*.

Training of health-care workers can contribute to treatment adherence and retention in care of adolescents living with HIV *(86)*.

Health-care providers can support adherence among adolescents by:

- assisting them in exploring factors influencing their adherence
- improving their understanding of HIV, ART and adherence
- recognizing developmental needs while supporting their emerging independence
- assisting them in integrating ART into daily life
- offering simplified ART regimes
- encouraging participation in peer support groups and community-based interventions *(116, 117, 118)*.

Implementation considerations

ART service delivery. The 2013 WHO consolidated ARV guidelines *(4)* offer a number of service delivery recommendations, including decentralization of ART care and integrating ART services into other clinical services such as TB services, ANC and services where OST is provided.

Approaches to support ART delivery, retention in care and adherence. People from key populations often face more barriers than other populations to access to care and continuation in care. They often are hard to reach and mobile, have less access to and uptake of health services in general and may face stigma and discrimination in health services. Chapter 6 considers a range of approaches to support better access, retention and adherence models.

ART in prisons and other closed settings. HIV treatment, including ART, care and support, in prisons should be equivalent to that available to people living with HIV in the community and should be in line with national guidelines.

People who are incarcerated have the additional risk of acquiring TB. However, with adequate support and structured treatment programmes, excellent outcomes can be achieved in the prison setting *(4, 9)*. Given the high incarceration rates in key populations, efforts should be made to ensure that ART (and TB treatment) is available as part of prison health services *(4, 9)*.

Further reading

- *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach.* Geneva, WHO, 2013. http://www.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf

4.4.2 Prevention of mother-to-child transmission

Background and rationale

Prevention of mother-to-child transmission (PMTCT) of HIV, also known as prevention of vertical transmission, refers to interventions to prevent transmission of HIV from a mother living with HIV to her infant during pregnancy, labour and delivery or during breastfeeding. PMTCT also focuses on early initiation of ART in the mother and assuring the mother's health.

WHO recommends a four-pronged approach to a comprehensive PMTCT strategy:

1. Primary prevention of HIV infection among women of childbearing age
2. Preventing unintended pregnancies among women living with HIV
3. Preventing HIV transmission from women living with HIV to their infants
4. Providing appropriate treatment, care, and support to mothers living with HIV, their children and families.

Direct interventions to prevent vertical transmission consist of a cascade of services.

In the third prong, which focuses on the direct interventions to prevent vertical transmission, the preventive interventions consist of a cascade of services, from HIV testing and counselling, ART, safe delivery, safer infant feeding, postpartum interventions in the context of ongoing ART, early infant diagnosis and final diagnosis for HIV-exposed infants, through linkage of both the mother and child to appropriate care and treatment (prong 4).

All pregnant women from key populations should have the same access to PMTCT services and follow the same recommendations as women in other populations.

Recommendations and guidance

ALL PREGNANT WOMEN[1] IN KEY POPULATION GROUPS

- All pregnant and breastfeeding women living with HIV should initiate triple antiretrovirals (ARV), which should be maintained at least for the duration of risk of mother-to-child transmission. Women meeting treatment eligibility criteria should continue ART for life (CD4 <500 cells/mm^3) *(strong recommendation, moderate quality of evidence) (4)*.
- For programmatic and operational reasons, particularly in generalized epidemics, all pregnant and breastfeeding women living with HIV should initiate ART and maintain it as lifelong treatment (option B+) *(conditional recommendation, low quality of evidence) (4)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

Special consideration should be given to ensuring that pregnant female prisoners have ready access to PMTCT services, as women often face greater barriers to HIV testing, counselling, care, and treatment in prison than outside prison.

[1] This includes pregnant transgender men.

PEOPLE WHO INJECT DRUGS

All pregnant women and their families affected by substance use disorders should have access to affordable prevention and treatment services and interventions delivered with a special attention to confidentiality, national legislation and international human rights standards; women should not be excluded from health care because of their substance use *(119)*.

Implementation considerations

Equity and overcoming barriers to access. In most countries women from key populations have less access to PMTCT than women in the general population. In particular, people who inject drugs, their partners, and sex workers have less access. Also, adolescent girls generally and adolescent girls from key populations in particular have less access to PMTCT interventions and have worse outcomes. Special efforts should be made to understand and overcome barriers to access and to provide acceptable services that reach adult and adolescent women from key populations.

Later presentation. Adult and adolescent women from key populations often present late to antenatal care (ANC) or first present at labour without any ANC, and consequently they access PMTCT interventions very late. Also, they often face special challenges to follow-up and ongoing interventions postpartum. This has adverse consequences for their own health and their infants', and it decreases the effectiveness of PMTCT interventions. Strategies need to be developed to promote and support earlier attendance at ANC by pregnant women from key populations.

Supporting adherence. Special effort and initiatives are needed to optimize access to care and adherence support for women from key populations and to support effective linkages to long-term treatment. This is especially true during breastfeeding, a period when follow-up is often poor.

Further reading

- *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach.* Geneva, WHO, 2013. http://www.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf
- *Guidelines for the identification and management of substance use and substance use disorders in pregnancy.* Geneva, WHO, 2014. http://apps.who.int/iris/bitstream/10665/107130/1/9789241548731_eng.pdf

4.4.3 ART drug interactions

Background and rationale

Possible drug interactions add complexities when prescribing ARV drugs and monitoring treatment.

Providers should be aware of all drugs that people with HIV are taking when ART is initiated and new drugs that are added during continuing treatment. For many from key populations, this may include recreational drugs, drugs for coinfections and co-morbidities, and among transgender people cross-sex hormones. Possible drug interactions add complexities when prescribing ARV drugs and monitoring treatment. Counselling on the possible consequences of drug interactions and an environment that promotes and enables reporting of concomitant medications are critical components of high-quality care for all people with HIV.

Tuberculosis

WHO TB treatment guidelines review key considerations for managing coinfection with TB and HIV *(120)*. A key contraindicated drug combination is rifampicin and protease inhibitors (PIs). When people coinfected with TB and HIV are receiving a boosted PI, rifabutin may need to be substituted for rifampicin. If rifabutin is not available, only lopinavir/ritonavir (LPV/r) can be concomitantly used for the duration of TB treatment, provided the boosting dose of ritonavir is increased or double the standard dose of LPV/r is used.

Hepatitis C

Ribavirin and pegylated interferon alpha-2a are often used to treat chronic hepatitis C virus (HCV) infection. Administration of these agents along with zidovudine (AZT) has been associated with increased risk of anaemia and hepatic decompensation. People co-infected with HCV and HIV and receiving AZT may need to be switched to tenofovir (TDF) *(121)*.

Hormones used for contraception

ARV drugs have the potential to either decrease or increase the bioavailability of steroid hormones in hormonal contraceptives *(122)*. Limited data suggest potential drug interactions between contraceptive hormones and many ARV drugs (especially some non-nucleoside reverse transcriptase inhibitors (NNRTIs) and ritonavir (RTV)-boosted PIs). These interactions *may* alter the safety and effectiveness of both the hormonal contraceptive and the ARV drug. However, current WHO contraception guidelines conclude that none of the drug interactions between currently recommended ARVs for treatment and for PrEP, on one hand, and, on the other, hormonal contraceptives are significant enough to prevent their use together *(122)*. If women receiving ART decide to initiate or continue using hormonal contraceptives, consistent use of condoms is recommended both to prevent HIV transmission and to compensate for any possible reduction in the effectiveness of the hormonal contraception.

Hormones used in cross-hormonal treatment protocols for transgender women and men

There are limited data on the interactions between ARVs and a variety of other drugs used in cross-hormonal treatment protocols for transgender women, particularly with

anti-androgens (e.g. cyproterone acetate, flutamide). The same is true for androgens (e.g. dihydrotestosterone) commonly used by transgender men. Currently, there are no documented drug interactions between these medications and ARVs. However, this issue deserves more research, as transgender women and men often use several drugs combined and sometimes at high doses, with potential for multidirectional drug interactions. Meanwhile, as ARV treatment may lead to hormonal fluctuations among transgender women taking gender-affirming medications, close monitoring is recommended.

In addition, some ARV drugs may potentiate glucose and lipid metabolic abnormalities associated with alterations in hormone levels as well as increase the risk of thrombotic events and hepatic toxicity *(123)*. All these risks are further increased by the frequent practice of self-medication, which often involves products and doses that are less safe than those typically prescribed by health workers. More research in these areas also is needed.

Opioids

WHO recommends methadone and buprenorphine to treat opioid dependence *(50)*. Co-administering efavirenz (EFV) decreases methadone concentrations. This could subsequently cause withdrawal symptoms and increase the risk of relapse to opioid use. People receiving methadone and EFV should be monitored closely, and those experiencing opioid withdrawal may need to adjust their methadone dose *(50)*.

The limited evidence suggests no interactions between ARVs and recreational drugs. There can be dangerous interactions between recreational drugs, however. For example, concomitant amyl nitrite ("poppers") and sildenafil may cause cardiovascular complications.

Table 4.1 Key ARV drug interactions and suggested substitutions

ARV drug	Key interactions	Suggested management
AZT	Ribavirin and peginterferon alfa-2a	First-line: substitute AZT with TDF Second-line: substitute AZT with stavudine (d4T)
Boosted PI (ATV/r, DRV/r, LPV/r)	Rifampicin Estrogen-based hormonal contraception Methadone and buprenorphine	Substitute rifampicin with rifabutin[1] Advise additional use of male or female condoms Adjust methadone and buprenorphine doses as appropriate
EFV	Methadone Estrogen-based hormonal contraception	Adjust the methadone dose as appropriate Advise additional use of male or female condoms
Nevirapine (NVP)	Rifampicin Estrogen-based hormonal contraception	Substitute NVP with EFV Advise additional use of male or female condoms

[1] If rifabutin is not available, only LPV/r can be used, provided the boosting dose of ritonavir is increased or double the standard dose of LPV/r is used.

Further reading

- *HIV-drug interactions.* The University of Liverpool. http://www.hiv-druginteractions.org/

4.5 Prevention and management of coinfections and co-morbidities

An essential part of HIV treatment and care is the management of opportunistic infections such as TB and viral hepatitis. Addressing HIV effectively also requires addressing other co-morbidities such as other sexually transmitted bloodborne infections and mental health disorders. To synergize prevention and control efforts, it is appropriate to seek opportunities to combine the delivery of HIV testing, treatment and prevention services with those for these coinfections and co-morbidities.

4.5.1 Tuberculosis

Background and rationale

Tuberculosis is preventable and treatable, but it accounts for one in every five HIV-related deaths.

Despite being preventable and curable, TB is the leading cause of HIV-associated mortality, accounting for one of every five HIV-related deaths. The risk of developing TB is 30 times higher among people living with HIV than among people who do not have HIV infection *(124)*. In 2012 there were an estimated 1.1 million cases of TB among the 35 million people living with HIV worldwide *(124)*. Independent of their HIV status, key populations, in particular people who inject drugs and prisoners, have an increased risk of TB, including multidrug-resistant TB (MDR-TB) *(50, 125, 126, 127, 128)*. In addition, outbreaks of TB and MDR-TB have been reported among men who have sex with men and transgender sex workers *(129, 130)*. Common risk factors and social determinants that put key populations at increased risk of TB include HIV infection, poverty, malnutrition, stress, alcoholism, smoking, diabetes, indoor air pollution, drug use, incarceration and poor living and working conditions *(131)*.

Prisons play a key role in fuelling the epidemic of TB and MDR-TB, and TB is believed to be the leading cause of death among prisoners in high burden settings *(132, 133)*. Similarly, other congregate settings frequently attended by people living with HIV and marginalized groups can expose them to increased risk of TB if adequate TB infection control measures are not in place. Such settings could include brothels, bars, drop-in centres, drug treatment centres, health facilities and shelters *(130, 134, 135, 136)*.

To address TB among people living with HIV, including key populations, WHO recommends a 12-point package of collaborative TB/HIV activities. The package seeks to establish and strengthen mechanisms for delivering integrated TB and HIV services, to reduce the burden of TB among those living with HIV, and to reduce the burden of HIV in TB patients *(4, 65, 137, 138, 139)*.

Barriers to prevention and care for key populations need to be addressed to ensure access to integrated, client-centred services, preferably at the initial point of care, and to encourage treatment adherence *(65)*.

Prevention of TB. Isoniazid preventive therapy (IPT) and ART, given together, can reduce the risk of TB among people living with HIV by up to 97% *(140)*. Alone, IPT has been shown to reduce the risk of TB among people living with HIV by 68% *(137)*. Once active TB is ruled out, people living with HIV should be offered at least six months, IPT and support should be provided to ensure adherence. Also, appropriate TB infection control measures and contact tracing are essential to reduce transmission of TB in congregate settings *(50, 125)*.

Screening and diagnosis of TB. All people living with HIV should be screened regularly with the WHO-recommended four TB symptom screening algorithm – that is, a current cough, fever, night sweats or weight loss – at each contact with a health-care worker *(137)*. This screening helps determine eligibility for IPT by ruling out the likelihood of active TB and to identify those who need further evaluation, diagnosis and treatment for TB as necessary. WHO recommends using Xpert MTB/RIF as the first diagnostic test for all TB in all people living with HIV and for anyone suspected of MDR-TB (irrespective of HIV status) *(141)*. Stakeholders providing support to key populations can offer gateways to early TB detection and timely prevention and treatment of both TB and HIV. It is crucial, therefore, that personnel are aware of the symptoms of TB.

TB treatment. TB treatment consists of a standardized regimen of antibiotics taken for at least six months, irrespective of HIV status. Completing TB treatment is critical to reducing mortality and avoiding the development and spread of drug-resistant TB. It is vital to provide a supportive, non-judgemental and non-discriminatory environment that enables people from key populations to complete treatment, provides additional adherence support measures to improve treatment outcomes, and reduces the risk of continued TB transmission *(65)*.

Timely initiation of ART significantly reduces the risk of mortality from HIV-associated TB. As TB is one of the most common AIDS-defining illnesses, all those with presumptive or diagnosed TB should be offered HIV testing and counselling as a priority so that those testing positive can start ART as soon as possible, in any case no later than eight weeks after initiation of TB treatment, regardless of CD4 count.

Programmes serving key populations need to ensure access to integrated, client-centred services, preferably at the initial point of care, including TB screening, prevention and treatment, and support for treatment adherence *(65)*.

Key populations should have the same access to TB prevention, screening and treatment services as other populations at risk of or living with HIV *(138)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

- Routine HIV testing should be offered to all people with presumptive and diagnosed TB *(strong recommendation, low quality of evidence) (138)*.
- ART should be initiated in all individuals with HIV and active TB disease regardless of WHO clinical stage or CD4 cell count *(strong recommendation, low quality of evidence) (4)*.

Additional remark

- ART should be initiated as soon as possible, no later than eight weeks after initiation of TB treatment *(4)*.
- Alcohol dependence, active drug use and mental health disorders should not be used as reasons to withhold TB treatment *(65)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- Systematic screening for active TB should be considered in prisons and other closed settings *(124)*. It should be a priority where the prevalence of TB is high in the general population or in the prison population; where the incarceration rate is high; where the prevalence of HIV or MDR-TB is high; or where living conditions are poor.
- Medical examination, including TB screening, upon entry and any time thereafter, conforming to internationally accepted standards of medical confidentiality and care, should be conducted for all prisoners *(65)*.
- Prisoners should obtain care equivalent to that provided for the general population *(65)*.
- Given the high risk for transmission of TB and high rates of HIV-TB co-morbidity in closed settings, all prisons should engage in intensified case-finding, provide isoniazid preventive therapy for people living with HIV, and introduce effective tuberculosis control measures *(65)*.
- Essential for TB prevention in prisons is the improvement of living conditions by limiting the number of prisoners per cell and providing adequate ventilation and nutrition *(65)*.
- People in prisons or other closed settings known or suspected to have infectious TB should be separated (in a clinical setting) from other people until adequately treated and shown to be non-infectious *(65)*.
- Education activities for all prisoners should cover coughing etiquette and respiratory hygiene *(11)*.

- Continuity of TB treatment in prisons and other closed settings is essential to prevent the development of resistance and must be ensured at all stages of detention, including during prison transfer, and following release. This requires close collaboration between health services providing care for the general population and those caring for detainees, prisoners and the like *(11)*.

PEOPLE WHO INJECT DRUGS

- People with TB who inject drugs should have equitable access to TB treatment *(50)*.
- Co-morbidity, including viral hepatitis infection, should not contraindicate TB treatment for people who inject drugs and should be properly managed *(65)*.
- For patients with TB, OST should be administered in conjunction with medical treatment; there is no need to wait for abstinence from opioids to commence either anti-TB medication or antiretroviral medication *(50)*.
- Rifampicin, one of the first-line drugs used to treat TB, can significantly reduce the concentration and effect of both methadone and buprenorphine, resulting in opioid withdrawal *(142, 143, 144)*. See Section 4.4.3.

SEX WORKERS

Clinical programmes or community outreach services for sex workers can carry out TB screening and can support sex workers throughout the cycle of care, from TB prevention through diagnosis and treatment. They can teach sex workers to recognize TB symptoms and understand TB transmission, as well as to appreciate the importance of infection control and cough etiquette. They also can inform their clients of nearby health facilities for TB diagnosis and treatment *(71)*.

Implementation considerations

Collaboration. TB and HIV programmes, social services, drug treatment services and prison health services should collaborate in referrals and services for people from key populations to ensure access to comprehensive TB and HIV prevention, treatment and care in a holistic, person-centred way – in one setting if possible – that maximizes access and adherence *(65)*.

Training. Health-care workers (including community-based persons assisting with treatment and prophylaxis) who serve key populations need specific training to provide quality TB and HIV care to people from key populations. Personnel, including prison staff, should also know how to protect themselves from occupational exposure to HIV and TB *(65)*.

TB infection control. Every health-care and other congregate setting should have a TB infection control plan (preferably included in the general infection control plan), supported by all stakeholders, that includes administrative, environmental and personal protection measures to reduce transmission of TB and surveillance of TB among workers *(65)*.

Mainstream TB treatment services should be accessible and responsive to the needs of key populations *(65)*.

Further reading

- WHO, UNODC, UNAIDS. *Policy guidelines for collaborative TB and HIV services for injecting and other drug users – an integrated approach.* Geneva, WHO, 2008 [being updated as of spring 2014]. http://whqlibdoc.who.int/publications/2008/9789241596930_eng.pdf
- *WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders.* Geneva, WHO, 2012. http://whqlibdoc.who.int/publications/2012/9789241503006_eng.pdf
- *Guidelines for intensified tuberculosis case finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings.* Geneva, WHO, 2011. http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf

4.5.2 Viral hepatitis

Background and rationale

Viral hepatitis B and C disproportionally affect key populations, as a result of sexual transmission and the sharing of needles, syringes and ancillary injecting equipment. It is estimated that, globally, 240 million people are chronically infected with HBV and 150–170 million with HCV[1]. People who inject drugs account for approximately 1.1 million of those with HBV and 10 million of those with HCV *(145)*.

A comprehensive approach to addressing viral hepatitis among key populations includes prevention, screening, HBV vaccination, and treatment and care.

Worldwide, of the 35 million people living with HIV, chronic HBV infection affects an estimated 5–20% and HCV affects 5–15%. The burden of coinfection is greatest in low and middle income countries, particularly in South-East Asia, and, for HBV, particularly in sub-Saharan Africa. Among those living with HIV who are coinfected with HBV or HCV, liver disease progresses more rapidly and mortality is greater than among those with HBV or HCV who are not living with HIV.

HCV seroprevalence rates in prisons are even higher than HIV rates, and in many countries a history of HCV infection is associated with a history of incarceration *(146, 147, 148, 149, 150)*.

[1] Hepatitis C, Fact sheet N°164 Geneva, WHO, 2014. http://www.who.int/mediacentre/factsheets/fs164/en/

A comprehensive approach to addressing viral hepatitis among key populations includes prevention, screening, HBV vaccination, and treatment and care for people coinfected with HIV and HBV and/or HCV *(4)*.

Hepatitis B and C prevention

The major modes of viral hepatitis transmission include unsterile medical injections or other procedures, transfusions of contaminated blood, unprotected sexual intercourse and unsafe injecting *(39, 61, 149, 151, 152, 153)*. HCV is rarely transmitted through heterosexual sex. Over the past decade, however, several outbreaks of presumed sexually transmitted HCV infection have been reported among HIV-positive men who have sex with men. Similar HCV transmission among HIV-negative men who have sex with men and comparable drug-related behaviour has also been reported *(154)*.

Because modes of transmission for viral hepatitis overlap those for HIV, many interventions that prevent HIV also prevent HBV and HCV. Examples include correct and consistent condom use, needle and syringe programmes and OST and sterile tattooing practices.

Hepatitis B vaccine

HBV vaccine is safe, effective and fairly inexpensive. Most countries have both targeted and population-wide HBV vaccination programmes, including infant, catch-up and risk-group vaccination. Risk groups include people who inject drugs, men who have sex with men, sexual partners of people living with HIV, prisoners, and others such as recipients of blood products and health-care workers. By 2012, 181 countries had incorporated HBV vaccination into their national schedule as an integral part of national infant immunization *(155)*. An estimated 79% of the 2012 birth cohort globally received three doses of the HBV vaccine *(156)*. The implication of national HBV vaccination programmes is that HBV vaccination of high-risk groups will become less crucial over time as, increasingly, people are immunized in infancy and thus protected *(39)*.

There is currently no vaccine for HCV. Hence, there is an even greater need to intensify current efforts to prevent HCV transmission among key populations *(39)*.

Hepatitis B and C treatment

It is important to manage HIV coinfection with HBV and/or HCV appropriately. Coinfection with HIV and HCV accelerates HCV-related progression of liver fibrosis and leads to a higher rate of end-stage liver disease and mortality *(121, 151, 157)*.

Key populations should have the same access to hepatitis B and C prevention, screening and treatment services as other populations at risk of or living with HIV.

Recommendations and guidance

ALL KEY POPULATIONS

Hepatitis B

- Catch-up hepatitis B immunization strategies should be instituted in settings where infant immunization has not reached full coverage *(3, 10, 32)*.
- People from key populations with HIV and HBV coinfection who have severe chronic liver disease should be offered ART with a tenofovir (TDF) and lamivudine (3TC) (or emtricitabine (FTC))-based regimen irrespective of CD4 count or WHO clinical stage *(strong recommendation, low quality of evidence) (4)*.[1]

Hepatitis C

- HCV serology testing should be offered to individuals from populations with high HCV prevalence or who have a personal history of HCV risk exposure/behaviour *(strong recommendation, moderate quality of evidence) (158)*.
- An alcohol intake assessment is recommended for all persons with HCV infection, followed by the offer of a behavioural alcohol reduction intervention for persons with moderate-to-high alcohol intake *(strong recommendation, moderate quality of evidence) (158)*.
- Assessment for antiviral treatment of all adults and children with chronic HCV infection is recommended, including for people who inject drugs *(strong recommendation, moderate quality of evidence) (158)*.
- In addition, a number of recommendations on diagnosis and antiviral treatment regimens for HCV are available *(158)*.

Additional remarks

PIPELINE

- WHO is developing clinical guidance on hepatitis B treatment and screening strategies for hepatitis B and C. This guidance should be available in early 2015.
- WHO HCV guidelines provide detailed guidance on treatment and care *(158)*.
- There are challenges in diagnosing and treating active HCV infection in certain populations such as people who inject drugs, particularly in settings with limited access to HCV antibody and RNA assays, diagnostic tools for staging of liver disease and HCV therapy. People receiving ART and HCV drugs require close monitoring for possible drug interactions *(158, 159)*.

[1] There is insufficient evidence or favourable risk-benefit profile to support initiating ART in everyone coinfected with HIV and HBV with a CD4 count >500 cells/mm^3 or regardless of CD4 cell count or WHO clinical stage. Initiating ART regardless of CD4 count is, therefore, recommended only for people with evidence of severe chronic liver disease, who are those at greatest risk of progression and mortality from liver disease. For people without evidence of severe chronic liver disease, ART initiation should follow the same principles and recommendations as for other adults.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- It is important that prisons offer hepatitis B vaccination *(50, 60)*.
- It is important to offer voluntary HCV/HBV testing, treatment and care for people living with HIV soon after entry to prison, with assessment for and provision of treatment in accord with current WHO recommendations. Harm reduction measures should also be offered to prisoners.

PEOPLE WHO INJECT DRUGS

In addition to the comprehensive harm reduction package of nine interventions for people who inject drugs *(8)*, which include most importantly NSP and OST, specific recommendations include:

- offering the rapid hepatitis B vaccination regimen to people who inject drugs *(39)*;
- needle and syringe programmes should also offer low dead-space syringes *(39)*;
- offering peer interventions to reduce transmission of viral hepatitis among people who inject drugs *(39)*.

It is important also to consider the following:

- A higher-dose HBV vaccine should be used with the rapid regimen.[1]
- When the rapid vaccine regimen is not available, the standard regimen should be offered.
- For both the standard and rapid regimens, delivery of the first dose is the priority.
- To reduce transmission of viral hepatitis, needle and syringe programmes should offer all types of syringes and other equipment used for the preparation of injecting drugs, including cookers, sterile water, alcohol swabs, filters and tourniquets, as appropriate to local needs.

Implementation considerations

Lost opportunities. Opportunities to vaccinate people who inject drugs often may be lost because of their poor access or reluctance to be vaccinated *(160)*. Providing incentives to people who inject drugs and offering convenient access may increase uptake and completion of the HBV vaccination schedule *(87, 152)*. Even partial immunization confers some immunoprotection, however *(89)*. The decision whether to offer incentives depends on local acceptability and resources *(161)*.

[1] The standard vaccination schedule for infants and unvaccinated adults is 0, 1, and 6 months, while the rapid schedule is 1, 7 and 21 days *(39)*.

Immunosuppression. Individuals with inadequately treated HIV or with chronic HCV may have suppressed immune response. Therefore, they may benefit more from the standard HBV vaccine regimen than the rapid regimen *(39)*.

Further reading

- *Hepatitis C, Fact sheet N°164.* Geneva, WHO, 2014. http://www.who.int/mediacentre/factsheets/fs164/en/
- *Guidelines for the screening, care and treatment of persons with hepatitis C infection.* Geneva, WHO, 2014. http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf
- *Guidance on prevention of viral hepatitis B and C among people who inject drugs.* Geneva, WHO, 2012. http://www.who.int/iris/bitstream/10665/75357/1/9789241504041_eng.pdf

4.5.3 Mental health

Background and rationale

People living with HIV – including those from key populations – and their families and caregivers may have a wide range of mental health needs. Common mental health co-morbidities include depression and anxiety. Dementia and other cognitive disorders are also associated with longer-term HIV infection. HIV care settings can provide an opportunity for the detection and management of mental health problems among people living with HIV, including pre-existing mental health issues.

People from key populations may face the double burden of mental health issues associated with HIV infection and of marginalization, discrimination and stigma.

In addition to being disproportionately burdened by HIV, key populations experience higher rates of depression, anxiety, smoking, harmful alcohol use and alcohol dependence, other substance use and suicide as a result of chronic stress, social isolation, violence and disconnection from a range of health and support services *(3)*.

Studies suggest that mental health disorders in people living with HIV may interfere with treatment initiation and adherence and lead to poor treatment outcomes *(162)*. The presence of mental health co-morbidities may affect adherence to ART, due to forgetfulness or poor organization, motivation or understanding of treatment plans. Psychosocial support, counselling, appropriate drug therapies, and interventions such as case management may help to improve adherence to ART and retention in care *(4)*. The WHO *Mental Health Gap Action Programme (mhGAP) intervention guide for mental, neurological and substance use issues in non-specialized health settings* makes recommendations related to general mental health care that can be relevant to people living with HIV, including those from key populations *(4, 46)*.

Adolescents from key populations. Mental health co-morbidities among adolescents are a particular concern. Suicide is one of the leading causes of death of adolescents worldwide; unipolar depressive disorders and self-harm are major causes of disability-

adjusted life years (DALYs) lost in 10–19-year-olds *(163)*. Adolescents from key populations may face social isolation, harassment and discrimination, which may add to their vulnerability to mental health co-morbidities, emotional distress and self-stigma.

Recommendations and guidance

ALL KEY POPULATION GROUPS

Routine screening and management for mental health disorders (particularly depression and psychosocial stress) should be provided for people from key populations living with HIV in order to optimize health outcomes and improve adherence to ART. Management can range from co-counselling for HIV and depression to appropriate medical therapies *(4)*.

Related recommendations and contextual issues for specific key population groups

ADOLESCENTS FROM KEY POPULATIONS

Peer support groups and safe spaces can help improve self-esteem and address self-stigma. Additionally, individual and family counselling can address adolescents' mental health co-morbidities. The involvement of supportive parents or guardians can be beneficial, especially for those requiring ongoing treatment and care. It is important, however, to have the adolescent's express permission before contacting parents or care-givers *(86)*.

Implementation considerations

Integrated and comprehensive services provide the opportunity for patient-centred prevention, care and treatment for the multiple emotional and mental health issues affecting key populations. In addition, integrated services enhance the likelihood of improved communication among, and thus of better care by, the different service providers working with key populations *(39)*.

Further reading

- *mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings*. Geneva, WHO, 2011. http://www.who.int/mental_health/publications/mhGAP_intervention_guide/en/

4.6 General care

4.6.1 Nutrition

Background and rationale

Collaboration between HIV programmes and existing national programmes for nutritional support is necessary and feasible.

Low energy intake combined with increased energy demand because of HIV infection and related infections or conditions often leads to HIV-related weight loss and wasting. In addition, an altered metabolism, reduced appetite, and diarrhoeal diseases may lower nutrient intake and absorption and so can also contribute to nutrient losses *(164)*. These effects may be magnified in low-income and food-insecure contexts, such as those experienced by many key populations. In turn, poor nutritional status can hasten the progression of HIV disease; low body mass index (BMI) in adults (BMI less than 18.5 kg/m^2) is an independent risk factor for HIV disease progression and mortality *(4)*.

Collaboration between HIV programmes and existing national programmes for nutritional support is necessary and feasible to achieve optimal health outcomes in food-insecure settings. Consideration should be given to providing nutritional support to people from key populations living with HIV in food-insecure circumstances *(4)*. ART in conjunction with nutritional support could accelerate recovery.

PIPELINE WHO is currently developing recommendations for nutritional care and support of adolescents and adults living with HIV.

Related recommendations and contextual issues for specific key populations

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

Inadequate nutrition is a major problem for many people in prisons and can have a significant impact on people with HIV or TB, jeopardizing treatment outcomes and adherence. Protecting and promoting the health of people in prisons and other closed settings should include provision of adequate nutrition, including access to safe drinking water and nutritional supplements *(11)*.

4.6.2 Sexual and reproductive health interventions

Health-care providers often overlook the sexual and reproductive health of people living with HIV.

Members of key populations, regardless of whether or not they are living with HIV, should be able to experience full, pleasurable sexual lives and have access to a range of reproductive options. Women from key populations should enjoy the same reproductive health rights as all other women; it is important that they have access to family planning and other reproductive health services, including reproductive tract cancer prevention, screening and treatment *(32)*. For many women from key populations, their main concerns often are not just HIV and

STIs, but also other reproductive health issues. Health-care providers, however, often overlook the sexual and reproductive health of people living with HIV.

4.6.2.1 Sexually transmitted infection prevention, screening and treatment

Background and rationale

Globally, STIs are a major cause of acute illness, infertility, long-term disability and death. Several STIs may facilitate the sexual transmission of HIV infection *(165)*.

In both men and women, STIs, particularly those involving genital ulcers, increase susceptibility to HIV infection. Also, acute STIs are an important marker for unsafe sexual behaviour and risk of HIV transmission. Men who have sex with men, sex workers and transgender people are often at increased risk of STIs.

Thus, it is important to offer clinical management of STIs to people from key populations who present with STIs, in keeping with existing WHO guidance *(138)*. In the absence of laboratory tests, syndromic management can be used. Testing and treatment should always be voluntary and free from coercion. Because the majority of STI cases are asymptomatic, particularly in women, STI screening programmes should be made available to key population groups.

Full updating of WHO STI guidelines is underway and should be completed by the end of 2014. PIPELINE

Screening, diagnosis and treatment of STIs should be offered routinely as part of comprehensive HIV prevention and care for key populations *(4)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

- Screening, diagnosis and treatment of STIs are crucial parts of a comprehensive response to HIV; this includes services for key populations *(4)*. STI management should accord with existing WHO guidance and be adapted to the national context *(166)*. Also, it should be confidential and free from coercion, and patients must give informed consent for treatment *(32, 166)*.
- Periodic screening of people from key populations for asymptomatic STIs is recommended *(conditional recommendation, low quality of evidence) (4, 10)*.
- In the absence of laboratory tests, symptomatic people from key populations should be managed syndromically in line with national STI management guidelines *(166)*.

Related recommendations and contextual issues for specific key population groups

PEOPLE WHO INJECT DRUGS

Health-care providers need to be alert to provide STI control and management for people who inject drugs. People who inject drugs may also engage in sex work, and men who inject drugs may have sex with other men, and thus they face higher STI risks *(153, 167)*.

SEX WORKERS

- We suggest offering periodic presumptive treatment (PPT) for asymptomatic STIs to female sex workers in settings with high prevalence and limited clinical services *(conditional recommendation, moderate to high quality of evidence)*.
- PPT should be implemented only as a free, voluntary, confidential, short-term measure as part of comprehensive sexual health services and while HIV/STI services are being further developed in settings where STI prevalence is high, e.g. >15% prevalence of *N. gonorrhoea* and/or *C. trachomatis* infection *(10)*.

TRANSGENDER PEOPLE

Health-care providers should be sensitive to and knowledgeable about the specific health needs of transgender people. In particular, genital examination and specimen collection can be uncomfortable or upsetting whether or not the person has undergone genital reconstructive surgery *(32)*.

Implementation considerations

Possible strategies to increase STI screening and treatment rates include the following *(3)*:

- Mainstream STI treatment services should be accessible and responsive to the needs of key populations.
- In settings where key populations are largely marginalized, specific and targeted services should be considered, including outreach and peer support.
- Active referral pathways should be established, and screening and testing programmes should be integrated with other services used by key populations.
- STI diagnosis and treatment services should be co-located with HIV services used by key populations.

Prisons and other closed settings should provide STI testing and related treatment that are voluntary, confidential and ensure the informed consent of the patient. If

adequate care cannot be provided in prisons, detainees should be able to obtain health services in the community *(11)*.

Further reading

- *Guidelines for the management of sexually transmitted infections.* Geneva, WHO, 2004. http://www.who.int/hiv/pub/sti/pub6/en/
- *Training modules for the syndromic management of sexually transmitted infections.* Geneva, WHO, 2007. http://www.who.int/reproductivehealth/publications/rtis/9789241593407/en/index.html
- WHO, UNFPA, UNAIDS, NSWP, World Bank. *Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions.* Geneva, WHO, 2013. http://www.who.int/hiv/pub/sti/sex_worker_implementation/en/

4.6.2.2 Contraceptive services

Background and rationale

It is important that health-care providers strongly recommend dual protection.

Contraception is a service that is often overlooked for key populations *(32)*. It is important that health-care providers strongly recommend dual protection to all persons at significant risk of HIV – either the simultaneous use of condoms with other methods or the consistent and correct use of condoms alone *(122)*.

Full updating of WHO contraception guidelines is currently underway and will be completed in 2015.

Members of key populations, including people living with HIV, should be able to experience full, pleasurable sex lives and have access to a range of reproductive options *(32, 122)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

It is important that contraceptive services are free, voluntary and non-coercive for all people from key populations.

Related recommendations and contextual issues for specific key population groups

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

It is important that prison health services offer contraception to women in closed settings *(9, 169, 170, 171, 172)*.

PEOPLE WHO INJECT DRUGS

It is important that health-care providers in contact with women who use drugs offer contraception, including hormonal contraceptives, as part of a standard package of care.

SEX WORKERS

Women at higher risk of HIV, including sex workers, initiating or using hormonal contraceptives should be strongly advised always to use condoms, male or female, and other HIV prevention measures because of evidence, albeit inconclusive, of possibly increased risk of HIV acquisition among women using progestogen-only injectable contraception *(4, 168)*.

Additional remarks

Female sex workers should be offered contraceptive counselling to explore pregnancy intention and offered a range of contraceptive options including dual protection.

TRANSGENDER PEOPLE

- It is important to counsel **transgender women** who use oral contraceptive pills for feminization about the higher risk of thrombotic events with ethinyl estradiol than with 17-beta estradiol.
- Consideration should be given to offering **transgender men** who have sex with men appropriate contraceptive options that do not lead to unwanted systemic feminization.

ADOLESCENTS FROM KEY POPULATIONS

- In order to meet the educational and service needs of adolescents, it is recommended that sexual and reproductive health services, including contraceptive information and services, be provided for adolescents without mandatory parental and guardian authorization/notification *(173)*.
- To act in the best interest of adolescents, health services may need to prioritize their immediate health needs, while being attentive to signs of vulnerability, abuse and exploitation. Appropriate and confidential referral, if and when requested by the adolescent, can provide linkage to other services and sectors for support *(73)*.

Further reading

- *Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations.* Geneva, WHO, 2014. http://apps.who.int/iris/bitstream/10665/102539/1/9789241506748_eng.pdf
- *Medical eligibility criteria for contraceptive use: fourth edition.* Geneva, WHO, 2010. http://whqlibdoc.who.int/publications/2010/9789241563888_eng.pdf. Currently updating, next edition 2015.

4.6.2.3 Safe abortion and post-abortion care

Abortion laws and services should protect the health and human rights of all women, including those from key populations.

Related recommendations and contextual issues for specific key population groups

ALL WOMEN FROM KEY POPULATIONS

- Where abortion is legal, it is important to establish linkages to safe abortion services.
- Where abortion is illegal, unsafe abortion may be common and present serious health risks. Women from key populations should be informed about these risks *(174)*.
- Access to appropriate post-abortion care is essential to reduce morbidity and mortality.

ADOLESCENTS FROM KEY POPULATIONS

Adolescents may be deterred from accessing health services if they think they will be required to obtain permission from their parents or guardians; this can increase the likelihood that they will go to providers of unsafe abortion *(174)*.

Implementation consideration

Safe abortion services. To the full extent permitted by law, safe abortion services should be readily available and affordable to all. This means services should be available at the primary care level, with referral systems in place for all required higher-level care.

Further reading

- *Safe abortion: technical and policy guidance for health systems.* Geneva, WHO 2012 http://www.who.int/reproductivehealth/publications/unsafe_abortion/9789241548434/en/

4.6.2.4 Cervical cancer screening and treatment

Cervical cancer screening and treatment is performed to detect cervical cancer or cervical changes that are precursors to cervical cancer and to treat adequately. Women living with HIV are at increased risk for human papillomavirus (HPV) infection and HPV-related tumours, including cervical intraepithelial neoplasia grade 2 or 3 (CIN2/3) and invasive cervical carcinoma *(175)*. The prevalence of HPV and CIN has been reported to increase with the increase in immunosuppression *(176, 177)*.

It is important to offer cervical screening to all women from key populations, and to transgender men where appropriate, as indicated in the WHO 2013 cervical screening guidelines *(178)*.

Related recommendations and contextual issues for specific key population groups

ALL WOMEN FROM KEY POPULATIONS

It is important in areas with high rates of endemic HIV infection to offer cervical cancer screening to sexually active girls and women as soon as they have tested positive for HIV *(178)*.

TRANSGENDER PEOPLE

Specific considerations are needed for transgender men *(178)*:

- Transgender men who retain their female genitalia often miss out on cervical screening and other sexual health services, as they may not seek out or may be excluded from those services. As a result, they face increased risk of ovarian, uterine and cervical disease.
- Following total hysterectomy, if there is a history of high-grade cervical dysplasia and/or cervical cancer, a Papanicolaou test of the vaginal cuff can be performed annually until three normal tests are documented, and then every two to three years.
- Following removal of ovaries, but where the uterus and cervix remain intact, WHO cervical screening guidelines for natal females can be followed. This may be deferred if there is no history of genital sexual activity. It is important to inform the pathologist of current or prior testosterone use, as cervical atrophy can mimic dysplasia.

ADOLESCENTS FROM KEY POPULATIONS

- HPV vaccination does not replace cervical cancer screening. In countries where the HPV vaccine is introduced, screening programmes may need to be developed or strengthened *(179)*.
- The WHO recommended target group for HPV vaccination is girls ages 9–13 years who have not yet become sexually active, including those living with HIV *(179)*.

4.6.2.5 Screening for anal cancer

People infected with HIV are at least 20 times more likely to be diagnosed with anal cancer than uninfected people *(180)*. Like cancer of the cervix, anal cancer is associated with human papillomavirus (HPV). Screening can be performed for anal cancer and its precursors, known as anal high-grade squamous intraepithelial lesions (HSIL), particularly for men who have sex with men, transgender people and other people from key populations who are more likely to engage in anal sex.

Further reading

- *WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention.* Geneva, WHO, 2013. http://www.who.int/reproductivehealth/publications/cancers/screening_and_treatment_of_precancerous_lesions/en/

4.6.2.6 Conception and pregnancy

It is important that all women from key populations have the same support and access to services related to conception and pregnancy care as women from other groups, as indicated by WHO guidelines.

Related recommendations and contextual issues for specific key population groups

ALL WOMEN FROM KEY POPULATIONS

- All adult and adolescent women from key populations who are living with HIV and are pregnant should receive appropriate HIV treatment and care, in line with WHO guidance, to prevent HIV transmission from mother to child *(4)*.
- Women living with HIV and those in serodiscordant couples who wish to have children should be provided information and support to help them to conceive as safely as possible.
- Many women from key populations, in particular adolescents, have inadequate access to antenatal care, attend late in pregnancy and have less access to PMTCT services (see Section 4.4.2).

CRITICAL ENABLERS

5

5 CRITICAL ENABLERS

HIV epidemics, particularly among key populations, continue to be fuelled by stigma and discrimination, gender inequality, violence, lack of community empowerment, violations of human rights, and laws and policies criminalizing drug use and diverse forms of gender identity and sexuality. These socio-structural factors limit access to HIV services, constrain how these services are delivered and diminish their effectiveness.

Thus, it is important to understand the varied political, geographic and social contexts in which key populations live and where HIV services for them are delivered. It also needs to be recognized that each key population group is heterogeneous, and effective programmes must account for this diversity.

Despite the challenges of marginalization, criminalization of the behaviour of certain key populations and in some settings direct human rights abuses, it remains necessary and feasible to deliver HIV-related services and to do so in ways that protect the safety and well-being of people from key populations and of service providers. Health-care providers have an ethical obligation to care for and treat people impartially and equitably. Programmes and countries can ensure confidentiality of services, facilitate access by people from key populations to mainstream health services, improve quality, train and sensitize health-care providers, and reduce stigma and discrimination. As safety allows, people from key populations should be encouraged and supported to participate in designing and delivering HIV prevention and response efforts. Despite legislative restrictions people from key populations in most countries persevere, still finding ways of acting in association to provide support, and they may also be reached online and through regional networks.

Integrating HIV and related health services into primary health care can contribute to increased and more equitable access to HIV services for key populations. To increase the effectiveness of HIV services in primary health care, health-care providers will benefit from understanding gender identity and the diversity of sexual behaviours and identities, as well as drug use and dependence, and how to address these when providing services. The health sector can take action to change the attitudes and behaviours of health-care providers to reduce stigma and discrimination, particularly that relating to homophobia, transphobia, sex work and drug use. Health-care workers should be given the necessary resources, training and support to provide services to key populations. At the same time, health-care providers should be held accountable when they fail to meet standards based on professional ethics and internationally agreed human rights principles *(1)*. Monitoring and evaluation is important to ensure not only technical quality and impact of services but also the spirit in which they are provided and, thus, their acceptability to people from key populations.

"Critical enablers", as used in this document, means strategies, activities and approaches that aim to improve the accessibility, acceptability, uptake, equitable

coverage, quality, effectiveness and efficiency of HIV interventions and services. Enablers operate at many levels – individual, community, institutional, societal and national, regional and global. They are crucial to implementing comprehensive HIV programmes for key populations in all epidemic contexts. Critical enablers aim to overcome major barriers to service uptake, including social exclusion and marginalization, criminalization, stigma and inequity. If left unaddressed, such barriers will undermine the provision of HIV services, especially for key populations *(2)*.

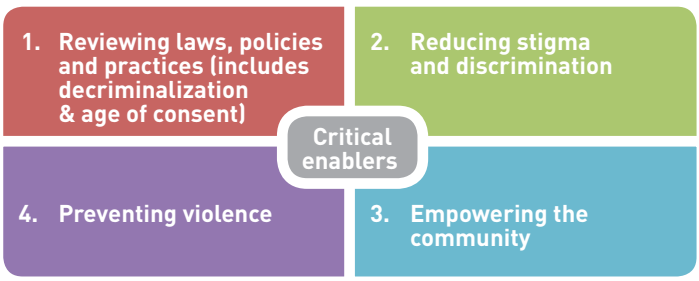
The barriers and critical enablers outlined in this chapter apply to both adults and adolescents in key populations. For adolescents from key populations, these factors may be further exacerbated by their rapid physical and mental development and complex psychosocial and socioeconomic vulnerabilities. Also, adolescents from key populations experience socio-structural barriers to services, notably policy and legal barriers related to age of consent. Those close to people from key populations, including partners and children, also can experience stigma and discrimination and so face the same difficulties in access to services. Thus, including dependents in the provision of HIV services can be important.

Successful implementation of critical enablers requires collaboration across different sectors.

The health sector has an important role to play, but successful implementation of critical enablers requires collaboration across different sectors, such as health, justice, housing, welfare and labour. It also requires multiple partners from government, civil society and the private sector. Full involvement of key populations and people living with HIV also is crucial *(3, 4)*.

This chapter outlines a range of barriers that compromise access to appropriate and good-quality HIV services for key populations, identifies critical enablers to overcome these barriers (as illustrated in Fig. 5.1) and makes a number of good-practice recommendations. These good practice recommendations are based on earlier WHO documents addressing key populations. While these barriers and enablers are interrelated, we attempt to discuss each individually.

Fig. 5.1 Critical enablers for key populations



5.1 Law and policy

5.1.1 Legal barriers

Sixty percent of countries report having laws, regulations or policies that are barriers to effective HIV services for key populations and vulnerable groups *(5)*. In particular, over 100 countries criminalize some or all aspects of sex work. At least 76 countries criminalize sexual relations between people of the same sex. Indeed, some countries impose the death penalty for convictions under such laws.

Additionally, transgender people are legally unrecognized in many countries *(5)* and face restrictive policies toward their gender expression. In many settings punitive policies on drug use call for harsh penalties for the possession of small amounts of drugs for personal use, and in some settings policies mandate compulsory detention as "treatment" for people who use or inject drugs *(5)*. In many prisons and other closed settings, HIV services are sub-standard or entirely lacking *(6)*.

While laws vary, in many settings adolescents under 18 years of age are classified legally as minors and, therefore, must have parental consent for medical care, including HIV-related services. Such laws and policies can be barriers to or can discourage adolescents from seeking services *(7)*. These restrictions may create complex dilemmas for providers who endeavour to act in the best interest of their clients but who may have concerns about their own legal liability as well as for the safety of their young clients.

5.1.2 Critical enablers

Reviewing laws and policies

Laws and policies can help to protect the human rights of key populations – both those living with HIV and those at risk for HIV. Legal reforms, such as decriminalizing sexual behaviours and drug use, legal recognition of transgender status, and lowering the age of consent and considering exceptions to a standard age of consent policy (such as mature minors), are critical enablers that can change a hostile environment for key populations to a supportive environment *(8)*. Specific consideration should be given to such legal reforms as part of any revision of policies or programmes for key populations. For example, in many countries possession, use and sale of clean needles and syringes or of condoms remains justification for arrest. If so, this warrants review.

Decriminalizing the behaviour of key populations

Without protective policies and efforts to decriminalize the behaviour of key populations, barriers to essential health services will remain.

Supporting the health and well-being of key populations whose sexual behaviours, drug use, gender expression or perceived sexual orientation are currently criminalized may require changing legislation and adopting new policies and protective laws in accordance with international human rights standards. Without protective policies and decriminalization of the behaviour of key populations, barriers to essential health services will remain; many people from key populations may fear that seeking health care will expose them to adverse legal consequences *(9)*.

Laws, legal policies and practices should be reviewed and, where necessary, revised by policy-makers and government leaders, with meaningful engagement of stakeholders from key population groups, to allow and support increased access to services for key populations *(10, 11, 13)*.

Good practice recommendations concerning decriminalization

ALL KEY POPULATION GROUPS

Countries should work toward decriminalization of behaviours such as drug use/injecting, sex work, same-sex activity and nonconforming gender identities, and toward elimination of the unjust application of civil law and regulations against people who use/inject drugs, sex workers, men who have sex with men and transgender people *(10, 11, 12, 13, 14)*.

MEN WHO HAVE SEX WITH MEN

Countries should work toward developing policies and laws that decriminalize same-sex behaviours *(11)*.

PEOPLE WHO USE AND/OR INJECT DRUGS

- Countries should work toward developing policies and laws that decriminalize injection and other use of drugs and, thereby, reduce incarceration.
- Countries should work toward developing policies and laws that decriminalize the use of clean needles and syringes (and that permit NSPs) and that legalize OST for people who are opioid-dependent.
- Countries should ban compulsory treatment for people who use and/or inject drugs *(12, 13, 14)*.

SEX WORKERS

- Countries should work toward decriminalization of sex work and elimination of the unjust application of non-criminal laws and regulations against sex workers.
- The police practice of using possession of condoms as evidence of sex work and grounds for arrest should be eliminated *(10)*.

TRANSGENDER PEOPLE

- Countries should work toward developing policies and laws that decriminalize same-sex behaviours and nonconforming gender identities.
- Countries should work towards legal recognition for transgender people *(11)*.

Good practice recommendations concerning age of consent policies and laws

ADOLESCENTS FROM KEY POPULATIONS

- Countries are encouraged to examine their current consent policies and consider revising them to reduce age-related barriers to HIV services and to empower providers to act in the best interest of the adolescent *(7)*.
- It is recommended that sexual and reproductive health services, including contraceptive information and services, be provided for adolescents without mandatory parental and guardian authorization/notification *(15)*.

Case study: Decriminalizing drug use in Portugal

GIRUBarcelos, APDES, Portugal
http://www.apdes.pt/en/

As of 2012, 21 countries globally had taken steps to decriminalize drug use and possession *(16)*. For example, Portugal changed its legislation in 2001 to turn possession of controlled drugs into an "administrative offence", with those caught with drugs for personal use being sent to a "dissuasion board" rather than face prosecution and possible jailing. An independent study *(17)* examined the impact of the changes and found that:

- The number of drug users in treatment expanded from 23 654 in 1998 to 38 532 in 2008.
- Between 2000 and 2008 the annual number of new cases of HIV among drug users fell from 907 to 267, a decrease attributed to the expansion of harm reduction services.
- Contrary to predictions, major increases in drug use did not take place; instead, evidence indicated reductions in problematic use, drug-related harms and overcrowding of the criminal justice system.

Community organizations continue to be essential to tackling stigma and discrimination and improving access to services. Agência Piaget para o Desenvolvimento (APDES), founded in 2004, works with vulnerable people and communities on access to health care, employment and education, seeking to empower these populations and reinforce social cohesion. They run GIRUBarcelos, a multidisciplinary outreach team working primarily with heroin and cocaine users and sex workers in northern Portugal, focusing their efforts on harm reduction. Through their efforts, discrimination towards people who use drugs, including by health-care professionals, has been reduced following regular meetings, mediation efforts between communities and service providers, debates and a radio programme on a local radio station entitled "GIRU Conversations". The presence of a peer educator on the team and the constant involvement of people who inject drugs are the cornerstones of GIRUBarcelos' interventions and considered critical to its success.

Addressing other policy issues for key populations

Along with decriminalization efforts, there are other policy changes that can enable people from key populations to exercise their human and health rights. Some common current policies limit access to the justice system and to health services. Key considerations are these:

Recognize transgender people in the law. For transgender people the legal recognition of preferred gender and name may be important to reduce stigma, discrimination and ignorance about gender variance. Such recognition by health services can support better access, uptake and provision of HIV services *(11)*.

Case study: In Uruguay a national dialogue supports legislative change

In 2010 the United Nations Development Programme (UNDP) launched the Global Commission on HIV and the Law to develop actionable, evidence-based answers and recommendations for a response to HIV that protects and promotes the human rights of people living with and who are more vulnerable to HIV (http://www.hivlawcommission.org). The Commission's work focuses on generating constructive dialogues between civil societies and governments on issues related to HIV and the law, going beyond identifying problems to develop and share practical solutions.

In Uruguay a national inter-sectoral commission was organized jointly by the Ministry of Health, the Ministry of Social Development, trade union organizations, the National Council for HIV/AIDS Response (CONASIDA), the Federation of Sexual Diversity and the Parliamentarian Commissioner for Prisons. This commission called for a national dialogue on HIV and human rights to harmonize and improving national legislation related to the HIV response. Conducted with the strong support of the UNDP Regional Office, UNFPA and UNAIDS, the two-month initiative provided an opportunity for people affected by and vulnerable to HIV to present evidence on issues that have been silenced or were unknown. Individuals and civil society organization presented almost three dozen selected cases of human rights violations. Those involved, in particular civil society organizations, provided technical support for the development and presentation of HIV-related issues of sexual orientation and gender identity; discrimination in health services, employment and education; sex work; police brutality; access to treatment; intellectual property; and the human rights of people living with HIV.

This national dialogue contributed to the on-going development of a new, comprehensive HIV law. The final report of the dialogue, presented to parliament in May 2014, identifies gaps in legislation, laws detrimental to the HIV response and the lack of implementation of laws that would promote the response. In addition, it suggests best practices and makes recommendations from a human rights perspective. The advocacy and mobilization of civil society , in particular people living with HIV and lesbian, gay, bisexual and transgender groups have driven this dialogue, along with the concerted efforts and the partnerships of UN agencies, the government and academia.

CONASIDA-CMM (National Council for the Prevention and Control of HIV/AIDS – Country Coordination Mechanism) will implement and follow up the main recommendations from the dialogue to support the HIV Law Project. Additionally, the recently developed National Institute on Human Rights in Uruguay, also affiliated with the dialogue, is now committed to contributing, monitoring and advocating the implementation of the updated laws.

Improve access to justice and legal support for key populations. Policies that criminalize and punish the behaviour of key populations constrain people from obtaining justice and legal services. Policies and procedures are needed to ensure that individuals from key populations can report rights violations such as discrimination, gender-based violence, issues with policing, violations of informed consent, violations of medical confidentiality and denial of health-care services. Reporting options beyond going to the police will encourage reporting of human rights violations. For example, persons from key populations can be trained as paralegals; an organization that works with key populations can serve as a third-party reporter of complaints.

Improve policies on access to health services and information. Ensuring that people from key populations are aware of their legal and human rights as individuals, specifically their right to health, can increase their access to health services. Since key populations are often the target of exploitation, marginalization, criminalization, stigma and discrimination, programmes are particularly needed to ensure that key populations know their legal and human rights, including applicable protective laws and where and how to obtain legal services and report violations. Health literacy, sexuality education and support programmes can help improve awareness *(18)*. If better informed, key population groups can better organize to advance their rights and raise awareness of their rights, needs and the policies and legal issues that critically affect them *(10, 19, 20)*.

Additionally, countries can review laws that penalize health-care providers for working with key populations (e.g. laws that make it illegal for outreach workers to carry condoms or clean needles and syringes for distribution).

Law enforcement can play an important role by ensuring that the human rights of key populations are not violated. Police should receive continual training on ways to support – or at least not to impede – key populations' access to essential health services, including not arresting people leaving drug treatment clinics; avoiding confiscation of drug treatment medication; avoiding surveillance of harm reduction centres; and not using possession of clean needles or condoms to justify arrest. Systems to promote good policing practices and to provide safe avenues for reporting human rights violations will help ensure that police are protecting both the public health and the human rights of all persons. Ensuring that medical records are kept confidential is one step that health-care providers can take to increase trust between health services and key populations.

Good practice recommendations for other policy issues

ALL KEY POPULATION GROUPS

- Countries should work toward developing non-custodial alternatives to incarceration of drug users, sex workers and people who engage in same-sex activity *(12)*.
- It is recommended that third-party authorization requirements be eliminated, including spousal authorization requirements for women obtaining contraceptives and related information and services *(15)*.

Additional remark: It is important that countries secure political commitment, with appropriate investment in advocacy and adequate financial resources for HIV-related key population programmes and health services.

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- As countries work toward developing non-custodial strategies, targets can be set for reducing prison overcrowding generally *(12)*.

SEX WORKERS

- The police practice of using possession of condoms as evidence of sex work and grounds to arrest sex workers should be eliminated *(10)*.
- The wide latitude of the police to arrest and detain sex workers without cause, including police extortion, should be eliminated *(10)*.

TRANSGENDER PEOPLE

- Countries should work towards legal recognition for transgender people *(11)*.

Case study: In Indonesia methadone maintenance treatment in prison

Australia Indonesia Partnership for HIV (AIPH) – HIV Cooperation Program for Indonesia (HCPI)

Methadone maintenance treatment (MMT) for incarcerated injecting drug users was pilot-tested in Kerobokan Prison, Bali, in 2005 after prison officials visited MMT programmes in Australian prisons. Accomplishments of the Kerobokan Prison pilot project include:

- Establishment of comprehensive harm reduction services (including MMT) and high levels of participation among prisoners with opioid dependence;
- The scaling-up of MMT, education and care, support and treatment services in 11 other prisons, detention centres and parole services; Kerobokan prison provides ongoing mentoring to many of these facilities;
- High levels of integration with other community health services in Bali, ensuring smooth transition from prison to community MMT programmes (and vice versa) and early or continuing access to HIV treatment.

Additionally, HIV testing and treatment now have been efficiently implemented in many prisons. More than 90% of high-risk prisoners have been tested, and a high proportion of those testing positive have begun ART.

As part of mainstreaming this initiative, in 2013 the Ministry of Health (MOH) and the General Directorate of Corrections signed a memorandum of understanding that the MOH would fully cover the cost of methadone. HCPI continues to provide training and limited financial support.

5.2 Stigma and discrimination

5.2.1 Barriers

People from key populations are often particularly subjected to stigma, discrimination and negative attitudes related to their behaviour – and doubly so if also living with HIV – by their families, communities and health workers. Such stigma is common in many health facilities and law enforcement services. It may seem to be tacitly endorsed by the lack of national laws and policies against discrimination. The effects of such HIV-related stigma and discrimination against key populations can be delayed HIV testing, concealment of positive serostatus, and poor uptake of HIV services *(21, 22, 23, 24, 25)*. It can undermine the efforts of national health programmes to effectively link people to HIV care and to engage and retain them in long-term care *(26, 27)*.

Within the health sector stigma and discrimination can take many forms at the individual and systems levels. The lack of training and educational programmes to inform health workers of the needs, health issues and strategies and interventions for key populations contributes to marginalization. It leaves providers ill-equipped to address health needs and perpetuates stigmatizing and discriminating practices, even to the point of refusing services.

5.2.2 Critical enablers

Efforts to reduce stigma and discrimination at a national level, such as promoting antidiscrimination and protective policies for all key populations, can foster a supportive environment, particularly within the health-care and justice systems *(20)*. Policies are most effective when they simultaneously address individual, organizational and public policy factors that enable or allow stigma and discrimination *(28)*. Programmes, within and outside the health sector, need to institute anti-stigma and antidiscrimination policies and codes of conduct. Monitoring and oversight are important to ensure that standards are implemented and maintained. Additionally, mechanisms should be made available to key populations to anonymously report occurrences of stigma and/or discrimination when they try to obtain health services.

Good practice recommendations for implementing and enforcing anti-stigma and antidiscrimination and protective policies

ALL KEY POPULATION GROUPS

- Countries should work towards implementing and enforcing antidiscrimination and protective laws, derived from human rights standards, to eliminate stigma, discrimination and violence against people from key populations.
- Policy-makers, parliamentarians and other public health leaders should work together with civil society organizations in their efforts to monitor stigma, confront discrimination against key populations and change punitive legal and social norms *(3, 10, 11, 12, 13, 19)*.

Providing key population-friendly services

It is important to make health services available, accessible and acceptable to key populations and to tailor these services to their needs *(20)*. Interventions and services for key populations, including adolescents from key populations, can adopt principles friendly to key populations, paying particular attention to accessibility and the expertise and attitudes of staff members *(7)*.

Approaches to making services friendly to key populations include:

- integrated health services, involving co-locating interventions and cross-training providers, such as providing ARVs at drug treatment centres;
- scheduling service hours that are regular, dependable and suit the intended clients;
- locating services strategically where key populations congregate or transit;
- involving the peer community in service development, promotion, delivery, and monitoring and evaluation;
- training staff to work with different key populations;
- taking steps to ensure that law enforcement activities do not interfere with clients' access to HIV services *(11, 12, 13, 20)*.

Case study: Sensitizing health-care workers in South Africa

South African National AIDS Council and the South African Department of Health, South Africa
http://www.health.gov.za/ and http://www.sanac.org.za

Discrimination by public health-care providers towards people from key populations and "unfriendly" health facilities are barriers to access to services, contributing to poorer health outcomes *(29)*. A multi-partner project in South Africa has developed an integrated approach to sensitizing health-care providers on issues affecting key populations and to empower public health staff members to interact appropriately (regarding both their attitude and their clincial expertise) with people from key populations. Trainings have been conducted in preparation for the implementation of the National *Operational Guidelines for HIV, STIs and TB Programmes for Key Populations in South Africa*. The full training programme includes in-person training and mentoring. Thirty trainers participated in an initial training of trainers (TOT) workshop and were linked to local training centres and health facilities. In turn, they trained 420 health-care workers in six months.

Where these trainings took place, people from key populations have reported improvements in health-care workers' attitudes. Communities' trust has increased, and so has use of health facilities, where the sensitization training has been linked with peer outreach and the prevention activities of civil society organizations. Further evaluation is planned to inform scale-up.

Training and sensitizing health workers

Creating inclusive health services requires sensitizing and educating providers and other staff members in health care and social services. This can be done in both pre-service and in-service training, through on-the-job support and supervision, and by creating an organizational norm of inclusiveness and non-discrimination.

Attitudes. Health-care providers working with adults or adolescents from key populations should be non-judgemental, supportive, responsive and respectful and should understand the issues that people from key populations face *(7, 10, 11, 20)*. Training, with the involvement of key population representatives and groups, can be developed to sensitize and educate health workers on issues specific to key populations, non-discriminatory attitudes and practices, and key populations' right to health, confidentiality, non-coercive care and informed consent.

Skills. It is important that health workers be able to respond to the specific needs of key populations and provide quality services, know what interventions, tools and materials are available to provide information, can advise on HIV risk reduction strategies, and know how to support treatment adherence and retention in care *(20)*.

Improving and maintaining providers' attitudes and skills is a continual process consisting of multiple components such as formal training events, job aids, supportive supervision, training follow-up and mentorship. Multi-disciplinary trainings and work environments can strengthen linkage to community-based providers so that referrals and adequate follow-up are more available. Particularly where there are workforce shortages, it is important that all providers receive adolescent-specific training, including lay counsellors, to enable task-shifting *(7)*.

Health services should be made available, accessible and acceptable to people from key populations, based on the principles of medical ethics, avoidance of stigma, non-discrimination and the right to health *(3, 7, 10, 11, 12, 13, 15)*.

Good practice recommendations for providing key population-friendly services

ALL KEY POPULATION GROUPS

- Health-care workers should receive appropriate recurrent training and sensitization to ensure that they have the skills and understanding to provide services for adults and adolescents from key populations based on all persons' right to health, confidentiality and non-discrimination.
- It is recommended to make contraceptives affordable to all, including adolescents, and that law and policy support access to contraception for disadvantaged and margfrom inalized populations *(3, 7, 10, 11, 12, 13, 15)*.

ADOLESCENTS FROM KEY POPULATIONS

- Services for adolescents from key populations should include psychosocial support, through counselling, peer support groups and networks, to address self-stigma and discrimination. Additional provision of counselling for families, including parents – where appropriate and requested by the adolescent – may be important to support and facilitate access to services, especially where parental consent is required *(7)*.
- Health-care providers should ensure adolescents from key populations know their rights – to confidentiality, health, protection and self-determination – so that they can advocate for themselves and seek the types of support they are entitled to *(7)*.
- Services should provide developmentally appropriate, comprehensive information and education, focusing on skills-based risk reduction *(7)*.
- Services should be safe spaces that increase protection from the effects of stigmas and discrimination, where adolescents can freely express their concerns, and where providers demonstrate patience, understanding, acceptance and knowledge about the choices and services available to the adolescent *(7)*.

Case study: In South Africa expanding competence to serve men who have sex with men

Health4Men, Anova Health Institute
www.anovahealth.co.za

The Health4Men project addresses men's diverse sexual health needs, particularly those of vulnerable and marginalized groups including men who have sex with men. The project's goal is to institutionalize competence in serving men who have sex with men in existing public clinics. The process involves:

- sensitization, to change attitudes
- medical training, to expand knowledge
- mentoring, to translate knowledge into skill
- on-going technical support including consultation, training and mentoring and provision of educational materials.

Under the leadership of the Anova Health Institute, Health4Men has developed two MSM Centres of Excellence, in Cape Town and Johannesburg, each supported by satellite clinics. The clinics provide services for men who have sex with men, while outreach activities stimulate demand for services.

Health4Men has developed innovative training content and materials to equip nurses, counsellors and medical officers to respond to the special needs of men who have sex with men in a sensitive and empathic manner. In partnership with provincial departments of health, the project establishes at least one Regional Leadership Site in each province to serve as the hub for competency development; nurse mentors and outreach teams operate from these sites. As of mid-2014, over 3000 health workers have been trained, 584 clinicians have been mentored and 64 clinics in four provinces have been declared medically competent to serve men who have sex with men. By the end of 2014, there will be over 120 competent sites across six provinces and, by the end of 2015, over 160 sites nationally.

5.3 Community empowerment

5.3.1 Barriers

Key populations often have little or no control over HIV risk factors driven by the legal, political and social environment and the context of their lives. For instance, sex workers are frequently exposed to HIV and other STIs, but they may not have the power to negotiate consistent condom use *(30, 31)*. This lack of control is exacerbated if people are unaware of available HIV-related services and of their legal and human rights, specifically their right to health, and what to do if these rights are violated.

In particular, few young people from key populations receive adequate information and education for their sexual lives. Instead, they receive conflicting or confusing messages about gender and sexuality. This leaves young people vulnerable to coercion, abuse and exploitation and to unintended pregnancy and STIs, including HIV *(18)*. The lack of community empowerment, too, and of community-wide awareness and knowledge limits the overall effectiveness of interventions to reduce HIV risk *(10, 20)*.

5.3.2 Critical enablers

Evidence shows that health policies and programmes are more effective and have a more positive impact on health outcomes when affected populations take part in their development *(32)*. Community empowerment is a guiding principle for all HIV programming and activities. Community empowerment is a collective process that enables key populations to address the structural constraints to health, human rights and well-being; make social, economic and behavioural changes; and improve access to health services *(10)*. Community empowerment can foster the wider reach and greater effectiveness of services for key populations *(10)*. Community empowerment has been undertaken in various settings, such as for sex workers (Fig. 5.2).

Community empowerment is a critical enabler for improving key populations' living conditions, developing strategies for health and rights interventions and redressing violations of the human rights of people from key populations. Community empowerment can take many forms, such as meaningful participation of people from key populations in designing services, peer education, implementation of legal literacy and service programmes, and fostering key population-led groups and key population-led programmes and service delivery *(10, 20)*.

Key populations are heterogeneous and mobile. Therefore, to be effective, programmes must account for the diverse legal, political, social and health environments in which people from key populations live and must remain sensitive to a diversity of cultures *(20)*. This flexibility, responsiveness and adaptability are essential to community empowerment initiatives. Initiatives should be able to evolve over time to meet the changing needs of key populations.

Programmes led by key-population organizations

It is important to foster and support services, facilities and research led by organizations of people from key populations. Key population-led organizations, collectives and networks can play key roles in training the staffs of health services, police and social

service agencies, facilitating interaction with the communities of key populations, and managing services. In fact, they may have special strengths in providing community-based and outreach services.

Case study: Building health literacy among young injecting drug users in Mexico

Programa de Política de Drogas (Espolea, A.C), Mexico
http://www.espolea.org/

Espolea, a youth-led organization in Mexico City, opened its Drug Policy and Harm Reduction Programme in 2008 and has since developed online and face-to-face channels to provide objective information about drugs and risk reduction to young people ages 15–29 years.

The organization has found that information is most effective when disseminated at places where young people use drugs, particularly electronic dance music festivals, rock concerts and cultural gatherings. At these events Espolea sets up a stand as a safe space for young people to obtain information about drugs that may be being consumed. The organization also facilitates workshops in schools and in communities with concentrations of most-at-risk young people.

Espolea has an active outreach strategy, using social media, including Facebook and Twitter as well as Internet blogs. One blog – www.universodelasdrogas.org – serves as a databank on drugs and has become the axis of the programme's harm reduction campaign. Staff members, collaborators, and young people produce the information. Printed materials offer facts and recommendations about nightlife, alcohol consumption, risky sexual behaviours, HIV and other STIs.

Fig. 5.2 Key elements of community empowerment among sex workers *(20)*

While this figure refers to sex workers, these community empowerment elements could be adapted for other key populations.

Meaningful participation

Even if key population-led organizations are not taking the lead, the meaningful participation of representatives of the community in programming is critical to assure the appropriateness and acceptability of services to the intended clientele. It is also important for building trusting relationships between the community and service providers, who may be accustomed to establishing the parameters by which services are provided and prescribing how relationships or partnerships are to be conducted *(20)*. Meaningful participation means that key populations: (1) choose whether to participate; (2) choose how they are represented, and by whom; (3) choose how they are engaged in the process; and (4) have an equal voice in how partnerships are managed.

Policies and programmes are more effective when affected populations take part in their development.

Meaningful participation can mean not only having a voice in decision-making but also contributing to service delivery. For example, adolescents from key populations can be given opportunities, empowered and trained as peer educators, counsellors, trainers and advocates *(33)*. Peer education is a successful strategy for improving young people's HIV knowledge, testing and counselling, and linking to care; it is more likely to lead to behaviour change than many other interventions. Additionally, peer education can help to mobilize communities and social networks *(34)*.

Partnerships are crucial, but they must be built and maintained in a way that risks no harm to the persons involved. The success of interventions that facilitate participation is measured not only by effectiveness of outcomes but also by the degree to which key populations are engaged and by the process and mechanisms of engagement *(35)*.

Key population-led groups and organizations should be made essential partners and leaders in designing, planning, implementing and evaluating health services.

Good practice recommendations for community empowerment

ALL KEY POPULATION GROUPS

- Programmes should implement a package of interventions to enhance community empowerment among key populations *(10, 11, 12, 15)*.
- Programmes should be put in place to provide legal literacy and legal services to key populations so that they know their rights and applicable laws and can receive support from the justice system when aggrieved *(10, 11, 12, 15)*.

MEN WHO HAVE SEX WITH MEN

- Men's health groups and organizations of men who have sex with men are essential partners in providing comprehensive training on human sexuality and delivering services and so should be actively engaged. They also can facilitate interaction with members of sexually diverse communities, thereby generating greater understanding of their emotional health and social needs and the cost of inaction against homophobia *(11)*.

SEX WORKERS

- Programmes should be put in place to sensitize and educate health-care providers on non-discrimination and sex workers' right to high-quality and non-coercive care, confidentiality and informed consent *(10)*.
- Programmes should implement a package of interventions to enhance community empowerment among sex workers (*strong recommendation, very low quality of evidence*) *(10)*.

Additional remarks: The interventions delivered through a community empowerment model include, but are not limited to, sustained engagement with local sex workers to raise awareness of rights, establishment of community-managed drop-in centres, formation of collectives that determine the range of services to be provided, as well as shaping outreach and advocacy activities.

- Community empowerment is a necessary component of sex worker interventions and should be led by sex workers.

TRANSGENDER PEOPLE

- Organizations of transgender people are essential partners in delivering comprehensive training on human sexuality and gender expression. They also can facilitate interaction with members of communities with diverse gender identities and expressions, thereby generating greater understanding of their emotional health and social needs and the cost of inaction against transphobia *(11)*.

ADOLESCENTS FROM KEY POPULATIONS

It is recommended that sexuality education programmes for adolescents, both in and outside of schools, be scientifically accurate and comprehensive and include information on contraceptives, including how to use them and where to get them *(15)*.

Case study: In Nepal meaningful participation of people who inject drugs

Bridging the Gap: Health and Human Rights for the Key Population, Naya Goreto, Nepal
www.nayagoreto.org.np

Recognizing the lack of specific laws or policies in Nepal to support people who inject drugs and the lack of services at the community level, Naya Goreto created *"Bridging the Gap: Health and Human Rights Programme for the Key Population"*. This programme aims to engage stakeholders across the spectrum, from parliamentarians to local councillors, public health officials to health volunteers, in advocacy on issues of concern to people who inject drugs.

Naya Goreto emphasizes the meaningful participation of people who inject drugs at all levels of the programme. More than 200 people from the community have been trained to lead activities ranging from situation analysis to advocacy campaigning and programme monitoring. The programme also has brought together various stakeholders, including former politicians, councillors, public health personnel, and the community to create a committee that lobbies for the health and human rights of people who inject drugs. Empowerment activities have included the following:

- conducting advocacy programmes in stigma-free small group environments, such as meetings at a local cafe, which make possible more personal and meaningful discussion of issues;
- forming key population-led networks such as Lalitpur Drug User's Advocacy Network;
- linking people who inject drugs with experts and other concerned stakeholders for easy access to adequate information on programmes and budgets;
- mobilization of trained people from the community to participate in consultation meetings with key governmental bodies, lobbying with duty bearers for the health and human rights of people who inject drugs.

Naya Goreto has built strong partnerships among people who inject drugs, creating a shared feeling of solidarity to collectively address the issues that directly affect them. Such issues are now included in the yearly action plans of local government and civil society organizations. Annual budgets have been secured from local government bodies to conduct drug awareness programmes by and for communities. There is now a seat for a community member on the District AIDS Coordination Committee. At a civil society level, there has been a rise in positive community awareness – for example, through national media – of issues that affect people who inject drugs.

Case study: Youth-led advocacy, leadership, and empowerment of young key populations

Youth LEAD, NewGen leadership programme, Asia–Pacific
http://youth-lead.org/

Youth LEAD is a network of and for young key populations most affected by HIV in 20 countries across Asia and the Pacific. In 2011 Youth LEAD created the NewGen Asia leadership course, a five-day youth-led programme for young people in advocacy, leadership, and empowerment. The course was pilot-tested in the Philippines; evaluations led to revisions and the development of training materials. A seven-day training of trainers took place the following year with 21 participants from five countries. This led to the implementation of NewGen and the adaptation of national trainings in Myanmar, the Philippines and Indonesia.

NewGen uses a range of participatory activities to help young people to think critically about the way in which social, political and institutional environments influence the well-being of members of key populations. Participants learn formal advocacy and communication skills and the use of data through speech-making and participation in meetings as representatives of their communities.

Overall, participants rate NewGen very highly. Participants find the training particularly useful for learning new leadership and advocacy skills, and they enjoy the participatory training methodology. Through working and learning together, participants develop a sense of community. Course graduates have helped establish new community networks of young people from key populations in many countries, often through social media.

5.4 Violence

5.4.1 Barriers

Violence against people from key populations has been shown to be a risk factor for HIV acquisition *(36)*. Such violence is common. It can take various forms – physical, sexual or psychological *(37)*. Violence is fuelled by the imbalance in the power dynamics of gender and by prejudice and discrimination against persons perceived to depart from conventional gender and sexuality norms and identities. Also, multiple structural factors influence vulnerability to violence, including discriminatory or harsh laws and policing practices and cultural and social norms that legitimate stigma and discrimination.

Women, especially young women, from key populations, including female drug users, female sex workers and transgender women, experience particularly high rates of physical, sexual, and psychological abuse *(38, 39, 40)*. Reported rates of violence against sex workers and transgender women are high *(41, 42, 43)* but nonetheless are likely to be underreported where certain behaviours of key populations are illegal.

Homophobic violence, too, is increasing in some countries, as more policies and laws have banned same-sex activity and made it a criminal offense *(44)*. This is likely to increase HIV risk *(45)*.

5.4.2 Critical enablers

Efforts to address violence against people from key populations must involve other sectors along with the health sector. Together, they must create an enabling environment to promote physical, sexual, and emotional well-being and safety. Critical enablers include mechanisms for documenting and monitoring violence, training people from key populations and other stakeholders to understand human rights and fostering the accountability of law enforcement officials to prevent and respond to violence and infringements of human rights *(46)*.

Prevention of violence against key populations

Law enforcement practices can increase the risk of violence faced by key populations. Indeed, law enforcement officers themselves can be perpetrators. Work with law officers

can involve training on the human rights of key populations as well as promoting accountability for rights-based law enforcement *(46)*. Efforts to prevent violence can be promoted through advocacy for law and policy reforms that protect the rights and safety of key populations, by increasing awareness of reporting mechanisms and disciplinary action, by conducting sensitization workshops for people with pivotal roles in the community (e.g. government officials, police, media, health-care workers and religious leaders), through the creation of safe spaces, and by creating early warning and rapid response mechanisms with the involvement of key population community members, health workers and law enforcement officials. Integrating community representatives into these efforts also helps to create channels of communication among key populations, civic officials and police *(47)*.

Support for persons experiencing violence

Those who experience sexual violence need timely access to post-rape care, including emergency contraception, post-exposure prophylaxis for HIV and other STIs, hepatitis B immunization and psychosocial care and support, as well as referrals to police and legal services. HIV prevention, treatment and care should include clinical and psychosocial care and support for survivors of violence, in line with WHO guidelines for responding to sexual violence *(46)*. Survivors may need treatment for physical injuries and longer-term mental health care. Health services also can document medico-legal evidence, which can assist survivors' access to justice. Supportive services also include hotlines staffed by trained peer counsellors to offer psychosocial support as well as crisis response interventions, with multi-disciplinary teams, linking survivors to various services and safe spaces *(10)*.

It also is important to monitor and document incidents of violence, both as evidence for advocacy and to inform programme design. Documenting the levels of violence faced by key populations is often the first step in creating awareness.

Good practice recommendations for reducing violence

ALL KEY POPULATION GROUPS

- Violence against people from key populations should be prevented and addressed in partnership with key population-led organizations. All violence against people from key population groups should be monitored and reported, and redress mechanisms should be established to provide justice *(10, 11, 12, 46)*.
- Health and other support services should be provided to all persons from key populations who experience violence. In particular, persons experiencing sexual violence should have timely access to comprehensive post-rape care in accordance with WHO guidelines.
- Law enforcement officials and health- and social-care providers need to be trained to recognize and uphold the human rights of key populations and to be held accountable if they violate these rights, including perpetration of violence *(10, 11, 12, 46)*.

PEOPLE IN PRISONS AND OTHER CLOSED SETTINGS

- Prison authorities should provide adequate staffing, effective surveillance, disciplinary sanctions, and education, work and leisure programmes for prisoners.
- Prisons and other closed settings and their staffs should make efforts to change institutional culture that tolerates rape and other sexual violence. Prisons should adopt multiple approaches to combating sexual violence, including policies and programmes for prevention (e.g. prisoner education, classification, and structural interventions such as better lighting, better shower and sleeping arrangements), staff training, investigation, disciplinary action, victim services (e.g. medical and mental health) and documentation of incidents *(12)*.

Case study: Building partnerships in India to address violence and improve legal literacy

The Karnataka Health Promotion Trust (KHPT)
http://www.khpt.org/

Addressing violence against sex workers is complex and requires partnership among like-minded organizations. The Karnataka Health Promotion Trust (KHPT) has been working on HIV prevention among sex workers in Karnataka, India, for the last 10 years. Sex workers have strongly expressed the need to prevent and respond to violence. KHPT has sensitized law enforcement police and the judiciary and advocated that they not perpetrate or condone violence against sex workers. In partnership with KHPT:

- The state's Women and Child Welfare Department made services for violence against women available to sex workers.
- Community-based organizations worked with sex workers in 30 districts to alert them to their rights.
- The Alternative Law Forum and the National Law School of India developed and conducted legal literacy training for sex workers.
- The Centre for Advocacy and Research, a nongovernmental organization, conducted media advocacy and trained sex workers as media spokespersons to talk about the violence they face, their resilience and actions to prevent and respond to violence.

Further reading

- *UNAIDS guidance for partnerships with civil society, including people living with HIV and other key populations.* Geneva, UNAIDS, 2011. http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2236_guidance_partnership_civilsociety_en.pdf
- Chapter 2: Addressing violence against sex workers. In: *Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions.* Geneva, WHO, 2013. http://www.who.int/hiv/pub/sti/sex_worker_implementation/en/
- *Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations.* Geneva, WHO, 2014. http://apps.who.int/iris/bitstream/10665/102539/1/9789241506748_eng.pdf?ua
- *Evidence for action technical papers: effectiveness of interventions to address HIV in prisons.* Geneva, WHO, UNODC, 2007. http://whqlibdoc.who.int/publications/2007/9789241596190_eng.pdf?ua=1
- Global Commission on HIV and the Law. *HIV and the law: risks, rights and health.* New York, UNDP, 2012. http://www.hivlawcommission.org/index.php/report
- *Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines.* Geneva, WHO, 2013. http://www.who.int/reproductivehealth/publications/violence/9789241548595/en/index.html
- *The human rights costing tool (HRCT): a tool to cost programs to reduce stigma and discrimination and increase access to justice.* Geneva, UNAIDS, 2012. http://www.unaids.org/en/media/unaids/contentassets/documents/data-and-analysis/tools/The_Human_Rights_Costing_Tool_v_1_5_May-2012.xlsm
- *The user guide for the HIV-related human rights costing tool: costing programmes to reduce stigma and discrimination and increase access to justice in the context of HIV.* Geneva, UNAIDS, 2012. http://www.unaids.org/en/media/unaids/contentassets/documents/document/2012/The_HRCT_User_Guide_FINAL_2012-07-09.pdf
- *UNAIDS guidance note: key programmes to reduce stigma and discrimination and increase access to justice in national HIV responses.* Geneva, UNAIDS, 2012. http://www.unaids.org/en/media/unaids/contentassets/documents/document/2012/Key_Human_Rights_Programmes_en_May2012.pdf
- *Understanding and acting on critical enablers and development synergies for strategic investment.* New York, UNDP, 2011. http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/201211_UNAIDS_UNDP_Enablers_and_Synergies_en.pdf
- *Guidance for HIV testing and counselling and care for adolescents living with HIV.* Geneva, WHO, 2013. http://www.who.int/hiv/pub/guidelines/adolescents/en/

SERVICE DELIVERY

6

6 SERVICE DELIVERY

6.1 Overview

The comprehensive package of interventions, outlined in Chapters 3 and 4, includes health interventions common to all key populations as well as additional services for specific population groups. Most of these interventions are the same HIV prevention, diagnosis, treatment and care interventions as for the general population *(1)*. However, there are often complex challenges and barriers, as discussed in Chapter 5, to implementation and delivery of these services to key populations. Programmes need to address these challenges and barriers and provide sustainable HIV services for diagnosis, linkage, retention and adherence for key populations. To maximize impact, services should be made 1) **accessible**, 2) **acceptable**, 3) **affordable** and 4) **equitable**. Furthermore, key populations need to be made aware of the available services.

This chapter focuses on the service delivery elements important to the comprehensive package of health interventions for key populations. Box 6.1 lists a number of WHO tools that can help guide implementation.

Box 6.1 WHO guidance on HIV-related service delivery approaches

The consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (1) provides broad guidance in six essential operational and service delivery areas:

- adherence to ART
- retention across the continuum of care
- service delivery, comprising service integration and linkage and decentralization of HIV care and treatment
- human resources, including task shifting
- laboratory and diagnostic services
- procurement and supply management systems.

Implementation tools to support HIV programming for key populations

WHO and other UN agencies have produced normative guidance on HIV prevention, treatment and care for key populations, which this publication consolidates. To support implementation of HIV programming for these groups, these agencies are now partnering to develop implementation tools. The first of these is *Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions (2)*. Other tools will address HIV programming for men who have sex with men, people who inject drugs and transgender people. Also, WHO and other UN agencies have developed tools to support the design and implementation of specific interventions, such as needle and syringe programmes *(3)*.

WHO regional guidance on service delivery for key populations groups

Regional WHO offices have developed tools for the specific priorities and needs in their regions, including:

Regional Office for Africa:
Preventing HIV in sex work settings in sub-Saharan Africa (4)

Regional Office for the Eastern Mediterranean:
MENAHRA: The Middle East and North Africa Harm Reduction Association best practices in strengthening civil society's role in delivering harm reduction services (5)

Regional Office for Europe:
How to improve opioid substitution therapy implementation (6)

Regional Office for the Americas:
Improving access of key populations to comprehensive HIV health services (7)

Blueprint for the provision of comprehensive care to gay men and other men who have sex with men in Latin America and the Caribbean (8)

Regional Office for South-East Asia:
Management of common health problems of drug users (9)

Priority HIV and sexual health interventions in the health sector for men who have sex with men and transgender people in the Asia–Pacific Region (10)

Regional Office for the Western Pacific:
Joint technical brief: HIV, sexually transmitted infections and other health needs among transgender people in Asia and the Pacific (11)

The time has come: enhancing HIV, STI and other sexual health services for MSM and transgender people in Asia and the Pacific (12)

Regional assessment of HIV, STI and other health needs of transgender people in Asia and the Pacific (13)

6.2 Key service delivery strategies

Based on evidence and experience, WHO recommends three overarching strategies that can improve service delivery *(1)*: 1) **integration**, 2) **decentralization** and 3) **task shifting**. These strategies, separately or in combination, can improve the accessibility of care. The community and community-led and community-based approaches are integral to these strategies, particularly for key populations. Given the heterogeneity of key populations and of social and epidemiological contexts, their application will need to be based on a situational assessment and undertaken in consultation with key population groups and service providers.

6.2.1 Integration of services

WHO recommends the integration of HIV services with a range of other relevant clinical services, such as those for TB, maternal and child health, sexual and reproductive health services and drug dependence treatment *(1)*.

Integration of services facilitates provision of comprehensive and consistent care. It allows individuals to take care of their various health needs at the same time and in the same location.

WHO recommends integration of HIV services into other relevant clinical services, such as TB, MCH, sexual and reproductive health services and drug dependence treatment.

Integration of services involves not only providing related services in a single setting but also linkage systems to share information and provisions for referrals across settings and among providers *(1)*. Collaboration between programmes at every level of the health system is important to the success of HIV and other related health and social services.

Aspects of coordination that need consideration include mobilizing and allocating resources; training, mentoring and supervising health workers; procuring and managing drugs and other medical supplies; and monitoring and evaluation. The goal of programme planning should be to create delivery systems that best facilitate access.

Recommendations and guidance

ALL KEY POPULATION GROUPS

Delivering ART in antenatal care and maternal and other child health settings

- In generalized epidemic settings ART should be initiated and maintained in eligible pregnant and postpartum women and in infants at maternal, newborn and child health-care settings, with linkage and referral to ongoing HIV care and ART where appropriate *(strong recommendation, very low quality of evidence) (1)*.

Delivering ART in TB treatment settings and TB treatment in HIV care settings

- In settings with a high HIV prevalence (≥5%) among TB patients, ART should be initiated for HIV-positive individuals with TB in TB treatment settings, with linkage to ongoing HIV care and ART *(strong recommendation, very low quality of evidence) (1)*.
- In settings with a high burden of HIV and TB, TB treatment should be provided for individuals with HIV in HIV care settings where TB diagnosis has also been made *(strong recommendation, very low quality of evidence) (1)*.

PEOPLE WHO INJECT DRUGS

ART in settings providing opioid substitution therapy

- In settings where opioid substitution therapy is provided, ART should be initiated and maintained in people with HIV who are eligible for ART *(strong recommendation, very low quality of evidence) (1)*.

Case study: Integrated services for sex workers in Zimbabwe

CeSHHAR, Zimbabwe
http://www.ceshhar.co.zw

The nongovernmental organization Centre for Sexual Health and HIV AIDS Research (CeSHHAR) Zimbabwe runs the Sisters with a Voice programme, which provides integrated services for sex workers in multiple sites across Zimbabwe on behalf of the National AIDS Council. Collaboration with key government ministries (AIDS, Health, and Social Welfare) and the involvement of sex workers in implementation have contributed greatly to the programme's successes.

Supported by a network of peer educators trained in participatory community mobilization and empowerment, the Sisters with a Voice programme offers HTC, syndromic STI treatment, contraceptives, health education and legal advice. Cervical screening is being rolled out; nurses are being trained in visual inspection and treatment of pre-cancerous lesions using cryotherapy.

Peer educators run community mobilization sessions. The 36 sessions cover issues for sex workers themselves (self-worth, behaviour change, contraception, HIV and cervical cancer), issues relating to clients and partners (communication, assertiveness, serodiscordance, sexual networks and multiple concurrent partnering) and issues relating to the "sisterhood" (advocacy, stigma, rights and support).

Since 2009 the programme has expanded from five sites to a comprehensive network of 36 sites nationally. By 2013 the six fixed facilities and 30 outreach sites together served more than 14 000 women. Moreover, at a site where two population-based surveys were conducted, the proportion of HIV-negative women that reported having a recent HIV test increased from 35% in 2011 to more than 70% in 2013. Over the same period the proportion of women living with HIV who were obtaining ART increased from 28% to 45%.

An example of integrating services is provided by the next case study, where specific health services for transgender people are provided within a general health facility.

Case study: Comprehensive transgender services within a community health clinic

Transgender Family Program, Community Healthcare Network, United States of America
http://www.chnnyc.org/

The Transgender Family Program was established in 2004 at the Community Healthcare Network clinics in New York City to improve access to HIV prevention and linkages to primary health care.

To understand how best to integrate comprehensive transgender services into a community health clinic, the Network undertook community mapping, consultations and forums and learning from similar programmes. Importantly, the programme asked patients to form the Client Advisory Board to help guide integration and implementation of services for the transgender community.

Integrated services include transgender care, HTC, medical case management, support for treatment adherence, STI screening and treatment, prevention interventions and mental health and nutritional services. In addition, the programme provides risk reduction counselling, support groups, outreach, bilingual educational workshops and referrals to legal and social services. Recruitment strategies of staff members and trained peer leaders include face-to-face contacts, community-based activities and online methods including advertising and social media tools. Clients are encouraged to engage family members. This has proved to be an important strategy to encourage access and attendance.

Over 750 people have received transgender-specific services. Identified benefits of integrated transgender services include:

- improved tolerance of, sensitivity to and long-term acceptance of this population in the larger community
- improved accessibility through convenient location of services
- flexible hours as a result of larger capacity
- increased access to a range of in-house support services.

In addition, in-depth evaluation has found significant decreases in sex work, needle sharing and unregulated hormone injections and increased likelihood of regular condom use.

6.2.2 Decentralization of services

Decentralization aims to deliver all HIV services closer to the individual. In many settings transport costs and long waiting times in central hospitals are significant barriers to access to services and retention in care. Particularly in rural areas, decentralization can reduce the difficulty and cost of travel and shorten waiting times. If carefully planned and implemented, decentralization may provide safer, discreet and more accessible health-care options, particularly for key populations. However, decentralization of services for key populations may not always be appropriate or acceptable. In some settings general HIV services may provide greater anonymity.

WHO recommends decentralization of ART services specifically. Decentralization of a full range of HIV prevention, diagnosis, treatment, care and support services for key populations can also be considered. Decentralizing HIV care and treatment can further strengthen community engagement, can link community-based interventions with health facilities, and may improve access to services, care-seeking behaviour and retention in care *(1)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

- The following options should be considered for decentralization of ART initiation and maintenance:
  - Initiation of ART in hospitals, with maintenance of ART in peripheral health facilities *(strong recommendation, low quality of evidence)*.
  - Initiation of ART and maintenance of ART in peripheral health facilities *(strong recommendation, low quality of evidence)*.
  - Initiation of ART at peripheral health facilities, with maintenance at the community level between regular clinic visits (i.e. outside of health facilities, in settings such as outreach sites, health posts, home-based services or community-based organizations) *(strong recommendation, moderate quality of evidence) (1)*.

Case study: Mobile outreach to sex workers in South Africa

Re-Action Consulting, South Africa
http://www.re-action.co.za

In conjunction with the Department of Health, Re-Action! operates a five-year programme to reduce new HIV infections among sex workers and their clients in two rural districts in Mpumalanga province of South Africa. Currently, the programme reaches about 4100 female sex workers.

A nursing team offers multiple free services including health risk screening and testing (including Point of Care CD4 testing), HTC, care and treatment and referral to other health and social services through a mobile clinic. The team visits locations at least twice per week at times convenient to their clientele. With the help of a 28-day calendar, sex workers know where they can obtain services in case of emergencies. If needed, the nurse can provide services, including ART, in the client's workplaces.

Nurses trained in nurse-initiated and managed ART can diagnose, stage clients and enrol them into the appropriate ART services. The nurses supply patients with medication from the Department of Health, and they visit patients to follow up and teach about adherence to treatment. When a client defaults on treatment, outreach workers provide assistance and follow-up. The programme has a very low default rate of 2.3%, most of it attributed to women moving elsewhere.

6.2.3 Task-shifting the delivery of services

Task shifting can enable the existing workforce to serve more people.

Task shifting involves the rational redistribution of tasks among health-care workers. Where appropriate, tasks are reassigned from highly qualified health workers to health workers with shorter training and fewer complementary qualifications *(1)*. Many countries face a shortage of health-care workers; task shifting can increase the effectiveness and efficiency of available personnel, enabling the existing workforce to serve more people. Community-led organizations can also play important roles in reaching key populations, engaging with them, linking them to services and providing ongoing care and support.

Peer-support workers can provide valuable services and can link the community and health services. Like other health workers, they need regular training, mentoring and supervision *(1)*. They should receive adequate wages and/or other appropriate incentives *(14)*.

Recommendations and guidance

ALL KEY POPULATION GROUPS

- Trained non-physician clinicians, midwives and nurses can initiate first-line ART *(strong recommendation, moderate quality of evidence)*.
- Trained non-physician clinicians, midwives and nurses can maintain ART *(strong recommendation, moderate quality of evidence)*.
- Trained and supervised community health workers can dispense ART between regular clinical visits *(strong recommendation, moderate quality of evidence) (1)*.

Case study: Community distribution of naloxone in India

Social Awareness Service Organisation (SASO), Manipur, India
http://sasoimphal.org/

In the state of Manipur, India, since 2000 the Social Awareness Service Organisation (SASO) has provided, among other services, opioid overdose management with free naloxone, through outreach (e.g. at "shooting sites") and at drop-in centres. Also, through small meetings, one-to-one contacts and counselling, SASO provides information and education about drug overdose and its management to all people who inject drugs and their family members.

The programme was scaled up and strengthened in 2008–09 by involving key stakeholders to facilitate community implementation of naloxone to ensure wider coverage. Ethical concerns about non-medical staff dispensing a medication to people who inject drugs have been overcome through the demonstration of the life-saving nature of overdose management. Between 2004 and 2012 more than 450 overdoses were managed at five centres, and over 90% of those lives were saved. In addition, more than one-third of overdose clients have increased access to drug treatment and other health care, such as HIV/HCV testing and ART.

6.2.4 Community-based approaches

Community-based approaches to service delivery can increase accessibility and acceptability for key populations. Outreach, mobile services, drop-in centres and venue-based approaches are useful for reaching those with limited access to, or underserved by, formal health facilities. These approaches allow for critical linkages and referrals between the community and health facilities, and they support decentralization (see Section 6.2.2). Community-based programmes can also refer to programmes that are led and delivered by members of the key population community. Staff members, including peers, involved in community-based approaches need to be appropriately supported, in terms both of training, supervision and management and of incentives and remuneration.

The community plays a vital role in the HIV response.

Community-led services, in which community members take the lead in delivering outreach and overseeing an HIV prevention programme, have demonstrated significant benefits in terms of HIV outcomes. They also enable community members to address structural barriers to the exercise of their rights and empower them to change social norms, thus reducing vulnerabilities that go beyond HIV.

Community-led services are interventions designed, delivered and monitored by community members. They can play many roles – for example:

- providing adequate and reliable access to commodities (condoms, lubricants, and needles and syringes) and clinical services through outreach and referrals;
- responding to violence against community members and implementing other structural interventions;
- supporting the safe and effective use of naloxone in the community by people who witness an opioid overdose;
- promoting behavioural and social change that strengthens not only knowledge but also skills and systems in order to sustain prevention and retention in care and treatment;
- offering formal and informal means for the community to provide feedback on the quality of services and to engage with services beyond the HIV programme *(2)*.

Peer interventions – also termed peer-based or peer-driven interventions – are an important modality for delivering services and exchanging information and skills that promote safer behaviours to individuals or networks of people from key populations. Beyond providing services, peers can act as role models and offer non-judgemental and respectful support that may contribute to reducing stigma, facilitating access to services and improving their acceptability.

Recommendations and guidance

ALL KEY POPULATION GROUPS

In all HIV epidemic settings, WHO recommends community-based HIV testing and counselling with linkage to prevention, care and treatment services for key populations in addition to provider-initiated testing and counselling *(strong recommendation, low quality of evidence) (1)*.

PEOPLE WHO INJECT DRUGS

See Section 4.1.2.4 for specific recommendations on peer support and community delivery of naloxone.

ADOLESCENTS FROM KEY POPULATIONS

Community-based approaches can improve treatment adherence and retention in care of adolescents living with HIV *(conditional recommendation, very low quality of evidence) (15)*. (See Box 6.2.)

Case study: Community-led service delivery centres in Pakistan

Naz Male Health Alliance, Pakistan

Naz Male Health Alliance is a community-based organization in Pakistan serving the community of men who have sex with men and of transgender people. As part of its on-going work to empower the community, the organization operates six service delivery centres in five cities, with 47 000 registered clients. Each service delivery centre is divided into a clinic and a drop-in centre that provides a safe and relaxing atmosphere for the low-income beneficiaries. The centres are located strategically close to "hotspots" for men who have sex with men and where there are concentrations of *hijra deras* (dwellings of transsexual people). Drop-in centres and outreach activities are complementary: The drop-in centres allow the establishment of long-lasting relationships with the clients, and outreach provides linkage to the drop-in centre.

Service sites are separate for each key population community in order to effectively address their different needs. Each centre has a multidisciplinary staff of about 15 people, including STI specialist doctors, a psychologist, and peer educators. The teams consist primarily of community members; more than 95% of staff staff are men who have sex with men and transgender people.

Box 6.2 Adolescents from key populations

The service delivery approaches and considerations discussed in this chapter for all key populations are applicable for adolescents from key populations. However, additional considerations are required. It is essential that services for adolescents from key populations are designed and delivered in ways that take into account the multiple, overlapping vulnerabilities that confront adolescents from key populations and the diversity of their needs, based on their age, their specific behaviours and the complexities of their social and legal environment.

Additional considerations and approaches for adolescents from key populations include:[1]

- Acknowledge and build upon the strengths, competencies and capacities of adolescents from key populations, especially their ability to articulate what services they need. Engage them in decisions about services, recognizing their evolving capacity and their right to have their views taken into account. This is an important consideration when addressing issues of parental consent for services and treatment (see Section 5.1.2).
- Give primary consideration to the best interests of young people in all laws and policies aimed at protecting their rights (Convention on the Rights of the Child, Article 3) *(16)*.
- Make the most of existing services and infrastructure for youth and add components for reaching and providing services to adolescents from key populations, ensuring that services are friendly to youth from key populations as well as to other youth.
- Adopt a multidisciplinary approach, ensuring that services are as comprehensive as possible so as to address overlapping vulnerabilities.
- Provide developmentally appropriate information and education for adolescents from key populations, focusing on skills-based risk reduction. Information can be disseminated via multiple media, including the Internet, mobile phone technology and participatory approaches.
- Provide psychosocial support, through counselling, peer support groups and networks, to address self-stigma and discrimination and other mental health issues. Additional provision of counselling for families, including parents – where appropriate and requested by the adolescent – may be important to support and facilitate access to services, especially where parental consent is required *(7)*.
- Facilitate access to social services and state benefits, including immediate shelter and long-term housing, and address food security issues, including nutritional assessments.
- Support access to livelihood development and economic strengthening, and encourage adolescents to stay in school or, if out of school, to return to school, where appropriate.
- Address social norms and stigma concerning sexuality, gender identities and sexual orientation through comprehensive sexuality education in schools, supportive information for families, training of educators and health-care providers and non-discrimination policies in employment.

[1] See also Web Annex 6 briefs on young key populations.

6.3 Key factors to consider when providing services for all key populations

In summary, assuring access, acceptability and affordability requires attention to multiple, specific elements of programme design and delivery. Action on all these elements, appropriate to the specific context, will yield programmes that best serve key populations.

ACCESS

Generate demand

Demand for HTC and prevention services can be generated through targeted campaigns in identified key population settings, using community-based outreach, mobile phone technology, social networking and broadcast and online media.

Case study: Online strategies to increase uptake of HTC services in Bangkok

Thai Red Cross AIDS Research Centre, Bangkok, Thailand
http://en.trcarc.org/

In Bangkok the Men's Health Clinic provides comprehensive and friendly services to men who have sex with men. One of the Clinic's tools to increase uptake of HTC has been the first bilingual (Thai/English) edu-tainment web site for men who have sex with men (http://adamslove.org), launched in 2011.

The web site's goal is to encourage regular HIV testing among men who have sex with men. To link web site visitors to HTC services, a section titled "HIV testing site near you" offers information about how to obtain HTC at sites that are friendly to men who have sex with men in Bangkok and other provinces. Other means of continuous demand creation for HTC services include mass media and targeted media activities such as regular columns in gay magazines, peer-driven interventions and celebrity meet-and-greet HIV testing events.

The number of clients who have obtained HTC services has increased almost fivefold, from 967 in 2008 to 4371 in 2012. The Adam's Love web site attracted more than 500 000 visitors in two years and has its own Facebook page as well, with more than 15 000 fans. One-quarter of clients of the Men's Health Clinic report obtaining HTC services because of the site.

Address age barriers

Age of consent laws should be examined to determine their effect on access to services. Countries can consider revising age of consent policies and creating exceptions to age limits (i.e. mature minor status). Countries also can consider how best to assess adolescents' capacity to consent.

Make services convenient

Programmes can consider offering mobile and/or drop-in services and weekend and/or night service times that facilitate access. Outreach, including venue-based and home-visiting services, also can increase access.

Decentralize services

Shifting services from centralized locations to community-based and/or mobile outreach and peripheral health facilities can increase access. For example, school-based sex education, peer counselling and community-level activities can disseminate behavioural messages, promote follow-up on referrals to services, improve adherence to treatment and increase people's participation in their own health care.

Case study: In Vietnam decentralization facilitates earlier access to HIV services

Vietnam Authority of HIV/AIDS Control/Ministry of Health and WHO Vietnam

In 2012 the Vietnam Authority of HIV/AIDS Control in the Ministry of Health started pilot-testing a project to expand earlier access to HIV services among key populations, particularly to people who inject drugs, and thus to maximize the therapeutic and preventive benefits of ART by enabling people to start treatment as soon as possible. The pilot project involved decentralizing HTC services from district facilities to commune health stations in Dien Bien and Can Tho provinces. The pilot project introduced such innovations in Vietnam as a fixed dose combination ARV formulation, point-of-care HIV and CD4 testing, and decentralized follow-up.

The project actively engaged community partners, including peer educators, self-support groups and village health-care workers, providing them with community mobilization trainings and holding regular meetings to discuss outreach activities and challenges. Commune health station staff received training on HIV service delivery, including HIV testing using rapid tests, pre- and post-test counselling, adherence support, basic care and dispensing ARV drugs.

This decentralized, community-based model has been shown to promote earlier diagnosis and treatment. People diagnosed at communes have significantly higher median CD4 counts when starting ART (median 294 cells/mm^3) than those diagnosed at district facilities (median 88 cells/mm^3). Community outreach and trust-building are recognized as critical to facilitating earlier access to HIV services among people who inject drugs.

Integrate services and assure referrals and linkage to care

Service integration, including integrated HTC and care services and integrated HIV and drug dependence services (e.g. OST, NSP), makes services more convenient and thus facilitates access. To decrease loss to follow-up, standard operating procedures should specify linkages to care and help with transport from HTC to ART sites. Systems that share information between clinics (e.g. TB and HIV clinics), use of outreach workers for follow-up and support from peers can facilitate retention in care.

Case study: Promoting regular testing and supporting linkage to care in Spain

Projecte dels NOMS-Hispanosida (BCN Checkpoint), Spain
http://www.bcncheckpoint.com/

BCN Checkpoint is a community-based centre in the gay district of Barcelona for the detection of HIV and other STIs among men who have sex with men. Managed by the nongovernmental organization Projecte dels NOMS-Hispanosida, BCN Checkpoint offers free rapid HIV and syphilis testing by peers for early detection, vaccination against hepatitis A and B and promotion of sexual health. To encourage annual repeat HIV testing, BCN Checkpoint uses e-mail, text messages and telephone reminders.

Between 2007 and 2013 the programme performed over 22 000 HIV tests, detecting 756 new infections. For those with HIV-positive results, BCN Checkpoint offers an education and information programme with trained HIV-positive peer counsellors and referrals within one week to the hospital's HIV treatment unit. To ensure linkage to care, all recently diagnosed individuals are followed through a register. Currently, nearly 90% are linked directly to care, while 5% find their own care, and about 4% are in Barcelona only temporarily and obtain care in their home countries. Less than 2% are lost in linkage to care.

Invest in critical enablers

Countries can support key populations' access to services by investing in critical enablers such as integrated treatment and rights literacy programmes, legal services, programmes to reduce stigma and discrimination, and training for health-care workers and law enforcement personnel.

Case study: Using social media in Ghana to reach men who have sex with men

SHARPER project, FHI360, Ghana
http://www.fhi360.org/projects/strengthening-hivaids-response-partnership-evidenced-based-results-sharper

The SHARPER project tested use of social media by community liaison officers to identify unreached networks of men who have sex with men. The project launched MSM.net in two locations through informal mapping of the community's networks. Community liaison officers were selected from networks not previously reached by peer educators and were trained on HIV, health information and services. They used social media on smart phones and laptop computers to reach men who have sex with men. "Reached" is defined as receiving a risk assessment, information on HIV prevention and a referral to HIV testing and counselling (or another HIV service).

In 2013 more than 15 000 men who have sex with men were reached through Facebook (45.6%), WhatsApp (13.4%) and other social media platforms. In Accra 82% of the men reached by this approach had not had previous contact with a peer educator. In Kumasi 66% had never been reached before by any intervention. The community liaison officer in Accra identified eight male sex worker brothels and networks previously unknown to the project and other MSM organizations.

Social media proved to be an important means to reach men who have sex with men that peer educators would not usually reach. MSM reached by community liaison officers tended to be older, more educated, single, have a higher monthly income, and (in Accra) to report a larger social network of men who have sex with men than those reached by peer educators.

ACCEPTABILITY

Train health-care providers

Sensitize and educate health-care providers (including community workers, peer outreach workers, support staff and management) on issues specific to key populations and on non-discriminatory practices and eliminating stigma, using pre-service and in-service training, job aids, supportive supervision, and training follow-up. Where possible, training should involve representatives of key populations.

Create a safe and supportive environment

Safe spaces (for both health-care and social services) and confidential and stigma-free environments can encourage access by people from key populations. For example, providing separate and well-lit entrances or locating services in an appropriate setting can decrease barriers to services.

Provide high-quality services

Services should be acceptable and of high quality. One way to assess quality is monitoring clients' experience, using national and global indicators.

Assure voluntary and informed consent

Programmes must promote individuals' right to decide on their own treatment and accept their right to refuse services. All services should be voluntary, without any feeling of coercion or conditional requirements for obtaining services or commodities such as HIV testing, condoms or clean needles. Information on services and treatment should be clear, explicit and in the appropriate language. Additionally, information for adolescents needs to be suited to their specific developmental stage.

Ensure confidentiality

Attention should be devoted to protecting privacy and confidentially, e.g. closing the consultation room door or finding a private place to talk. Clients should be reassured of confidentiality, e.g. seeking permission before disclosing information to other health-care providers. Programmes should address the complexities of maintaining confidentiality in community, outreach and peer approaches particularly.

Case study: Confidential and anonymous services in Lebanon

Marsa Sexual Health Center, Lebanon
http://www.marsa.me

Marsa Sexual Health Center in Beirut, Lebanon, offers sexual health and reproductive health services to the public in a friendly environment free of stigma and discrimination against age, sex, gender and sexual orientation. Intended clients are youth, unmarried sexually active women and marginalized communities with limited access to other sexual health care facilities, including men who have sex with men and transgender people.

Clients' anonymity and confidentiality when they obtain Marsa services play a key role in attracting the clientele. The center uses a unique file number for each client as a form of identification. The client decides if they would like to provide identifying information for their file.

In addition, the staff of experienced and sensitized professionals is required to maintain confidentiality. Clients feel comfortable to open up to their care providers, disclose intimate details about their lifestyles and seek information from specialists, knowing that their identity will not be disclosed, even among staff members.

Case study: Online and telephone counselling assures anonymity for young men who have sex with men living with HIV in the Russian Federation

Positive Life programme, menZDRAV Foundation & Phoenix PLUS NGO, Russia

In partnership with a nongovernmental organisation, the menZDRAV Foundation offers services to young men who have sex with men, ages 18–25, living with HIV in six regions of the Russian Federation. Many young men are reluctant to attend support groups for fear that their sexual orientation or HIV status will be publicly identified, and so the Positive Life programme offers individual counselling via phone, social media and Skype.

In each of six cities, peer counsellors staff a telephone hotline with a publicized number. Counselling is also offered via Skype, and young men can send questions to counsellors via email, Facebook, Vkontakte or via a counsellor's profile on gay-oriented web sites.

Counsellors offer callers information on sexuality, safe sex, STIs, adherence to ART, ARV side-effects and disclosure of HIV status to sexual partners. Callers are informed about project services and encouraged to visit the project office for assessments or referrals. Those who are reluctant to visit for fear of being identified can be referred to one of 20 medical specialists across the six regions who have been trained and sensitized to the specific needs of men who have sex with men living with HIV and will provide services without stigma or discrimination.

There are about 80 trained peer counsellors, both project staff members and volunteers. All Positive Life counsellors take part in a centralized training. They receive further training and supervision at the project's regional offices as well as from central project staff who travel to the regions. In 2013 Positive Life counsellors provided almost 1900 phone consultations and 1350 online consultations.

Engage members of key populations

Members of the key population should be involved in the design of programmes, including their planning, implementation and monitoring and evaluation. Such involvement can increase the community's sense of ownership and, thus, programme success. People from key populations also can be involved as service providers and advocates.

Case study: Capacity building for transgender community services in the USA

Center of Excellence for Transgender Health, University of California, USA
http://transhealth.ucsf.edu

The mission of the Center of Excellence for Transgender Health is to increase access to comprehensive, effective and affirming health-care services for transgender and gender-variant communities. The ultimate goal is to improve the overall health and well-being of transgender people by developing and implementing programmes in response to community-identified needs. Core faculty and staff with diverse backgrounds and experience offer programmes informed by a national advisory board of 14 trans-identified leaders from throughout the United States of America.

The projects of the Center of Excellence address a wide range of health issues for transgender people. One activity is developing guidelines on a range of primary care topics, including primary and preventive care, hormone therapy, mental health, youth and surgery. Protocols have been published online (http://Transhealth.UCSF.edu/protocols). In addition, the Transitions Project helps build the capacity of community-based organizations to adapt, implement and evaluate evidence-based HIV prevention interventions for transgender communities.

Case study: Capacity building and training sessions in Tanzania

Médecins du Monde, Tanzania
http://doctorsoftheworld.org/where-we-work/africa/tanzania/

Médecins du Monde, Tanzania, provides comprehensive harm reduction services, including needle and syringe programmes and referral to OST, as well as income generating activities and legal aid. More broadly, Médecins du Monde is involved in building the capacity of nongovernmental and community-based organizations to run harm reduction services, especially drop-in centres with needle and syringe programmes; these include dedicated centres for women, with additional services offered for their children. In 2013 more than 2000 stakeholders were trained in harm reduction approaches and interventions.

The organization also has helped create national and district-level harm reduction committees with representation from governmental and nongovernmental institutions. Sub-committees at both levels focus on resource mobilization. A continuous dialogue with municipal, district and national authorities and sensitization sessions for police, medical staff and journalists have been important elements of the work.

AFFORDABILITY

Ensure monetary resources

Government commitment and funding are important. Public–private partnerships can spread costs.

Minimize or eliminate fees

Wherever possible, services should be provided free of charge or at reduced price. Insurance or health subsidies should cover any fees for services.

Reduce costs

Costs to the health system and for the user can be reduced through the integration and decentralization of services, community outreach and venues, and convenient locations. Costs to the individual can be reduced also by shortening waiting times at the facility through a flexible appointment systems and separating clinic consultation visits from picking up medicines.

DEVELOPING THE RESPONSE: THE DECISION-MAKING, PLANNING AND MONITORING PROCESS

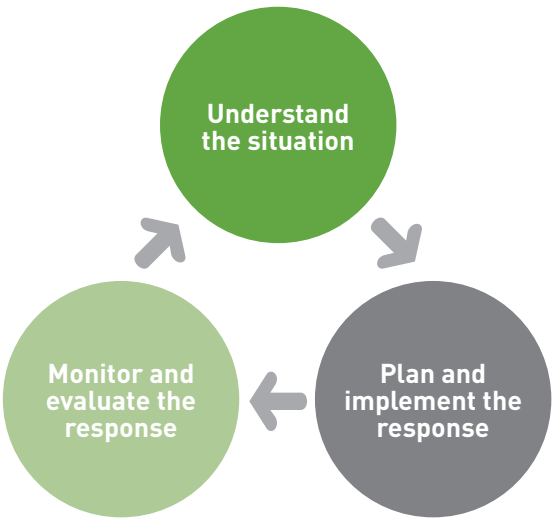
7

7 DEVELOPING THE RESPONSE: THE DECISION-MAKING, PLANNING AND MONITORING PROCESS

7.1 Introduction

Action on the recommendations in these guidelines requires a strategy informed by evidence and appropriate to the local context. Planning, decision-making and monitoring are parts of an ongoing process: Once an evidence-based plan is developed and implemented, it must be monitored and evaluated. The resulting findings then inform revision of the strategy and its implementation (Fig. 7.1).

Fig. 7.1 The programme planning, implementation and evaluation cycle



7.1.1 Guiding principles

An effective process for developing and implementing a national or sub-national response to HIV among key populations follows these guiding principles:

- **An ethical and rights-based approach** should inform all decision-making. The planned response to HIV among key populations, and the decision-making process itself, should be non-discriminatory and accountable to the populations it seeks to serve, respecting and upholding their autonomy and rights. Principles of fairness and equity should be followed.
- **Meaningful participation by affected communities** is critical to ensure that the decisions made, the plans formulated and the programmes developed are acceptable to community members, equitable, and responsive to community needs. Representatives from key population constituencies should be involved at all stages from designing the response through its implementation to monitoring and evaluation (M&E) *(1)*. Successful community empowerment (see Section 5.3) develops the capacity of community members and organizations to participate in these processes in a meaningful way. Community-led organizations play a crucial role in delivering services that best meet the needs of key populations.
- **Involvement of all stakeholders.** Addressing HIV among key populations requires a multisectoral response. Accordingly, planning of the response needs to involve multiple sectors. Box 7.1 lists potential stakeholders to include in the planning process.
- **Coordinated approach.** The national HIV programme manager and an appropriate body such as a national HIV/AIDS commission should take responsibility for managing the overall planning process and facilitating stakeholder and community participation. Designating an individual to work specifically on developing and coordinating services and issues related to key populations within the national AIDS commission (or similar peak body) may facilitate this. In large and diverse countries, developing a national programme requires formulating strategies at the local and sub-national levels as well, with guidance and coordination centrally, at the national level.
- **Openness and transparency.** The evidence and rationale for decisions should be publicly available, including information on expected effectiveness and risk and the distribution of health benefits and burdens for different groups.
- **Evidence-based.** Policies, interventions and approaches should be based on sound evidence or experience.
- **Equity.** Programmes should aim to achieve equitable health outcomes across all populations and settings and to promote gender equity.
- **Efficiency and sustainability.** Programmes should seek to deliver effective services most efficiently and to ensure that they are sustainable over the long term.

Box 7.1 Potential stakeholders to include in the planning process

- Programme experts, managers and health-care workers from the following fields in both the public and private sectors: HIV programmes and clinics (HIV testing and counselling, ART and PMTCT, sexual and reproductive health, maternal and child health, mental health, hepatology and TB services, drug dependence and harm reduction services, and prison health programmes;
- civil society, including people living with HIV, women's and youth groups, religious leaders, people with disabilities;
- technical specialists in specific areas, such as laboratory services, pharmacology, drug resistance, toxicity management, supply chain and community health;
- government partners, including representatives of relevant ministries, such as health, justice and law enforcement, internal affairs, finance and planning, and regional (such as provincial) authorities;
- nongovernmental organizations, including international agencies, faith-based organizations, other local nongovernmental and community-based organizations, and private-sector service organizations;
- finance and budget experts, such as programme budget officers and health economists;
- academic institutions, including experts in operational research, implementation science, ethics, training and supervision;
- professional associations of various cadres of health workers (such as physicians, nurses and community health workers).

7.2 Understanding the situation

The efficacy of the interventions in the essential package is well proven. Experience in multiple countries has demonstrated the generalizability of these interventions in diverse settings. Local factors do, however, have a bearing on intervention effectiveness and impact. It is critical to understand local epidemic dynamics; the characteristics of the populations affected; the physical, social and political environments that influence risk and vulnerability; the needs of people from key populations and any factors that might enable or hinder efforts to address these needs; and the health systems and community infrastructure. With this information in hand, an evidence-based plan can be developed and implemented.

People from key populations face greater HIV risk than the general population and have specific health-related needs. While many of these risks and needs may be common to people from key populations in different settings, some factors will differ among key populations, and some will be specific to a particular context. Accordingly, for a local

response to be appropriate, acceptable and most effective, these risks and needs must be examined locally, and local people from key populations must be consulted and actively involved in the situational analysis.

It is also important to recognize the considerable diversity and varying levels of risk within each key population. Those most at risk are likely to be people who could be considered members of more than one key population; for example, some men who have sex with men may also inject drugs or engage in sex work. Thus, they risk exposure to HIV by several routes. People from key populations may also have other characteristics that could increase their risk or vulnerability or create additional health or welfare needs. For example, people from key populations may be homeless, experience mental health conditions or have other acute or chronic health concerns.

Data should guide the response, but lack of data is not a reason to stop or not initiate a response to HIV among key populations.

Key population size and distribution vary from place to place. To determine the required scale of the response, the appropriate balance among different interventions and where interventions should be targeted, it is important to appreciate the size and distribution of key populations, among other factors (see Box 7.2 and Section 7.3).

It is critical that information gathering processes, and the information itself, serve to protect, and not put at risk, the safety and privacy of people from key populations. At all times ethical principles must be observed, and the human rights of people from key populations, protected. In some circumstances, determining population size or mapping key populations can unintentionally endanger community members or subject them to stigma by identifying these populations and where they are located. Such information could also lead to arrest or imprisonment of people from key populations whose behaviour is criminalized. When undertaking information-gathering exercises, it is important to strictly maintain privacy, confidentiality and the security of the information collected. If the safety and the human rights of people from key populations cannot be protected, collection of certain data, such as mapping where people from key populations congregate, is better avoided.

The makeup, characteristics and needs of key populations change over time, as do various contextual and environmental factors. Ongoing M&E will identify changing parameters and make it possible to refine or refocus the response.

A situational analysis will almost certainly identify gaps in knowledge. An agenda for further research can address these gaps.

It is also important, whenever analysing and interpreting data, to evaluate the quality of the data and the presence of any sources of bias.

Box 7.2 Key information required for decision-making and planning

Information required	Source of information (see also Box 7.4)
Key population size	• population size estimation
HIV prevalence among key populations	• sero-surveillance
Key population location/geographic distribution	• mapping exercises
Key population characteristics, risk behaviours and health concerns	• demographic surveys • behavioural surveys • general health surveys
Important structural factors, barriers to implementing a response to HIV, and the needs of key populations	• audit of current legislation, policy and practice • consultation with community members, community-led organizations and other stakeholders • behavioural surveys
Accessibility, coverage, quality, outcome and impact of intervention	• programmatic (administrative) data • disease notification registries • integrated bio-behavioural surveys. *(See Box 7.3 for further description of national programme monitoring and evaluation framework.)*

Rapid assessment and response guides are available to help guide initial and ongoing assessments, using multiple methods to gather data and to conduct analyses at multiple levels:

- *Rapid assessment and response adaptation guide on HIV and men who have sex with men.* Geneva, WHO, 2002. http://www.who.int/hiv/pub/prev_care/en/msmrar.pdf?ua=1
- *The rapid assessment and response guide on injecting drug use (IDU-RAR).* Geneva, WHO, 1998. http://www.who.int/substance_abuse/publications/en/IDURARguideEnglish.pdf?ua=1
- *The rapid assessment and response guide on psychoactive substance use and sexual risk behaviour (SEX-RAR).* Geneva, WHO, 2002. http://www.who.int/entity/mental_health/media/en/686.pdf?ua=1
- *Rapid assessment and response adaptation guide for work with especially vulnerable young people.* Geneva, WHO, 2004 http://www.who.int/hiv/pub/prev_care/en/youngpeoplerar.pdf?ua=1

7.3 Planning and implementing the response

The following are some of the decisions that need to be taken while developing and implementing a national response to HIV among key populations.

Targeting the response

- Which key populations and which sub-groups within key populations are most at risk?
- Which legislation, policies and guidelines need to be developed or revised?

Implementation

- Which interventions need to be implemented, and how should their implementation be prioritized?
- Where and at what scale do interventions need to be provided?[1]
- What targets and timelines should be set for the implementation and scale-up of interventions?
- How and to what extent should services be decentralized and integrated to provide the best service coverage for key populations?
- Which modes of service delivery are most appropriate?
- What are the roles and responsibilities of the various stakeholders in implementing the response and achieving the agreed targets?

Resources required

- Do the costs of implementing the response outweigh the costs of inaction?
- What financial, human and other resources and infrastructure are required to implement the response? What resources are currently available, what additional inputs will be required, and how might these be obtained? What types of health-care and other workers are required, and how will they be recruited and trained? How can task shifting and sharing optimize the use of available human resources and expand service delivery?
- How will economies of scale and synergies among HIV interventions and with other health interventions save on costs and improve service provision?

Monitoring and evaluation

- How will implementation of the response be monitored and evaluated?
- How do strategic information systems for M&E need to be strengthened?

[1] For ART the WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* (2013) provides information on considerations for implementing and scaling up services in line with key recommendations.

Risks, outcomes and impacts

- What are potential risks and vulnerabilities of the planned response, and what strategies would mitigate their impact? Risks might include domestic factors such as budget cuts, theft of consumables, attrition of health-care workers, and emergence of drug resistance. External factors could include loss of external financial support, political instability, and natural disasters.

7.4 Monitoring and evaluating the response

A monitoring and evaluation system is needed to assess both structural and health sector components of the response to HIV in key populations. It is critical that these systems are practical, not overly complicated, and that they collect information that is current, useful and readily used.

WHO and UN partner agencies have developed frameworks for monitoring the response to HIV in the general population and key populations. The following documents described these frameworks:

An M&E system is an essential part of the HIV response for key populations.

- *Tool for setting and monitoring targets for prevention, treatment and care for HIV and other sexually transmitted infections among men who have sex with men, sex workers and transgender people*. Geneva, WHO, forthcoming.
- *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision*. Geneva, WHO, 2012. http://www.who.int/hiv/pub/idu/targets_universal_access/en/
- *Consolidated HIV M&E guidelines*. Geneva, WHO, forthcoming.

Each of these frameworks recommends a set of national-level indicators. These indicators assess key factors related to the enabling environment; measure the availability, coverage and quality of specific interventions; and examine their outcome and impact (Box 7.3). The indicators can also be used when preparing proposals or reporting progress to donor organizations.

The following documents provide additional guidance on M&E, including how to undertake assessments at the sub-national level:

- *Operational guidelines for monitoring and evaluation of HIV programmes for sex workers, men who have sex with men and transgender people*. Geneva, UNAIDS, 2012. http://unaids.org.cn/en/index/Document_view.asp?id=712
- *Operational guidelines for monitoring and evaluation of HIV programmes for people who use drugs*. Geneva, UNAIDS, 2011, draft. http://www.cpc.unc.edu/measure/tools/hiv-aids/operational-guidelines-for-m-e-of-hiv-programmes-for-people-who-inject-drugs/idu-service-delivery-level-guidelines/view

The M&E process requires data from a variety of sources, including behavioural and sero-surveillance surveys, programmatic and administrative data, as well as information gathered through reviewing policy documents and legislation and consultation with

experts and stakeholders (Box 7.4). The quality and limitations of these data should be assessed and considered when undertaking analysis and interpretation.

7.5 Ongoing planning and development of the response

Setting clear, achievable but ambitious targets is crucial when planning to scale up interventions to meet the objectives of the HIV response. Targets concretely define what a successful national programme or project should achieve within a specified time frame. Targets can be set for both intervention-specific indicators and cross-cutting outcome and impact indicators (Box 7.3).

Intervention and enabling environment indicators reflect the *availability, coverage* and *quality* of an intervention or service or assess changes in environmental factors, such as revision of legislation, within a specified timeframe. Targets are set with the aims of achieving reductions in HIV and STI risk sufficient to control the epidemic and ensuring the adequate provision of appropriate treatment and care for those living with HIV or with an STI.

Outcome and impact indicators seek to gauge the impact that interventions have had on outcomes that affect exposure to risk, such as changes in risk behaviours (for example, the percentage of people who use condoms consistently) or on impacts on the course of HIV or STI epidemics (for example, reductions in incidence of HIV or STIs).

Like planning overall, the target-setting process should be collaborative, involving the range of stakeholders. Those setting the targets should consider whether they are realistic and whether data can be practically collected. Targets, in keeping with programme strategies, should be tailored to the local epidemic and what the strategy can realistically achieve with obtainable funding and resources. Modelling can help to identify how different target levels would affect the epidemic.

Baseline assessment. Initial assessment should measure the scale of the current response, assessing the availability, coverage, and quality of current interventions, and appraising current environmental enablers and barriers. This information serves as a baseline for tracking progress. Also, currently available resources and technical capacity must be determined in order to estimate what more is needed and how to scale the intervention appropriately. From this information, realistic, achievable targets can be set and the time frame, specified.

Estimating cost. Estimating the costs associated with implementation is a key step in planning the roll-out. Several costing tools and resources are available. Spectrum, for example, is a suite of models and analytical tools to support decision-making. It comprises several software applications, including AIM (AIDS Impact Model) and Goals (Cost and Impact of HIV Interventions). Most countries already have AIM files prepared as part of their national epidemiological estimates, and so both modules can be rapidly applied. Spectrum can be accessed online at: http://www.unaids.org/en/dataanalysis/datatools/spectrumepp2013/.

OneHealth is a software tool designed to strengthen health system analysis and costing and to develop financing scenarios at the country level. It is specifically designed for low- and middle-income countries. It provides planners with a single framework for

planning, costing, impact analysis, budgeting and financing of strategies for all major diseases and health system components. OneHealth can be downloaded free of charge (Futures Institute, 2013) at: http://www.futuresinstitute.org/onehealth.aspx.

UNAIDS has developed *The human rights costing tool (HRCT)*, a flexible tool for costing investments in critical enablers (such as integrated treatment and rights literacy programmes, legal services, stigma and discrimination reduction programmes, and training for health-care workers and law enforcement). This, too, can be downloaded free of charge along with a user guide *(2,3)* at: http://www.unaids.org/en/media/unaids/contentassets/documents/data-and-analysis/tools/The_Human_Rights_Costing_Tool_v_1_5_May-2012.xlsm and http://www.unaids.org/en/media/unaids/contentassets/documents/document/2012/The_HRCT_User_Guide_FINAL_2012-07-09.pdf

Box 7.3 Indicators for monitoring and evaluating the response

To understand how well the response is functioning and its effects, its various key requirements need to be monitored for each key population. For each of these requirements there are a number of useful indicators.

These indicators are described in detail in WHO key population guidance: *Tool for setting and monitoring targets for prevention, treatment and care for HIV and other sexually transmitted infections among men who have sex with men, sex workers and transgender people*, forthcoming; and *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision*, http://www.who.int/hiv/pub/idu/targets_universal_access/en/.

Successful implementation and impact requires supportive policy, legislation and other structural factors.

Measured by ***structural*** (or enabling environment) indicators:

- audit of current legislation and policy
- number of key population-led organizations
- meaningful involvement of people from key populations in policy and strategy formulation
- legal support services for key populations
- support services for people from key populations who experience violence
- sensitization training on key populations for law enforcement officers
- sensitization training on key populations for health-care and social services providers.

Interventions need to be accessible to people from key populations.

Measured by ***availability*** indicators:

- the number of sites where the intervention is available
- the number and percentage of key population-focused programme sites where the intervention is provided
- the number and percentage of mainstream programme sites where the intervention is provided and that meet key population sensitization standards
- the percentage of all sites where the intervention is currently provided that are either mainstream programmes meeting key population sensitization standards or are key population-focused programmes
- the percentage of the key population sample reporting that the intervention is readily accessible
- geographic mapping of key populations in relation to where interventions are provided.

Interventions must reach those who need them.

Measured by ***coverage*** indicators:

- number and percentage of key population provided with the intervention during a specified reporting period
- number of consumable items (such as needles and syringes or condoms) distributed per member of key population during a specified reporting period
- percentage of the key population sample reporting that they received the intervention during a specified reporting period.

Interventions need to be properly implemented to be effective.

Measured by ***quality*** indicators:

- review of programme policy and practice using programme quality assessment checklist
- percentage of staff that has received key population sensitization training
- percentage of key population reporting intervention was received and also a specific important activity or service was delivered (such as the provision of compatible lubricant with condoms)
- percentage of occasions when intervention was provided along with specific important activity of service (see previous).

Intended aims should be achieved.

Measured by ***outcome*** and ***impact*** indicators:

- prevalence of risk behaviour in key population
- incidence of infection in key population
- prevalence of infection in key population
- incidence of HIV-related mortality in key population
- prevalence in key population of experiencing stigma or discrimination
- incidence of violence against people from key population.

Box 7.4 Data sources

Behavioural and **sero-surveillance surveys** of key populations can provide prevalence data and information on the experiences, risks and service utilization of people from these groups. Many countries already undertake bio-behavioural surveys of key populations periodically as part of the ongoing monitoring of the HIV epidemic. The generalizability of survey findings depends on how representative the sample is of the entire key population; it is important to consider selection bias in how participants were recruited. Behavioural surveys are susceptible to bias toward socially desirable responses and to recall bias.

Programmatic or administrative data. Most programmes routinely record at least some basic information when providing a service. This might include the number of people who received a service, basic information about the client, and numbers of supplies used or distributed.

To assess services provided to people from key populations, programme data must be disaggregated by key population. Key population-focused programmes may be able to provide data specific to the populations they serve, but this information is not commonly available from programmes that provide services to many different groups or to the general population.

Desk review and expert consultation. Reviewing various policy documents and legislation can identify the presence or absence of various laws or policies that may affect people from key populations.

Population size estimation. Deriving reliable population size estimates for key populations can be challenging. Various methods can be employed; each has its own advantages and limitations. Common methods include census and enumeration, general population surveys, and capture-recapture, multiplier, and network scale-up methods. Deriving multiple estimates through different methodologies and triangulating the results is helpful. Definitions of key populations should be clear.

Sources of guidance

- *Tool for setting and monitoring targets for prevention, treatment and care for HIV and other sexually transmitted infections among men who have sex with men, sex workers and transgender people.* Geneva, WHO, forthcoming.
- *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision.* Geneva, WHO, 2012. http://www.who.int/hiv/pub/idu/targets_universal_access/en/
- *Consolidated HIV monitoring and evaluation guidelines.* Geneva, WHO, in preparation.
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CHAPTER 5 CRITICAL ENABLERS

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NOTES

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