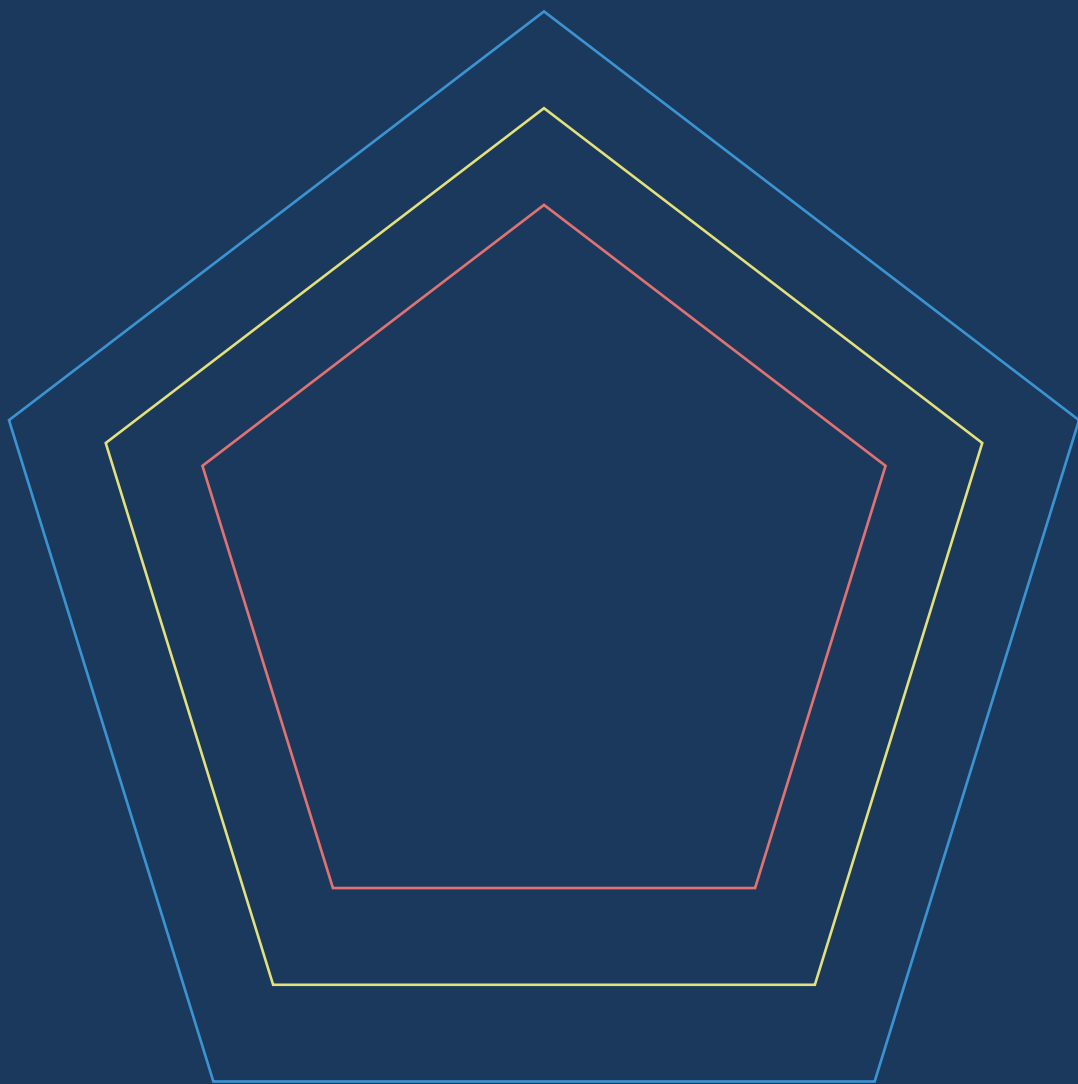


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# Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations



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# Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations

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Web Annex B. Values and preferences report

<https://apps.who.int/iris/bitstream/handle/10665/360444/9789240053441-eng.pdf>

Web Annex C. Systematic review findings and GRADE tables

<https://apps.who.int/iris/bitstream/handle/10665/360445/9789240053458-eng.pdf>

Web Annex D. Evidence to decision making tables

<https://apps.who.int/iris/bitstream/handle/10665/360446/9789240053465-eng.pdf>

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# Acronyms and abbreviations

AIM	AIDS impact model	NSPs	needle and syringe programmes
ALT	alanine aminotransferase	NSWP	Global Network of Sex Work Projects
ANC	antenatal care	OAMT	opioid agonist maintenance therapy
ART	antiretroviral therapy	PEP	post-exposure prophylaxis
ARV	antiretroviral drugs	PICO	population, intervention, comparator, outcome
CRC	United Nations Convention on the Rights of the Child	PPT	periodic presumptive treatment
DAA	direct-acting antiviral	PrEP	pre-exposure prophylaxis
FGD	focus group discussions	py	person years
GRADE	Grading of Recommendations Assessment, Development and Evaluation	QALY	quality-adjusted life-year
HBsAg	hepatitis B surface antigen	RCT	randomized controlled trial
HBeAg	Hepatitis B e antigen	RDT	rapid diagnostic test
HBV	hepatitis B virus	SDG	Sustainable Development Goal
HCV	hepatitis C virus	SITE	syphilis interventions towards elimination
HPV	human papillomavirus	SSI	semi-structured interviews
HRCT	human rights costing tool	STI	sexually transmitted infection
HSV	herpes simplex virus	SVR	sustained virological response
HTS	HIV testing services	TB	tuberculosis
ICER	incremental cost-effectiveness ratio	UHC	universal health coverage
IUD	intrauterine device	UNAIDS	Joint United Nations Programme on HIV/AIDS
LMIC	low- and middle-income countries	UNFPA	United Nations Population Fund
M&E	monitoring and evaluation	UNICEF	United Nations International Children's Emergency Fund
MEC	medical eligibility criteria for contraceptive use	UNODC	United Nations Office on Drugs and Crime
MhGAP	mental health gap action programme	WHO	World Health Organization
NAAT	nucleic acid amplification test		
NSP	national strategic plan		

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# Glossary

**Acute hepatitis C (HCV):** a recently acquired HCV infection that meets certain clinical criteria (discrete onset of symptoms such as nausea or malaise plus either jaundice or elevated serum alanine aminotransferase (ALT) levels (tenfold increase).

**Adolescents:** individuals between the ages of 10 and 19 years old are generally considered adolescents. Adolescence is the developmental transition to adulthood accompanied by hormonal, physical and psychological developments in the period from puberty to adulthood. 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. This document primarily uses the term “adolescents”. Adolescents may also belong to one or more key population groups. Other terms covering overlapping age groups include **youth** – this term refers to individuals between the ages of 15 and 24, and **young people** – this term refers to those between the ages of 10 and 24.

**Antiretroviral therapy (ART):** refers to using a combination of antiretroviral (ARV) drugs for treating HIV infection.

**Antiretroviral (ARV) drugs:** refer to the medicines used to treat HIV.

**Chemsex:** for the purpose of these guidelines, is defined as when individuals engage in sexual activity, while taking primarily stimulant drugs, typically involving multiple participants and over a prolonged time.

**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”.

**Chronic hepatitis B (HBV) infection:** persistence of HBsAg for at least six months. The persistence of HBsAg in two specimens at least six months apart is frequently used in clinical practice to confirm chronic hepatitis B infection.

**Chronic hepatitis C infection (HCV):** defined by HCV antibody positivity and HCV RNA positivity with a duration of infection longer than six months.

**Cirrhosis:** an advanced stage of liver disease characterized by extensive hepatic fibrosis, nodularity of the liver, alteration of liver architecture and disrupted hepatic circulation.

**Community-led organizations:** groups and networks are those that are led by and for the constituencies they serve. They are self-determining and autonomous entities where the majority of governance, leadership, staff, spokespeople, membership and volunteers reflect and represent the experiences, perspectives and voices of their constituencies, and which have transparent mechanisms of accountability to their constituencies.

**Community-led responses:** can be understood as the actions and strategies undertaken by these groups to improve the health and human rights of their constituencies. These responses are informed and implemented by and for communities themselves and the organizations, groups and networks that represent them.

Community-led responses are determined by and respond to the needs and aspirations of their constituents, and include a range of activities, such as advocacy, campaigning and holding decision-makers to account; monitoring of policies, practices, and service delivery; participatory research; education and information-sharing; service delivery; capacity-building; and funding of community-led organizations, groups and networks.



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**Decentralization:** the process of delegating or transferring significant authority and resources from the central ministry of health to other institutions or to field offices of the ministry at other levels of the health system (such as provincial, regional, district, subdistrict, primary health care post and community).

**Differentiated service delivery:** an approach that simplifies and adapts services to better serve the needs of people living with HIV, viral hepatitis or Sexually transmitted infections (STIs), and to optimize the available resources in health systems.

**HCV self-testing (HCVST):** a process in which an individual collects their own specimen (blood or oral fluid), performs a rapid diagnostic test for the presence of HCV antibodies, and then interprets the result, often in a private setting, either alone or with someone they trust.

**HCV sustained virological response (SVR):** undetectable HCV RNA in the blood at a defined time point after the end of treatment, usually at 12 or 24 weeks (SVR12 or SVR24).

**Human immunodeficiency virus (HIV):** There are two types of HIV: HIV-1 and HIV-2. The vast majority of HIV infections globally are HIV-1.

**HIV self-testing:** a process in which a person collects their own specimen (oral fluid or blood), performs a test and interprets the result, often in a private setting, either alone or with someone they trust.

**Integrated service delivery:** integrated health services are health services that are managed and delivered in a way that ensures that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation and palliative care services at the different levels and sites of care within the health system and according to their needs throughout the life-course.

**Key populations:** defined groups who, due to specific higher-risk behaviours, are at increased risk of HIV, viral hepatitis or STIs 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) trans and gender diverse people. People in prisons and other closed settings are also included in these guidelines because of the often high levels of incarceration of the other groups, and the increased risk behaviours and lack of HIV, viral hepatitis and STI services in these settings. The key populations are important to the dynamics of HIV, viral hepatitis and STI transmission. They also are essential partners in an effective response to the epidemic.

**Lay provider:** any person who performs functions related to health care delivery and has been trained to deliver specific services, but has not received a formal professional or paraprofessional certificate or tertiary degree.

**Men who have sex with men:** refers to all men who engage in sexual 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.

**Nucleic acid amplification test (NAAT):** a molecular technology, for example, polymerase chain reaction (PCR) or nucleic acid sequence-based amplification (NASBA) that can detect very small quantities of viral nucleic acid (RNA or DNA), either qualitatively or quantitatively.

**Ongoing risk exposure for HCV:** includes engagement in activities that increase the risk of HCV transmission: e.g., exposure to HCV infectious blood or body fluids that contain blood, including injection drug use and male-to-male sexual contact.



**Partner services:** (sometimes referred to as disclosure, contact tracing, index testing or assisted partner notification): a voluntary process whereby a trained provider asks people diagnosed with HIV about their sexual partners and/or drug injecting partners, and then, if the HIV-positive client agrees, offers the partner voluntary HIV testing services (HTS). Partner services are provided using provider-assisted referral or patient referral approaches.

**People-centred care:** care that is focused and organized around the health needs and expectations of people and communities rather than diseases.

**People in prisons and other closed settings:** there are many different terms used to denote places of detention that hold people who are awaiting trial, those who have been convicted, or people 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, females, trans and gender diverse individuals, 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.

**People who inject drugs:** refers to people who inject psychoactive substances for non-medical purposes. These drugs include, but are not limited to, opioids, amphetamine-type stimulants, cocaine and hypno-sedatives, including new psychoactive substances.<sup>1</sup> 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. While these guidelines focus on people who inject drugs because of their specific risk of HIV and HCV transmission due to the sharing of blood-contaminated injection equipment, much of this guidance is also relevant for people who use substances through other routes of administration such as snorting, smoking and ingestion.

**People who use drugs:** include people who use psychoactive 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 widely used substances such as alcoholic and caffeine-containing beverages and foods.

**Point-of-care testing:** is conducted at the site at which clinical care is being provided, with the results being returned to the person being tested or caregiver on the same day as sample collection and testing, to enable clinical decisions to be made in a timely manner.

**Pre-exposure prophylaxis (PrEP):** is the use of ARV drugs by people who do not have HIV, to prevent the acquisition of HIV before exposure.

**Post-exposure prophylaxis (PEP):** is the use of ARV drugs by people who do not have HIV, to prevent the acquisition of HIV after exposure.

**Recent hepatitis C infection:** evidenced by:

- positive HCV RNA or antigen test in an individual that returned a negative antibody, RNA or antigen result within the preceding year (including instances where this represents re-infection);
- positive HCV RNA or antigen test AND a current negative HCV antibody test; and
- positive antibody, RNA or antigen test AND, within the preceding year, clinical symptoms of acute hepatitis.

<sup>1</sup> The United Nations Office on Drugs and Crime (UNODC) uses the term “new psychoactive substances” which are defined as “substances of abuse, either in a pure form or a preparation, that are not controlled by the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, but which may pose a public health threat”. For more information visit the UNODC Early Warning Advisory on New Psychoactive Substances 2022 [Available from: <https://www.unodc.org/LSS/Page/NPS>].



**Sex workers:** include female, male, trans and gender diverse 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. 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.

**Social network-based HIV testing:** is an extension of partner services. A trained provider asks people with HIV, or those who are HIV-negative but at ongoing risk of HIV, to encourage and invite individuals in their sexual, drug-injecting or social networks to participate in voluntary HIV testing services. A social network refers to a group of individuals linked by a common set of relationships and includes sexual and drug-injecting partners, as well as social contacts.

**Substantial risk (of HIV infection):** HIV acquisition risk varies considerably within populations and geographical locations. Population-level HIV incidence is an important determinant of individual-level risk of HIV acquisition. However, when considering who could benefit from PrEP, it is important to consider the characteristics and behaviours of individuals and their partners that could lead to HIV exposure. Even in locations with a low overall HIV incidence, there may be individuals at substantial risk who could benefit from PrEP services. Individuals requesting PrEP should be given priority when offering PrEP since requesting PrEP indicates that there is likely to be a risk of acquiring HIV. When PrEP use is risk-informed (taken during periods of risk of HIV acquisition), PrEP can be cost-effective. Cost-effectiveness will vary across countries, populations, and PrEP products. However, cost-effectiveness should not be the only consideration when implementing PrEP programmes, since remaining HIV-negative and having control over HIV risk has intangible value to people and communities.

**Task sharing:** the rational redistribution of tasks between cadres of health care workers with longer training and other cadres with shorter training, such as lay providers.

**Trans and gender diverse people:** an umbrella term for those whose gender identity, roles 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 nonconforming or gender incongruent. Trans and gender diverse people may self-identify as transgender, female, male, transwoman or transman, transsexual or one of many other gender nonconforming identities. They may express their genders in a variety of masculine, feminine and/or androgynous ways. The high vulnerability and specific health needs of trans and gender diverse people necessitate a distinct and independent status in the global HIV response.

**Unprotected sex:** refers to sex which does not involve evidence-based prevention interventions. These include condoms plus lubricants, which are protective against HIV, viral hepatitis and STIs and HIV pre-exposure prophylaxis. Successful ART with viral suppression prevents HIV transmission to sexual partners.





# Executive summary

## Purpose

The *Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations* outlines a public health response to HIV, viral hepatitis and sexually transmitted infections (STIs) for five key populations (men who have sex with men, trans and gender diverse people, sex workers, people who inject drugs and people in prisons and other closed settings). The guidelines present and discuss new recommendations and consolidate a range of recommendations and guidance from current World Health Organization (WHO) guidelines.

These guidelines focus on the above five groups, originally defined as “key” in the HIV response across the three infectious disease areas. This is for the following reasons.

- The structural barriers which limit the five key populations’ access to HIV services also limit their access to viral hepatitis and STI services.
- HIV risk behaviours such as condomless sex and unsafe injecting, which are in general more common in key populations, are also among those that increase the risk of acquiring viral hepatitis and STIs.
- Many of the interventions recommended for HIV prevention also have an impact on transmission of viral hepatitis and STIs.

Particularly for key populations, social, legal, structural and other contextual factors both increase vulnerability to HIV, viral hepatitis and STIs and obstruct access to health and other essential services. These guidelines highlight the critical importance of addressing structural barriers in all settings as a priority.

## Guidelines principles

These guidelines are developed with the following principles:

- human rights;
- gender equality;
- equity and inclusion;
- medical ethics;
- universal health coverage;
- evidence-based public health;
- key population community-led response.

## Guidelines development methodology

This publication is an update to the 2016 *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*. These guidelines include relevant existing recommendations, updated recommendations and new recommendations, good practice statements and other guidance.

For the development of new recommendations, WHO developed population, intervention, comparator, outcome (PICO) questions, and external researchers, supported by the WHO team, conducted the systematic reviews of the evidence to answer these questions.

WHO also commissioned four global networks of key populations (men who have sex with men, sex workers, trans and gender diverse people, and people who inject drugs) to undertake new qualitative research on values and preferences among their networks. The results formed part of the evidence synthesis.

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The evidence was synthesised and incorporated into an evidence-to-decision framework to help inform the discussions at a virtual Guideline Development Group meeting that occurred over six days between 30 August and 8 September 2021, chaired by two members of the Guideline Development Group, and all conflicts of interest were managed. The methodologist facilitated the Guideline Development Group's judgements, assisted by the chairs, on the potential benefits and harms of the intervention, stakeholder values and preferences, acceptability, feasibility, resource use and considerations of human rights and equity. Taken together and using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, these judgements contributed to determining the strength and direction of the recommendation. All recommendations were made through consensus.

In these updated guidelines, guidance is provided to national programme managers, donors and advocates on how to prioritize different packages of health interventions to have the greatest impact on HIV, viral hepatitis and STIs, and to ensure universal coverage to address other health issues for key populations.

Each of the interventions listed, included in these guidelines based on initial scoping, was classified for each key population as follows.

### 1. Essential for impact: enabling interventions

This includes all interventions recommended to address structural barriers to health services' access for key populations.

### 2. Essential for impact: health interventions

This includes health sector interventions that have a demonstrated direct impact on HIV, viral hepatitis and STIs in key populations.

### 3. Essential for broader health

This includes health sector interventions to which access for key populations should be ensured, but which do not have direct impact on HIV, viral hepatitis or STIs.

### 4. Supportive

This includes other interventions which support the delivery of health sector interventions, such as creating demand, providing information and education.



# Summary of essential health and enabling recommendations



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## Essential for impact: enabling interventions

Removing punitive laws, policies and practices

Reducing stigma and discrimination

Community empowerment

Addressing violence

## Essential for impact: health interventions

### Prevention of HIV, viral hepatitis and STIs

Harm reduction (needle and syringe programmes (NSPs), opioid agonist maintenance therapy (OAMT) and naloxone for overdose management)

Condoms and lubricant

Pre-exposure prophylaxis (PrEP) for HIV

Post-exposure prophylaxis (PEP) for HIV and STIs

Prevention of vertical transmission of HIV, syphilis and HBV

Hepatitis B vaccination

Addressing chemsex

### Diagnosis

HIV testing services

STI testing

Hepatitis B and C testing

### Treatment

HIV treatment

Screening, diagnosis, treatment and prevention of HIV-associated tuberculosis (TB)

STI treatment

Hepatitis B and hepatitis C treatment

## Essential for broader health: health interventions

Anal health

Conception and pregnancy care

Contraception

Gender-affirming care

Mental health

Prevention, assessment and treatment of cervical cancer

Safe abortion

Screening and treatment for hazardous and harmful alcohol and other substance use

TB screening and prevention



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# CHAPTER 1

## Introduction





## Key populations for HIV, viral hepatitis and STIs

The original (2014) and updated (2016) versions of the World Health Organization (WHO) *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* (3) focused on HIV prevention, diagnosis, treatment and care for five key populations: men who have sex with men, sex workers, people in prisons and other closed settings, people who inject drugs, and trans and gender diverse people. However, members of these populations are also disproportionately affected by viral hepatitis and sexually transmitted infections (STIs), and there is increasing acknowledgement of the importance of addressing all three infectious disease areas in an integrated, community-led, and person-centred manner. Further, the risk behaviours and vulnerabilities of key populations and their networks determine the dynamics of HIV, viral hepatitis and STI epidemics, creating syndemics (defined as two or more infections interacting synergistically, contributing to excess burden of disease in a population), and meaning that preventing, diagnosing and treating HIV, viral hepatitis and STIs in key populations is central to the elimination of these infectious diseases as public health threats.

While strategies for viral hepatitis and STIs include additional priority populations (such as health care workers for hepatitis B virus (HBV) and pregnant women for syphilis and HBV) (4, 5), and other populations vulnerable to HIV, in these guidelines we will focus on the above five groups, originally defined as “key” in the HIV response across the three infectious disease areas. This is for the following reasons.

- The structural barriers which limit the five key populations’ access to HIV services also limit their access to viral hepatitis and STI services.
- HIV risk behaviours, such as condomless sex and unsafe injecting, which in general are more common in key populations, are also among those at increased risk of acquiring viral hepatitis and STIs.
- Many of the interventions recommended for HIV prevention also have an impact on transmission of viral hepatitis and STIs.

It is important to note that people can be members of more than one key population group, have more than one risk behaviour, and some people may engage in risk behaviours without identifying as members of a particular group; for example, men who have sex with other men but do not identify as gay. People who inject drugs often stop using drugs, sex workers stop sex working and people move in and out of prison; therefore, it is important to recognize the complexities and changes in people’s lives.

In most countries, inadequate coverage and poor quality of services for key populations continue to undermine responses to HIV, viral hepatitis and STIs. All countries should prioritize reaching these key populations and supporting key population communities to lead the response and provide equitable, accessible and acceptable services to these groups.

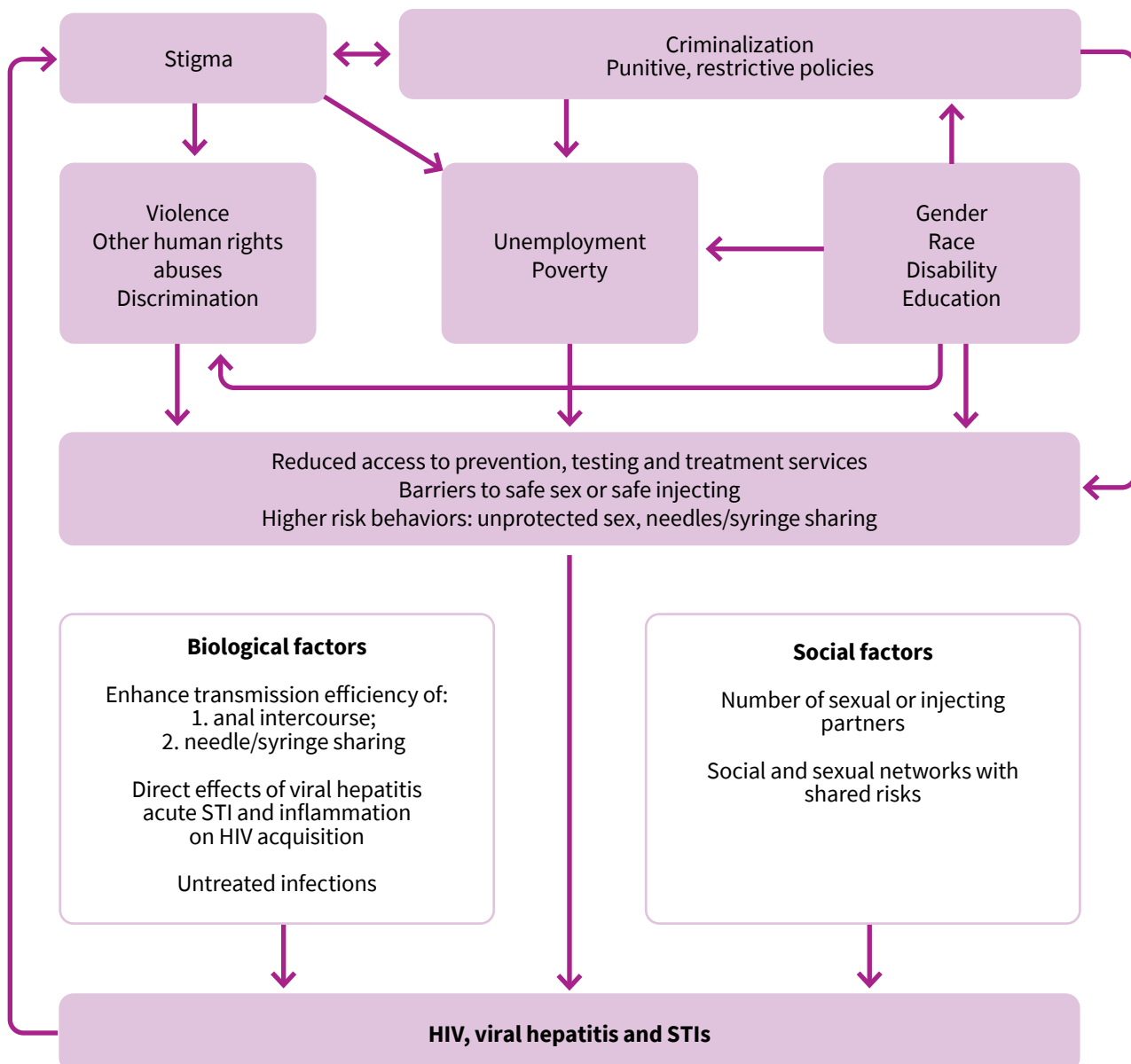
### Structural barriers

Particularly for key populations, social, legal, structural and other contextual factors both increase vulnerability to HIV, viral hepatitis and STIs, and obstruct access to health and other essential services. In many settings, one or more aspects of key population members’ behaviour, work or gender expression are criminalized, and members are subject to punitive legislation and policing practices. Stigma and discrimination from/by the general population and health care workers and law enforcement officials are perpetuated by criminalization, which also means legal or policy change is more difficult to achieve. Stigma and discrimination in health care settings are common experiences among key populations and create significant barriers to achieving universal health coverage. Stigma and discrimination are related to unemployment as well as violence and human rights abuse. Violence and other human rights abuses are exacerbated by criminalization, making key population members less likely to report abuses and increasing vulnerability to such abuses.

In combination, these reduce access to HIV, STI, viral hepatitis and other health services; can lead to poorer uptake and inconsistent use of prevention methods such as condoms, pre-exposure prophylaxis (PrEP) and post exposure prophylaxis (PEP) for HIV, and sterile needles/syringes; and to delayed diagnosis and poorer linkage and retention in treatment programmes (see Fig. 1).

Importantly, the complex intersections between the structural barriers which affect key populations and their gender, disability, education, race, religion and socioeconomic status cannot be ignored. For example, cisgender women and trans and gender diverse people experience extremely high rates of violence, racial minorities are over-represented in many prison settings, and all these factors increase stigma and discrimination.

Fig. 1. Factors contributing to HIV, STIs and viral hepatitis in key populations







## HIV, viral hepatitis and STIs in key populations: dynamics and syndemics

There is a clear epidemiological rationale for HIV, viral hepatitis and STI programmes to focus on key population groups. This is related to each disease separately and also through biological and social interaction as syndemics.

As noted above, all five key populations are disproportionately affected by HIV, and in almost every setting have a higher prevalence and incidence than people outside of these groups. HIV epidemic models, which look beyond what are termed “static” modes of transmission (namely, looking at ongoing transmission over time, among networks of people rather than just incidence at one time point), show that preventing new infections and reducing viral load among key populations living with HIV has greater impact on ongoing transmission and population incidence and prevalence than focusing on lower-risk networks of people outside key population groups (7–9). This means that all countries – those with high HIV burden across all populations as well as those with largely key population epidemics – must prioritize and address key population health needs for an effective, accelerated response.

HBV and hepatitis C virus (HCV) infections account for a significant global disease burden and high mortality from liver cancer and cirrhosis. HBV and HCV infections occur in all WHO regions; the HCV burden is particularly high in the Eastern Mediterranean and European regions, and the HBV burden in the African and Western Pacific regions. HCV burden has been documented as being high in people who inject drugs (10), people in prisons (11) and men who have sex with men, particularly in men who have sex with men living with HIV (12). Modelling shows that preventing, screening and treating HCV infection in key populations is needed to reach hepatitis C elimination goals (13–16). Increased HBV prevalence and burden has been documented in all key populations (17–20). Key populations also have higher rates of hepatitis D virus infection – which is a super-infection to HBV when compared to the larger population (21). Outbreaks of hepatitis A are common among men who have sex with men (22).

Sexually transmitted infections are spread predominantly by sexual contact (namely, vaginal, anal and oral sex), and have a profound impact on sexual and reproductive health worldwide. Some STIs are also responsible for severe adverse birth outcomes such as fetal and neonatal death and congenital anomalies. STIs are defined by multiple neglected pandemics that cause a significant global disease and economic burden. In 2020, more than 1 million curable STIs were estimated to be acquired every day worldwide, primarily caused by *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum* (syphilis) and *Trichomonas vaginalis*. Before the introduction of human papillomavirus (HPV) vaccines, over one in seven women were estimated to have prevalent HPV infection at any point in time (23, 24). High-risk HPV types lead to cervical cancer cases and cervical cancer-related deaths and are important risk factors for anal cancer. In 2016, WHO also estimated that almost 500 million adults are currently living with herpes simplex virus (HSV) infection that causes genital herpes (25).

Population groups that are at higher risk of STIs include sex workers and their clients, men who have sex with men, trans and gender diverse people in almost all settings (26–31). There is increasing evidence of higher risk of STIs among people who inject drugs as well (32). Adding to the burden of STI-related morbidity and mortality, emerging resistance to widely available antibiotics poses a risk of untreatable gonococcal infection. While this is not new, the rapid increase in resistance to some of the remaining effective therapies is leaving fewer options for treatment (33).

Multiple epidemics and other adverse health outcomes may interact and mutually reinforce one another, increasing the risk and consequences of infection. These syndemic conditions generally develop in the context of social disadvantage and inequality, and are more commonly experienced by marginalized groups, such as key populations.

Coinfections of HIV and HBV and HCV can increase morbidity and mortality. For example, coinfection with HIV and viral hepatitis increases risk from accelerated liver disease and consequently cirrhosis, liver failure and hepatocellular carcinoma. In addition, coinfecting individuals may have altered



immunological responses and are at increased risk of antiretroviral therapy (ART)-related hepatotoxicity (34, 35). Hepatitis C and HIV are highly prevalent among people who inject drugs, and disproportionately affect men who have sex with men and people in prisons and closed settings (10–12, 36, 37).

HIV infection is more likely to occur if another STI is present and vice versa, creating synergies and syndemics which are often overlooked. For example, STIs increase infectiousness of people living with HIV who are not on treatment by increasing the viral concentration in the genital tract, and by increasing the potential for HIV transmission (38, 39). Genital herpes (40, 41) and syphilis (42) almost triple the risk of HIV acquisition; while women living with HIV are at high-risk of infection with HPV and are approximately six times more likely to develop cervical cancer (43, 44).

## Responding to HIV, viral hepatitis and STIs in key populations

Sustainable Development Goal (SDG) 3 and related target 3.3 are: “By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases” (45). Given disease dynamics and syndemics as described above, this can only be achieved by prioritizing the prevention, diagnosis and treatment of these infections in key populations. [Figure 2](#) describes a theory of change for meeting these global targets by 2030 and is detailed in the text below.

To prevent, diagnose and treat infections, key populations need equitable access to services at an adequate scale to have impact. The Joint United Nations Programme on HIV/AIDS (UNAIDS) set HIV coverage targets for 2025 as part of its global strategy to end AIDS (45), which applies to all populations: 95% use combination prevention; 95% of people living with HIV know their HIV status; 95% of people living with HIV who know their status initiate treatment; 95% of people on HIV treatment are virally suppressed and 95% of women access HIV and sexual and reproductive health services. Global targets for viral hepatitis include 90% of people living with HCV or HBV diagnosed and 80% treated (HBV) or cured (HCV) by 2030. For STIs targets are that by 2030 >90% of priority populations are screened for gonorrhoea or syphilis and >95% treated if positive. Few countries reach this proportion of key populations with services, contributing to ongoing epidemics.

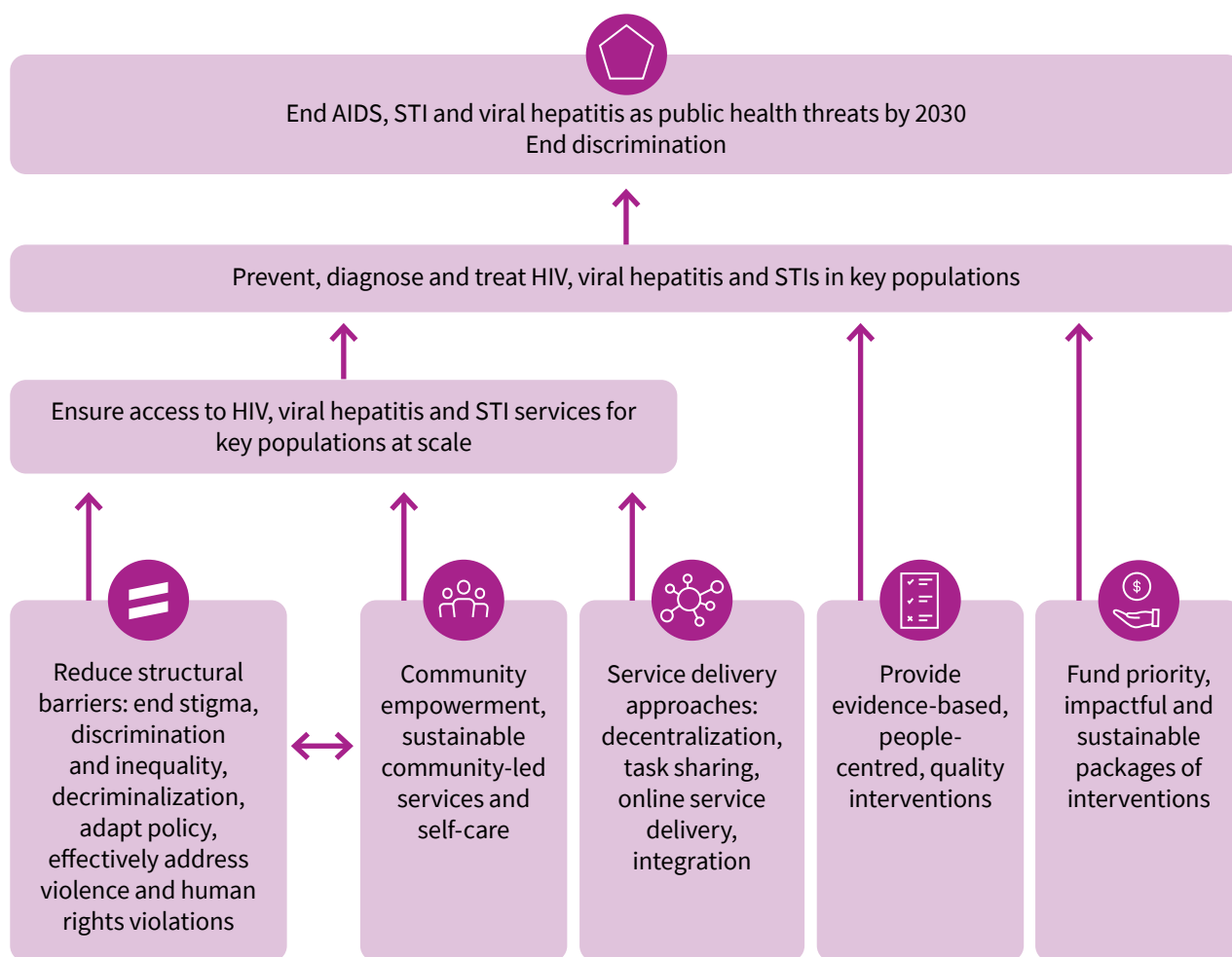
Access to services for key populations to have an impact on HIV, viral hepatitis and STIs can only be improved if structural barriers are removed, such as stigma and discrimination, criminalization, restrictive policies and violence, and if other human rights abuses and enabling environments exist (please see [Chapter 4](#) on enabling interventions for references). Women who belong to key populations, as well as women who are partners of key population members, experience alarmingly high risks of acquiring HIV and are less likely to access services. The UNAIDS Global Strategy to end AIDS (45) includes 2025 targets related to structural barriers: less than 10% of countries have punitive laws and policies that deny or limit access to services, less than 10% of people experience stigma and discrimination and less than 10% experience gender inequality and violence. Relatedly, community empowerment is needed to both increase access and coverage and to support necessary structural changes.

Putting key populations at the centre of health systems – by organizing services around people’s needs rather than around diseases, and by promoting integrated patient-centred approaches and linkages with primary health care services – is key to ending these epidemics. Different service delivery approaches, including task shifting to key population peers as health workers, decentralizing provision of services to key population community-led programmes, providing services online and service integration are also needed to increase access to and availability of HIV, viral hepatitis and STI services for key populations (46).

Prevention, diagnosis and treatment of STI, viral hepatitis and HIV can only be achieved if people are provided with correct and evidence-based interventions with consideration for their individual health needs through providing person-centred care. This requires understanding of what works to prevent, diagnose and treat these conditions.

Finally, several effective interventions which prevent and treat HIV, STI and viral hepatitis in key populations are cost effective and cost saving (47–50), but without adequate funding their impact cannot be realized. Funding needs to be sustainable, predictable and focused on supporting communities.

Fig. 2. Theory of change: addressing HIV, viral hepatitis and STIs in key populations



## Scope of these guidelines

These guidelines outline a public health response to HIV, viral hepatitis and STIs for five key populations. They present and discuss new recommendations and consolidate a range of recommendations and guidance from current WHO guidelines.

They summarize the components of a package of interventions for each key population and consider implementation issues, challenges and opportunities. The guidelines also provide guidance to countries on how to prioritize packages of interventions to have greatest impact.

## Goals and objectives

High incidence and prevalence of HIV; viral hepatitis and STIs in key populations; dynamics of the epidemics; and persistent discriminatory barriers, inequalities and human rights abuses compel national programmes and implementers to prioritize the provision of evidence-based health and enabling interventions to these populations to meet the Global Health Sector Goals for the three groups of infections.

The objectives of these updated key population guidelines are as follows:

1. To develop new recommendations through quality assessment of evidence;
2. To consolidate the most recent guidance and recommendations related to HIV, viral hepatitis and STI prevention, diagnosis, treatment and care applicable to key populations;
3. To promote a set of evidence-based enabling interventions relevant for all key populations; and
4. To outline priority HIV, STI and viral hepatitis health-service packages that are impactful, beneficial and acceptable for different key populations.





## Audience

These guidelines are addressed primarily to national HIV, viral hepatitis and STI programme managers and other decision-makers within ministries of health and those responsible for health policies, programmes and services in prisons. They also endorse the Global AIDS Strategy target that 80% of service delivery for HIV prevention programmes, 30% of testing and treatment services and 60% of programme support achievement of societal enablers for key populations and women are delivered by community key population-led and women-led organizations, and to expand this to include viral hepatitis and STIs. In addition, the guidelines will be relevant for managers and policy-makers at national and sub-national levels responsible for services for tuberculosis (TB), sexual and reproductive health, needle and syringe programmes (NSPs), opioid agonist maintenance therapy (OAMT), drug dependence, adolescent health, and mental health; community-led civil society organizations and implementing programmes; judiciary, law enforcement and senior prison management; advocates and development and funding agencies.

## Guidelines' principles

These guidelines are developed with the following principles:

### Human rights

The framework for the development of these guidelines is based on human rights principles reflected in a number of international agreements (51, 52). Namely, the right to:

- the highest attainable standard of physical and mental health for all, without discrimination;
- accessible, acceptable, available and quality health facilities, goods and services, including medicines for the treatment of HIV, viral hepatitis and STIs on an equal basis without discrimination – including, but not limited to – on the basis of sex, gender, health status, disability, nationality, sexual orientation, gender identity, race, ethnicity, age and marital status;
- access to justice and the right to a fair trial;
- freedom from arbitrary arrest and detention;
- freedom from torture and cruel, inhuman and degrading treatment;
- privacy, bodily autonomy, security of the person and to be free from violence; and
- enjoy the same standards of health care in prisons and other closed settings that are available in the community.

The above are grounded in underlying core principles of human rights; namely, accountability, equality and non-discrimination and participation of all concerned stakeholders.

### Gender equality

The promotion of gender equality is central to the achievement of HIV, viral hepatitis and STI prevention, diagnosis and treatment goals. This means recognizing and taking into account how unequal power in intimate relationships, harmful gender norms and lack of access to resources and control over them affects access to, and experiences with, health services.

### Equity and inclusion

Recognizing and addressing the social determinants of health and promoting equity and inclusion is central to achieving health for all.



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## Medical ethics

Health care providers and institutions must serve people from key populations based on the principles of medical ethics regardless of personal philosophy, politics, religion, moral theory or opinion (53). Particularly relevant are those related to the provider-patient/client relationships:

- patient or client autonomy;
- confidentiality;
- informed consent;
- voluntary involvement in health services.

Also relevant are codes of conduct and etiquette which require professionalism, quality, high standards and dedication to “providing competent medical service in full professional and moral independence, with compassion and respect for human dignity” (53).

## Universal health coverage

Universal health coverage (UHC) means that all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential health services, from health promotion to prevention, treatment, ongoing recovery and palliative care across the life course.

Achieving UHC requires multiple approaches: primary health care and life course approaches are critical. A primary health care approach focuses on organizing and strengthening health systems so that people can access services for their health and wellbeing based on their needs and preferences, at the earliest and in their everyday environments. Applying a life course approach optimizes people’s health by addressing their needs and maximizing opportunities across all phases of life.

Within the UHC framework, this guideline employs the principal of progressive universalism, where those who are most vulnerable are prioritized and reached first (54).

## Evidence-based public health

These guidelines only includes recommendations and good practice statements that are based on an impartial synthesis of evidence and guided by an independent group of experts, the Guideline Development Group.

## Key population community-led response

This guideline upholds the principle of the greater involvement of people living with HIV (the GIPA principle) (55), applies it to key populations, and commits to support the meaningful engagement of key populations in the response to HIV, viral hepatitis and STIs.

## How to use these guidelines

This guideline consolidates WHO recommendations related to the prevention, diagnosis and treatment of HIV, viral hepatitis and STIs for key populations. The majority of these recommendations are described in full in other WHO guideline documents, including many which were first described in the 2014/2016 consolidated key populations guidelines (3). For simplicity, in most cases the background, evidence and decision-making process related to each recommendation are not included in this guideline; rather the source document which includes this information is referenced. Certain recommendations were newly developed or updated in 2021/2022 as part of this guideline process; these are marked with a star and details of evidence and decision-making are provided in [Chapter 9: Additional information on the development of new recommendations](#). All relevant recommendations are presented in [Chapter 4: The recommended package of interventions](#). [Chapter 5](#) presents prioritized packages by key population.

This guideline also includes chapters on service delivery, enabling interventions, considerations for young key populations and decision-making, planning and monitoring the response. Web Annexes A–D provide full details of the supporting evidence for the new and updated recommendations.

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# CHAPTER 2

## Methods







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## Overview

The WHO Department of the Global HIV, Hepatitis and STIs Programmes led the development of these consolidated key populations guidelines, following the WHO procedures and reporting standards laid out in the *WHO handbook for guideline development*, second edition, 2014 (56). The recommendations in the guidelines are based on the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach to reviewing evidence and formulating recommendations.

These guidelines are an update of the *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*, which were initially published in 2014 and updated in 2016 (3). Importantly, these updated guidelines now combine existing WHO recommendations, new recommendations and guidance published by WHO related to viral hepatitis and STI prevention, in addition to HIV diagnosis, treatment and care for key populations.

## Contributors to the guidelines

These guidelines were developed by technical staff of the WHO Department of the Global HIV, Hepatitis and STIs Programmes. The development process involved the formation of five main groups to guide and implement the process. Their specific roles are described in the next subsection. The members of all these groups and other contributors are listed in the Acknowledgements.

**WHO Guideline Steering Group.** The Testing, Prevention and Population Unit within the Global HIV, Hepatitis and STIs Programmes led this group and served as the WHO secretariat. Participants included WHO staff from other units within these programmes, as well as from the following WHO departments: Mental Health and Substance Use, and Sexual and Reproductive Health and Tuberculosis. This group also included WHO technical staff from two WHO Regional Offices (AFR and EUR).

**Guideline Development Group.** This group consisted of 25 members, with a balanced representation of geographic regions, gender and backgrounds, including academia and research, programme implementation and policy, and community organizations and networks. The global networks of people who use drugs, female, male and trans and gender diverse sex workers, gay men and other men who have sex with men and trans and gender diverse people were all represented on the Guideline Development Group. There is no global network of people in prisons and there were no prisoner representatives on the Guideline Development Group because participation was not feasible. The group members were selected in coordination with the Steering Group and WHO country and regional offices. This group was responsible for the formulation of the new and updated WHO recommendations. A full compilation and summary of the declarations of interest for Guideline Development Group members is available in [Web Annex A](#).

**External Review Group.** This group was selected to ensure geographic and gender balance. It comprised 20 peer reviewers from academia, policy and research, programme implementation, UN agencies and community organizations and networks, including key population networks and civil society organizations and NGOs working in prisons.

**External guideline contributors, guided by methodologist.** Seven systematic reviews were conducted by three separate independent teams of experts, guided by one guideline methodologist, and with input from members of the WHO Steering Group and responsible technical officers. Qualitative research related to key populations' values and preferences was conducted by the global networks of people who inject drugs, sex workers, men who have sex with men and trans and gender diverse people. Additional evidence on feasibility, values and preferences and cost-effectiveness were also compiled and summarized by the systematic review teams. The Guideline Development Group, along with WHO technical officers, worked closely with the guideline methodologists to appraise the evidence using the GRADE methodology.



**External partners and observers.** Representatives of the United States Agency for International Development (USAID), Centers of Disease Control and Prevention (CDC), Global Fund, Bill & Melinda Gates Foundation, Joint United Nations Programme on HIV/AIDS (UNAIDS), United Nations Development Programme (UNDP), United Nations International Children’s Emergency Fund (UNICEF), United Nations Population Fund (UNFPA), United Nations Office on Drugs and Crime (UNODC), World Hepatitis Alliance (WHA), Clinton Health Access Initiative (CHAI) and World Professional Association of Transgender Health (WPATH) attended the Guideline Development Group meeting as observers. All representatives and organizations are potential donors and implementers of the proposed guideline, with a long history of collaboration with WHO’s Global HIV, Hepatitis and STIs Programmes.

## Competing interests

All external contributors to the development of guidelines, including members of the guideline development groups and the external review groups, completed a WHO declaration of interest form. Every effort is made to ensure that any potential influence of conflicts of interest is minimized. Individual participation was reviewed with regard to the interests declared. All declaration of interest forms are on electronic file at the WHO Department of Global HIV, Hepatitis and STIs Programmes, and will be maintained for 10 years.

To assess competing interests of the Guideline Development Group, the WHO responsible technical officers reviewed declarations of interest forms, curricula vitae and performed Google searches. The proposed membership list was posted for public review and comment 14 days prior to the guideline meeting before finalization. A management plan for each declared conflict was agreed on and recorded at the time of the meetings. One potential conflict related to receipt of funds that was considered significant in relation to one topic area was identified. The WHO team decided that this member would participate partially, excusing themselves from participating in decision-making discussions and formulation of a recommendation related to hepatitis C treatment (see [Web Annex A](#)).

## Defining the scope of the guidelines

This publication is an update of the 2016 *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*. In line with principles of Universal Health Care (UHC), a person-centred care and the rationale for increased public health impact, we identified areas for improvements to the former guidelines:

- 1) including and consolidating relevant recommendations related to viral hepatitis and STIs for key populations;
- 2) providing guidance to countries on prioritized packages of health interventions for each key population group; and
- 3) highlighting the central importance of critical enablers in ensuring UHC for key populations.

For initial scoping for the updated guidelines, WHO technical officers reviewed all the health intervention recommendations included in the 2014/2016 guidelines with the following objectives:

1) identify ways in which the guideline could be clearer, and easier to read and implement; 2) identify recommendations that required updating; and 3) identify where new recommendations were needed. Technical officers from HHS/TPP rated all of the 146 recommendations from the 2014/2016 key populations guidelines using the following actions:



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**Remove:** It has been superseded and is no longer relevant. Review of the evidence is not necessary, and the recommendation is deleted (“remove (not relevant)”) OR it should be removed from recommendations box because it is a “consideration” and can be highlighted in the narrative or in a separate section on structural interventions (“remove (move to narrative or structural)”).

**Validate:** The recommendation is clearly established, and it is unlikely anyone would disagree with the recommendation. A review of the evidence and decision-making process is not necessary; the recommendation should be retained unchanged.

**Edit:** There is no change in the evidence or in the intention of the recommendation, but the precise wording needs editing to improve clarity.

**Update:** New evidence synthesis is required, and the topic and new evidence synthesis need to be reviewed by the Guideline Development Group with a full evidence-to-decision procedure, **or** there has been an update of the recommendations since 2016 conducted by another team or department in WHO.

**New:** A new topic, subgroup or intervention needs to be covered. A new evidence synthesis is required and the Guideline Development Group needs to perform a full evidence-to-decision procedure.

Following this exercise, a community and expert consultation was organized. The objectives of the consultation were: 1) to give an update on the consolidated key populations guidelines process and future timelines; 2) to discuss changes to the guidelines format and structure; 3) to gain feedback on proposed recommendations to be updated and new areas for future recommendations; and 4) to improve community engagement and transparency. Participants in the consultation included members of the key population community, young people and adolescents, donors, technical partners, implementers, representatives of national programmes and UN partners. The consultation also included a post-meeting survey. Overall, participants agreed with the proposed structure of the guidelines, with separate packages per key population, inclusion of STIs and viral hepatitis and the inclusion of prioritized packages of health interventions.

## Values and preferences of key population members

WHO commissioned a qualitative study of key populations’ values and preferences related to the new and updated recommendations being considered by the Guideline Development Group, as well as their general health priorities, service delivery preferences and experience of structural barriers. Unfortunately, it was not possible to include people in prisons in this study, given a lack of networks of people in prisons and logistical issues.

Global Action for Trans Equality (GATE), International Network of People who Use Drugs (INPUD), Global Action for Gay Men’s Health and Rights (MPACT) and Global Network of Sex Work Projects (NSWP), following ERC approval of the protocol, conducted a total of 61 individual semi-structured interviews (SSIs) and 32 multi-country focus group discussions (FGDs). The global key population networks selected participants through their regional and country-based networks to participate in SSIs and FGDs, with attention given to balancing representation by region, gender, age and HIV status. All SSIs and FGDs were conducted virtually over secure communication platforms. Interviews were conducted in English, French, Spanish or Russian, as appropriate. Three interviews were additionally conducted by NSWP consultants in Thai, Hindi and Nepali, using community interpreters.



Data were collected by community experts engaged by the global key population networks as consultants. Participant responses were documented, electronically recorded and, where possible, participant responses were transcribed verbatim with respect to the safety and anonymity of personal data. Responses were then collated and coded using an inductive, thematic analysis approach based on an analytical framework developed by the key population networks. Data summaries from each of the key population studies were prepared by one principal investigator from each network, inputted into a joint draft, and analysed to create a consolidated key population report (see [Web Annex B](#) for the full report).

## Developing prioritized packages

In this updated guideline, guidance is provided to national programme managers, donors and advocates on how to prioritize different packages of health interventions to have the greatest impact on HIV, viral hepatitis and STIs, and to ensure universal coverage to address other health issues for key populations.

Each of the interventions listed and included in this guideline, based on initial scoping, was classified for each key population as:

### 1. Essential for impact: enabling interventions

This includes all interventions recommended to address structural barriers to health services access for key populations.

### 2. Essential for impact: health interventions

This includes health sector interventions which have a demonstrated direct impact on HIV, viral hepatitis and STIs in key populations.

### 3. Essential for broader health

This includes health sector interventions to which access for key populations should be ensured, but which do not have direct impact on HIV, viral hepatitis or STIs.

### 4. Supportive

This includes other interventions which support the delivery of health sector interventions, such as creating demand, providing information and education.

## Plans for dissemination and updating

These guidelines will be updated in full or in part, based on regular scoping exercises of available evidence and experience from country implementation that will guide and trigger the need for new guidance. As the evidence base or user needs change, consideration will be given to producing technical updates on specific subjects.

The guidelines will be disseminated electronically on the WHO Global HIV, hepatitis and STIs Programmes' website and made available as a print publication on demand. Dissemination will be supported by publication of selected systematic reviews and evidence in peer-reviewed journals, as well as policy briefs, web and mobile phone-based apps.





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# CHAPTER 3

## Critical enablers





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HIV, viral hepatitis and STI epidemics, particularly among key populations, continue to be fuelled by laws and policies criminalizing sex work; drug use or possession; diverse forms of gender expression and sexuality; stigma and discrimination; gender discrimination; violence; lack of community empowerment and other violations of human rights. These sociostructural factors limit access to health services, constrain how these services are delivered and diminish their effectiveness.

“Critical enablers<sup>2</sup>”, as used in this guideline, means strategies, activities and approaches that aim to improve the accessibility, acceptability, uptake, equitable coverage, effectiveness and efficiency of HIV, viral hepatitis and STI services. Enablers operate at many levels – individual, community, institutional, societal and national, regional and global. They are crucial to developing strategies and implementing comprehensive HIV, viral hepatitis and STI programmes and services for key populations in all epidemic contexts.

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, education, welfare and labour. It also requires multiple partners from government, civil society, religious institutions and the private sector. Full and meaningful involvement of key population-led organizations is crucial.

### Special considerations for adolescents and young people

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, familial, and social, educational and economic vulnerabilities. Also, adolescents from key populations experience sociostructural barriers to services, notably policy and legal barriers related to age of consent. Children of key populations can experience stigma and discrimination, and hence face the same difficulties in access to services. Health care providers may be prosecuted for providing services to adolescents without parental/guardian consent, further reducing access to services.

## Key populations’ experience, values and preferences related to structural barriers and critical enablers

Qualitative research conducted by the global key population-led networks for the development of this guideline (for a detailed report, please see [Web Annex B](#)) found that all key populations reported criminalization, stigma and discrimination as persistent barriers to accessing health services and remaining in treatment, as well as being driving factors in perpetuating vulnerability, human rights abuses and poor health outcomes. Participants from the trans and gender diverse people’s network additionally emphasized structural barriers to legal gender recognition.

The criminalization of drug use or possession, sex work, same-sex relations and gender expression deter members of key populations from accessing services due to fears of legal repercussions. It was also noted how criminalization perpetuates the exclusion of key population-led and rights-based health programming from funding mechanisms and state health responses. Participants in the qualitative study additionally noted that law enforcement using the possession of condoms and injecting equipment as so-called evidence of sex work and drug use or possession further hinders the use of evidence-based prevention services and commodities.

<sup>2</sup> These are referred to as societal enablers in the *Global AIDS Strategy 2021–2026 (45)*.



Stigma and discrimination, exacerbated by criminalization, also remain a salient barrier to accessing services and remaining in treatment for key populations. Participants across key population groups emphasized the pervasive problem of provider-based stigma and discrimination, including judgemental attitudes, breaches of confidentiality, denial of treatment, violence and abuse – even in contexts where legal protections exist.

To improve key populations' access to, and retention in, HIV, STI and viral hepatitis services, and to promote their health and human rights in general, participants stressed the need for legal and policy reform, community-led responses, community empowerment and capacity-building, and anti-violence initiatives.

Community empowerment was emphasized across all key population-led networks participating in the qualitative research project. Participants discussed the importance of key population-led responses, including peer outreach and other peer-based services, awareness-raising, advocacy, drop-in-centres, capacity-building and resource mobilization to ensure sustainable, community-led programming. These initiatives were seen both as a means to improve access to services, as well as an essential measure for addressing structural barriers undermining key populations' health and human rights.

In addition, participants noted the importance of sensitizing health care staff, law enforcement, NGO workers and the broader community. Key population-led sensitization training was perceived as an effective intervention to decrease stigma and discrimination and improve the acceptability of health services. Participants also recommended anti-violence interventions as enabling interventions.

Participants felt that because violence can be common (largely due to the effects of criminalization that require systemic solutions), violence prevention interventions need to be incorporated in an ongoing way into an overall wellness approach that views health as much more than “simply a set of interventions”. In this context, they stressed the need for services to think more about what might bring people in and empower them to think about and address their health.

Lastly, all key population-led networks noted the critical role that funding plays in community-led initiatives, indicating an ongoing need to prioritize funding for key population-led programming, given the serious lack of funding for community and key population-led initiatives, and highlighting the importance of achieving the Global AIDS Strategy targets; namely, 80% service delivery for HIV prevention programmes for key populations, delivered by key populations; 30% testing and treatment services, delivered by community-led organizations; and 60% programme support achievement societal enablers, to be delivered by community-led organizations.

## Essential interventions for impact: critical enablers

This chapter outlines a range of structural barriers that compromise access to health services for key populations, and then identifies critical enablers to overcome these barriers. This chapter includes a number of good-practice recommendations that are based on those made in the 2014/2016 WHO consolidated key population guidelines (3) with updated references, where available. While these barriers and enablers are interrelated, we attempt to discuss each individually.

## Legal and policy barriers and enablers

Key population members are entitled to the full protection of their human rights, as specified in international human rights instruments. Human rights include, but are not limited to, the right to equal enjoyment of rights and non-discrimination; security of person and privacy; recognition and equality before the law; fair trial of law; the highest attainable standard of mental and physical health; education; employment and just and favourable conditions of employment; freedom of movement; peaceful assembly and association; freedom from arbitrary arrest and detention, and from cruel and inhumane treatment; and protection from violence. States have an obligation to ensure that the above rights are enjoyed without discrimination on the basis of race, nationality, sex, age, religion, sexuality, gender identity, health status, disability, marital status or other status (57–60).





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Most countries have laws, regulations or policies that are barriers to effective HIV, viral hepatitis, STI and other health services for key populations, including criminalization of sex work, drug use and possession, gender identity or expression, and sexual relations between people of the same sex. A number of countries criminalize gender identity in a de facto manner, by criminalizing cross-dressing or impersonation of the opposite sex. For trans and gender diverse people, the lack of legal gender recognition is a key barrier to access, and retention of, health services, in addition to the full enjoyment of other rights, such as freedom of mobility, housing, education and employment. This further isolates trans people and increases their vulnerabilities. In many settings, adolescents under 18 years of age are classified legally as minors and, therefore, must have consent from a legal responsible adult for medical care. Other barriers are related to restrictive or punitive policies and practices, such as criminalizing the possession of needles/syringes, which restricts the ability of programmes to operate NSPs, and using possession of condoms as evidence of sex work and as a basis for arrest (61). Other harmful practices include forced anal examinations, which are used to investigate or punish alleged same-sex behaviour between consenting men or transgender women (62).

These legal barriers have measurable, detrimental effects on the health of members of key populations, shown by modelling and other research (63–74). For example, a systematic review found associations between exposure to arrest and HIV infection in people who inject drugs (64); in countries in sub-Saharan Africa, the odds of living with HIV were found to be 7.2 times higher for sex workers in countries that criminalize sex work compared to countries that partially legalize sex work (68); repressive policing of sex workers was associated with increased risk of HIV or other STIs (odds ratio of 1.87); and sex workers exposed to repressive policing were three times more likely to be physically or sexually assaulted (75). The criminalization of the clients of sex workers has also been repeatedly shown to negatively affect sex workers' safety and health, including reducing condom access and use, and increasing the rates of violence (68, 76). Studies show the negative effect of criminalization of same-sex practices on HIV prevalence and access to prevention, diagnosis and treatment services (77, 78).

For trans and gender diverse 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 (79). Additionally, it is likely to improve trans and gender diverse people's health and wellbeing (80). However, legal recognition must be accompanied by training, sensitization, education and enforcement.

Legal reforms, such as decriminalizing drug use or possession, sex work and same sex relationships; legal recognition of trans or gender diverse status; lowering the age of consent for accessing health services; 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. Without protective policies and decriminalization of drug use or possession, and of diverse forms of gender identity and sexuality and sex work, 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. Specific consideration should be given to such legal reforms as part of any revision of policies or programmes for key populations.

Laws and policies that criminalize and punish key populations also 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 and other crimes, 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, and key population-led organizations and other organizations that work with key populations can serve as a third-party reporter of complaints (61, 81).



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Law enforcement has a statutory duty and obligation to ensure key populations enjoy equal protection under the law, and that the human rights of key populations are not violated. Law enforcement agents should receive continual training in ways to support – or at least not to impede – key populations’ access to essential health services, including not surveilling or arresting people accessing OAMT, NSPs and drug dependence treatment clinics; avoiding confiscation of drug treatment medication, and not using possession of sterile 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 (61).

Overarching recommendations related to enabling interventions to address legal and policy barriers are listed below. Please see the [recommended interventions chapter](#) for full details.

### Overarching good practice and guidance statements: removing punitive laws, policies and practices

**Existing good practice statement (adapted)<sup>3</sup>** Countries should work toward decriminalization of drug use/injecting, drug possession, 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 trans and gender diverse people (3, 45, 79, 82–85).

**Existing guidance statement** 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 (3, 79, 83, 84).

## Stigma and discrimination

Stigma is a difference that is pejoratively labelled, stereotyped or named. Stigma can lead to discrimination; namely, unfair and unjust action towards an individual or group on the basis of real or perceived status or attributes, a medical condition, socioeconomic status, employment, drug use, gender, race, sexual identity, age or other perceived differences or characteristics, with the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise – on an equal basis with others – of all human rights and fundamental freedoms (61).

People from key populations are often particularly subjected to stigma, discrimination and negative attitudes related to their behaviour, sexual orientation, gender identity or engagement in sex work – and doubly so if also living with HIV, viral hepatitis or STIs. Many key populations also face intersecting forms of discrimination on the basis of their age, sex, race or ethnicity, physical or mental health status, disability, nationality, asylum or migration status, or criminal record. This is the basis for discrimination, which 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 that protect key populations against discrimination, and by the implementation of punitive and restrictive policies.

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 rights-based strategies and interventions for key populations contributes to marginalization. It leaves providers ill-equipped to address health needs and perpetuates stigma and discrimination practices, even to the point of refusing services. Health care and regulations against people who use/inject drugs, sex workers, men who have sex with men and trans and gender diverse people.



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workers may be biased against certain people, but may also experience discrimination themselves when working with key populations (86).

The effects of stigma and discrimination against key populations can manifest in delayed testing and missed diagnoses, poor retention in treatment programmes and poor treatment outcomes, concealment of health status and, in general, poor uptake of health services (61, 87–102).

There are many interventions designed to reduce stigma and discrimination in health care settings, with some randomized controlled trials and observational studies showing positive effects (92, 103–114). However, given the heterogenous nature of the interventions and outcomes measured, meta-analyses are often not possible, and systematic reviews do not clearly indicate which are the most effective interventions when it comes to reducing stigma and discrimination in health care settings (86, 115–117). Instead, it is useful to consider a range of interventions that can address different aspects of stigma and discrimination as listed below (61, 115).

Intervention approach	Description
<b>Information based</b>	Providing information about health and health-related stigma
<b>Skills building</b>	Conducting sensitization or other skills-building activities for health care workers, law enforcement officers and others
<b>Counselling and support</b>	Supportive services for members of key population groups
<b>Contact with key populations</b>	Facilitating interactions between key population members and health care workers, law enforcement officers and others
<b>Structural</b>	Institute anti-stigma and anti-discrimination policies and codes of conduct with monitoring, oversight and opportunities for key population members to report discrimination, including redress and accountability mechanisms
<b>Biomedical</b>	Ensuring UHC and professional, non-discriminatory provision of care, including HIV, viral hepatitis and STI services for key populations



Enabling interventions to address barriers related to stigma and discrimination are listed below:

### Overarching good practice and guidance statements: stigma and discrimination

<b>Existing good practice statement</b>	Countries should work towards implementing and enforcing anti-discrimination and protective laws, derived from human rights standards, to eliminate stigma, discrimination and violence against people from key populations (3).
<b>Existing good practice statement</b>	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, 79, 81, 83–85, 118, 119).
<b>Existing guidance statement</b>	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, 79, 81, 83–85, 118–120).

## Community empowerment

Key populations often have little or no control over HIV, STI and viral hepatitis risk factors driven by the legal, political and social and programmatic environment, and the context of their lives. These constraints can hinder people’s control over their health and wellbeing, as well as increasing their risk of HIV, viral hepatitis and STIs. This lack of control is exacerbated if people are unaware of available health services, of their legal and human rights, specifically their right to health, and what to do if these rights are violated. Few young people from key populations receive adequate information and education centred on their sexual lives. Instead, they receive negative, critical, conflicting or confusing messages about gender, drug use, unintended pregnancy and STIs, including HIV (121).

Empowerment is the process by which people with little power work together to increase control over events that determine their lives and health. Community empowerment means increasing key population communities’ control over their health by addressing the structural constraints to health, human rights and wellbeing; making social, economic and behavioural changes; and improving access to health services. Community empowerment can take many forms, such as fostering key population-led groups and key population-led programmes and service delivery; meaningful participation of people from key populations in designing and operating services; peer education or navigation; task shifting to key population peers; self-care; implementation of legal literacy and service programmes; and ensuring civil space in which key populations can function without fear of reprisals.

Evidence, mainly among sex workers, shows that community empowerment has a measurable impact on key populations’ health (122–134), including reductions in STI incidence (127), HIV incidence (128, 134), high-risk sex (131) and increased uptake of family planning (132).

Figure 3 shows a framework for fostering key population services included in key population networks’ developed implementation tools (135–138).

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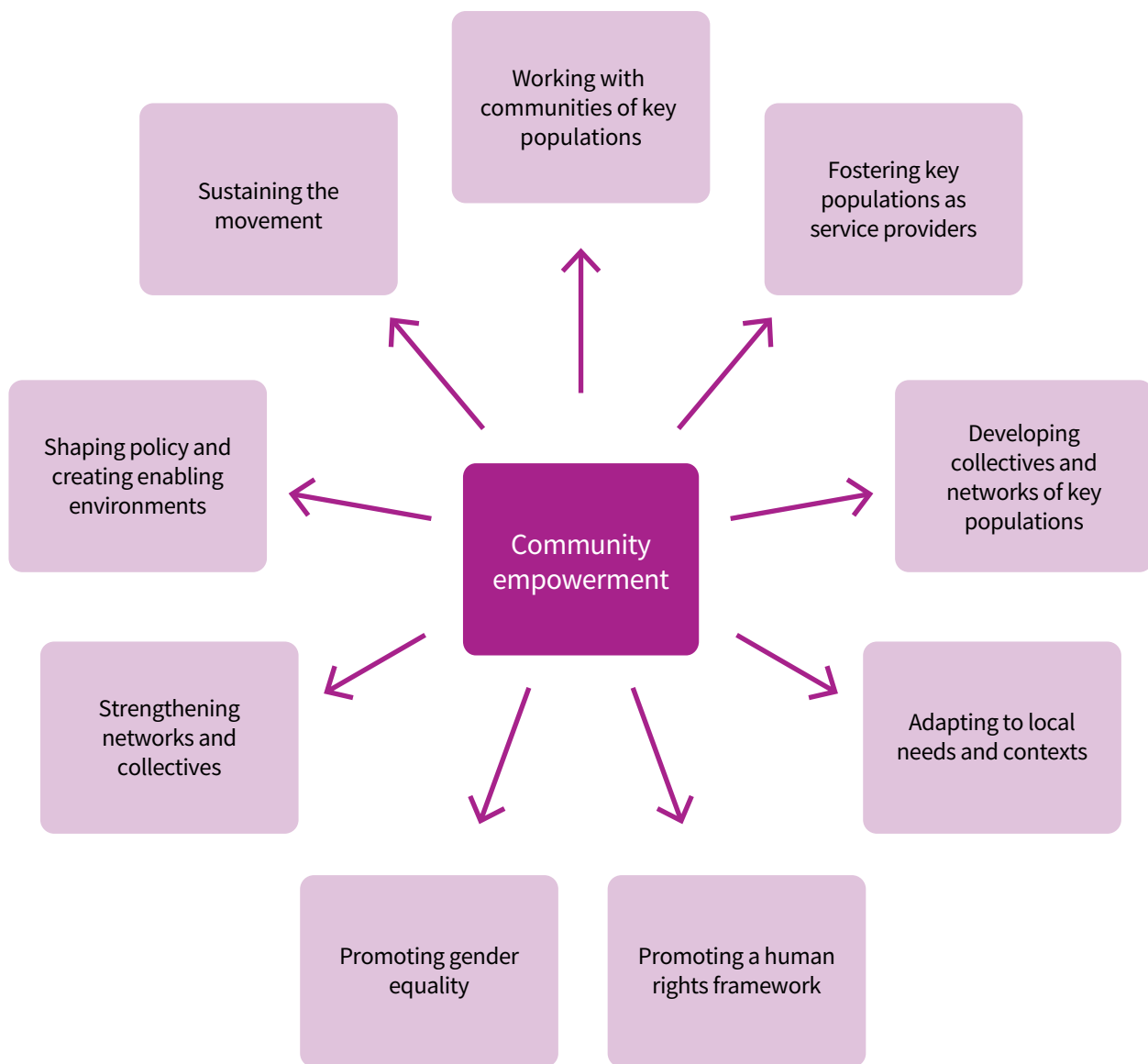
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Fig. 3. Framework for community empowerment



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 staff of health services, law enforcement and social service agencies; facilitating interaction with the communities of key populations; and developing, implementing, monitoring and managing services. Key population communities can build understanding of, and alliances with, other neglected, at-risk groups, such as youth networks, persons with disabilities, adolescent girls and young women. They have special strengths in providing and leading community-based and outreach services.

Meaningful participation can mean not only having a voice in decision-making, but also contributing to service delivery and monitoring and evaluation (M&E). Community-led monitoring, an accountability mechanism led by key populations and other affected communities, which involves trained peer monitors and structured reporting mechanisms, is particularly important (139).

WHO has several relevant recommendations related to roles for key population peers in service delivery, which can be found in the [service delivery chapter](#).





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The meaningful participation of key populations in programming is critical to ensure 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, a norm that needs to be shifted to allow for community empowerment and service access.

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.

Enabling interventions to improve community empowerment are listed below.

### Overarching good practice and guidance statements: community empowerment<sup>4</sup>

**Existing guidance statement** Key population-led groups and organizations should be made essential partners and leaders in designing, planning, implementing and evaluating health services (3).

**Existing good practice statement** Programmes should implement a package of interventions to enhance community empowerment among key populations (3, 79, 84, 85).

## Violence

Violence against people from key populations is a common occurrence and can take various forms – physical, sexual or psychological, and can be perpetrated by different people, including intimate partners, clients, family members, strangers, service providers, law enforcement officers and others in positions of power (140–147). Violence can be fuelled by the imbalance in the power dynamics of gender – by prejudice and discrimination against persons perceived to depart from conventional gender and sexuality norms and identities. Other characteristics such as age, disability or race can increase vulnerability to violence. Also, multiple structural factors influence vulnerability to violence, including discriminatory or harsh laws, and policing practices and cultural and social norms that legitimize stigma and discrimination.

Experience of violence has been shown to negatively impact on key populations' health, including increasing drug-related harms (142, 148–152), reduced uptake of sexual and reproductive health services (141), inconsistent condom use (141, 147, 149, 153), depression and other mental health issues (143, 154), and increased HCV infection risk (155, 156), as well as having a direct impact on HIV and STI acquisition (157). A modelling study estimated that reduced sexual violence against sex workers could reduce new HIV infections by 25% among sex workers and their clients (158). Women, especially young women from key populations, including women who use drugs, female sex workers, people in prisons and transgender women, experience particularly high rates of physical, sexual and psychological abuse (159).

The health sector has an important role to play in addressing violence by providing comprehensive health services, including: for sexual and reproductive health; providing referrals to other support services; gathering evidence through data and research; fostering prevention policies in other sectors; and advocating for violence to be recognized as a public health problem and for resource allocation (160).

Those who experience sexual violence need timely access to post-rape care, including emergency contraception, safe abortion, post-exposure prophylaxis for HIV and other STIs, hepatitis B

<sup>4</sup> Please note, in the WHO guideline: *Prevention and treatment of HIV and other sexually transmitted infections for sex workers in low and middle-income countries: recommendations for a public health approach*, WHO recommended a package of viral hepatitis and STI prevention, diagnosis and treatment for key populations should include, very little evidence of evidence. In 2011, all WHO recommendations related to key populations were re-evaluated, and a new good practice statement developed to expand this recommendation to all key population groups, as included in the table above.



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for survivors of violence, in line with WHO guidelines for responding to sexual violence (161-162). 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 and other counsellors, to offer psychosocial support, as well as crisis response interventions, with multidisciplinary teams that link survivors to various services and safe spaces, without restrictions based on ongoing drug use (84).

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 wellbeing and safety. Critical enablers include mechanisms for documenting and monitoring violence, training people from key populations and other stakeholders to understand human rights, and for fostering the accountability of law enforcement officials to prevent and respond to violence and infringements of human rights (162, 164). Evidence shows the effectiveness of participatory programmes that engage multiple stakeholders as well as community mobilization interventions (165). 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 (162). Efforts to prevent violence can be promoted by advocacy for law and policy reforms that protect the rights and safety of key populations; increasing awareness of reporting mechanisms and disciplinary action; conducting sensitization workshops for people with pivotal roles (for example, government officials, law enforcement officers, prison staff, media, health care workers and religious leaders); 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 law enforcement officers (162).

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.

Enabling interventions to address violence against key populations are listed below.

### Overarching good practice statements: violence

<b>Existing good practice statement</b>	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 (3, 79, 84, 85, 162).
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# CHAPTER 4

The recommended package  
of interventions







## Introduction

This guideline consolidates WHO recommendations related to the prevention, diagnosis and treatment of HIV, viral hepatitis and STIs for key populations. The majority of these recommendations are described in full in other WHO guideline documents, including many that were first described in the 2014/2016 consolidated key populations guidelines (3). For simplicity, in most cases the background, evidence and decision-making process related to each recommendation are not included in this guideline; rather the source document, which includes this information, is referenced. Certain recommendations were newly developed or updated in 2021/2022 as part of this guideline process; these are marked with a star, and details of evidence and decision-making are provided in the [additional information chapter](#).

The interventions listed here have been categorized as follows:

### 1. Essential for impact: enabling interventions

This includes all interventions recommended to reduce structural barriers to health services access for key populations.

### 2. Essential for impact: health interventions

This includes health sector interventions that have a demonstrated direct impact on HIV, viral hepatitis and STIs in key populations.

### 3. Essential for broader health

This includes health sector interventions to which access for key populations should be ensured, but do not have direct impact on HIV, viral hepatitis or STIs.

### 4. Supportive

This includes health sector interventions which support the delivery of other interventions, such as creating demand, and providing information and education.

The tables below include recommendations which have been made through the GRADE process (see methods for details), good practice statements and summaries and links to relevant documents. The GRADE recommendations include the strength of the recommendation and certainty of the evidence as agreed by relevant Guideline Development Groups.

Packages of recommended interventions are provided for each key population group in [Chapter 5](#).

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## Recommended package

Note that these interventions are not in order of priority.

Also please note that this package includes a mix of existing and new recommendations, good practice statements and guidance statements. These can be classified as follows:

- ★ **New GRADE recommendation** – a recommendation which was newly developed as part of this guideline’s development process, using the GRADE methodology as described in the methods section;
- Existing GRADE recommendation** – a recommendation which was developed as part of an already published WHO guideline;
- ★ **New good practice statement** – a good practice statement newly developed by the guideline development group as part of this guideline’s development process, as described in the methods section;
- Existing good practice statement** – a good practice statement which was developed as part of an already published WHO guideline;
- Existing guidance statements** – overarching statements which summarize groups of existing recommendations and approaches;
- WHO position** – from position papers of the WHO Strategic Advisory Group of Experts (SAGE) on immunization; and
- Adapted** – for some of the recommendations and good practice statements, small changes to the wording have been made without substantial change.

### Essential for impact: enabling interventions

#### Overarching good practice statements: removing punitive laws, policies and practices

<b>Existing guidance statement</b>	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 (3, 79, 83, 84).
<b>Existing good practice statement (adapted)<sup>5</sup></b>	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 trans and gender diverse people (3, 79, 82–85).

<sup>5</sup> In the 2014 *Consolidated guidelines for HIV prevention, diagnosis, treatment and care for key populations*, the wording of this good practice statement was: 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 trans and gender diverse people.

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## Essential for impact: enabling interventions

### Other good practice statements: removing punitive laws, policies and practices

<b>Existing good practice statement (adapted)<sup>6</sup></b>	Where criminalization continues, countries should work toward developing non-custodial alternatives to incarceration of people who use drugs, trans and gender diverse people, sex workers and people who engage in same-sex activity (3, 82, 85).
<b>Existing good practice statement (adapted)<sup>7</sup></b>	Countries should ban compulsory treatment <sup>8</sup> for key populations (3, 82, 83, 85, 166).
<b>Existing good practice statement</b>	Countries should work toward developing policies and laws that decriminalize the use of sterile needles and syringes (and that permit NSPs) and that legalize OAMT for people who are opioid dependent (3).
<b>Existing good practice statement</b>	The police practice of using possession of condoms as evidence of sex work and grounds for arrest should be eliminated (3, 84).
<b>Existing good practice statement</b>	Countries should work towards legal recognition for trans and gender diverse people (3, 79).
<b>Existing good practice statement</b>	Countries are encouraged to examine their current consent policies and consider revising them to reduce age-related barriers to HIV, STI and viral hepatitis services, and to empower providers to act in the best interests of adolescents (3, 120).

### Overarching good practice and guidance statements: stigma and discrimination

<b>Existing good practice statement</b>	Countries should work towards implementing and enforcing anti-discrimination and protective laws, derived from human rights standards, to eliminate stigma, discrimination and violence against people from key populations (3).
<b>Existing good practice statement</b>	Policy-makers, parliamentarians and other public health leaders should work together with civil society organizations, including key population-led organizations, in their efforts to monitor stigma, confront discrimination against key populations and change punitive legal and social norms (3, 79, 81, 83–85, 118, 119).
<b>Existing guidance statement</b>	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, 79, 81, 83–85, 118–120).

<sup>6</sup> In the 2014 *Consolidated guidelines for HIV prevention, diagnosis, treatment and care for key populations*, the wording of this good practice statement was: Countries should work toward developing non-custodial alternatives to incarceration of drug users, sex workers and people who engage in same-sex activity.

<sup>7</sup> In the 2014 *Consolidated guidelines for HIV prevention, diagnosis, treatment and care for key populations*, the wording of this good practice statement was: Countries should ban compulsory treatment for people who use and/or inject drugs.

<sup>8</sup> Compulsory, or involuntary, treatment includes treatment for drug dependence, so-called conversion therapy or rehabilitation of sex workers, which is against human rights and medical ethics principals of consent, freedom from arbitrary arrest, access to quality health, freedom from torture and cruel, inhumane and degrading treatment.





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## Essential for impact: enabling interventions

### Other good practice statements: stigma and discrimination

**Existing good practice statement** 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 (3).

**Existing good practice statement** Services should be safe spaces that increase protection from the effects of stigma and discrimination, where adolescents can freely express their concerns, and where providers demonstrate patience, understanding, acceptance, non-judgement and knowledge about the choices and services available to the adolescent (120).

### Overarching guidance statement: community empowerment

**Existing guidance statement** Key population-led groups and organizations should be made essential partners and leaders in designing, planning, implementing and evaluating health services (3).

### Other good practice statements: community empowerment

**Existing good practice statement** Programmes should implement a package of interventions to enhance community empowerment among key populations (3, 79, 84, 85).

**Existing good practice statement** Programmes should be put in place to provide legal literacy and legal services for and by key populations, so that they know their rights and applicable laws and can receive support from the justice system when aggrieved (3, 79, 84, 85).

### Overarching good practice statement: addressing violence

**Existing good practice statement** 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 (3, 79, 84, 85, 162).

### Other good practice statements: addressing violence

**Existing good practice statement** 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 (3, 162).

**Existing good practice statement** 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 (3, 79, 84, 85, 162).



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## Essential for impact: health interventions

### Prevention of STIs, HIV and viral hepatitis

#### Harm reduction (NSPs, OAMT and naloxone for overdose management)

<b>Existing GRADE recommendation</b>	All individuals from key populations who inject drugs should have access to sterile injecting equipment through NSPs ( <i>strong recommendation, low certainty of evidence</i> ) (3, 83, 167).
<b>Existing GRADE recommendation</b>	It is suggested that NSPs also provide low dead-space syringes (LDSSs), along with information about their preventive advantage over conventional syringes ( <i>this recommendation is conditional on local acceptability and resource availability</i> ) (168).
<b>Existing GRADE recommendation</b>	All people from key populations who are dependent on opioids should be offered OAMT <sup>9</sup> in keeping with WHO guidance ( <i>strong recommendation, low certainty of evidence</i> ) (3, 83, 169), including those in prison and other closed settings (170).  Important considerations related to OAMT, including recommended doses, use in pregnancy and drug interactions are included in:  <a href="#">Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence</a>  <a href="#">Guidelines for the identification and management of substance use and substance use disorders in pregnancy</a>
<b>Existing GRADE recommendation</b>	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 ( <i>strong recommendation, very low certainty of evidence</i> ) (27).  More details of community distribution of naloxone for overdose management can be found in the WHO guideline <a href="#">Community management of opioid overdose</a> .

#### Condoms and lubricant

<b>Existing GRADE recommendation</b>	The correct and consistent use of insertive and receptive condoms with adequate supply of condom compatible lubricants is recommended to prevent sexual transmission of HIV, viral hepatitis and STIs through anal or vaginal sex <sup>10</sup> ( <i>strong recommendation, moderate certainty of evidence</i> ) (3).
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<sup>9</sup> Methadone or buprenorphine.

<sup>10</sup> Both HCV and HBV can be transmitted sexually, although sexual transmission of HCV is rare as it requires blood contact.



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## Essential for impact: health interventions

### Prevention of STIs, HIV and viral hepatitis (cont.)

#### Pre-exposure prophylaxis (PrEP) for HIV

**Existing GRADE recommendation** Oral PrEP (containing tenofovir disoproxil fumarate) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches (*strong recommendation, high certainty of evidence*) (171).

**Existing GRADE recommendation** The dapivirine vaginal ring may be offered as an additional prevention choice for cisgender women at substantial risk of HIV infection as part of combination prevention approaches (*conditional recommendation, moderate certainty of evidence*) (171).

 **New GRADE recommendation** Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (*conditional recommendation, moderate certainty of evidence*) (172).

For detailed guidance on PrEP please see [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#).

For implementation guidance, please see *Differentiated and simplified pre-exposure prophylaxis for HIV prevention: Update to WHO implementation guidance*.

#### Post-exposure prophylaxis (PEP) for HIV and STIs

**Existing guidance statement** PEP should be available to all eligible people from key populations on a voluntary basis after possible exposure to HIV (3).

**Existing guidance statement** For women who have been raped, a package of PEP, emergency contraception and presumptive treatment of STIs is recommended (173).

For detailed guidance on HIV PEP regimens, please see [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#).

For detailed guidance on PEP for adults who have been sexually abused, please see WHO guidelines [Responding to intimate partner violence and sexual violence against women](#).

For detailed guidance on PEP for children and adolescents who have been sexually abused, please see WHO guidelines [Responding to children and adolescents who have been sexually abused](#).



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## Essential for impact: health interventions

### Prevention of STIs, HIV and viral hepatitis (cont.)

#### Prevention of vertical transmission of HIV, syphilis and HBV

##### Existing GRADE recommendation (adapted)<sup>11</sup>

HIV, syphilis and hepatitis B surface antigen (HBsAg)\* tests should be offered at least once and as early as possible in pregnancy, ideally at the first antenatal care (ANC) visit (*syphilis: strong recommendation, moderate quality of evidence; HBsAg\*: strong recommendation, low certainty of evidence*) (174, 175).

\* Particularly in settings with a  $\geq 2\%$  HBsAg seroprevalence in the general population.

Recommended time points for HIV retesting for pregnant and postpartum key populations: early in pregnancy (first ANC visit); late in pregnancy (third trimester ANC visit); one additional postpartum retest (14 weeks, six months or nine months postpartum) (175).

Please see also STI testing below; chlamydia and gonorrhoea screening is recommended for all key populations, including those who are pregnant.

##### Existing guidance statement

Dual HIV/syphilis rapid diagnostic tests (RDTs) can be the first test in HIV testing strategies and algorithms in ANC (176). HBsAG testing should be considered in addition when dual testing is performed.

##### Existing good practice statement (adapted)<sup>12</sup>

ART should be initiated urgently among all pregnant and breast and chest feeding people living with HIV, even if they are identified late in pregnancy or postpartum, because the most effective way to prevent HIV vertical transmission is to reduce maternal viral load (171).

##### Existing GRADE recommendation (adapted)<sup>13</sup>

For early syphilis in pregnancy, the WHO STI guideline suggests using benzathine penicillin G 2.4 million units once intramuscularly over procaine penicillin 1.2 million units intramuscularly once daily for 10 days (*conditional recommendation, very low certainty of evidence*) (177).

##### Existing GRADE recommendation (adapted)<sup>14</sup>

WHO recommends that those who test positive for HBV infection (HBsAg positive) with an HBV DNA  $\geq 5.3 \log_{10}$  IU/mL ( $\geq 200,000$  IU/mL) during pregnancy receive tenofovir prophylaxis from the 28th week of pregnancy until at least birth, to prevent vertical transmission of HBV. This is in addition to three-dose hepatitis B vaccination in all infants, including timely birth dose (*conditional recommendation, moderate certainty of evidence*) (178).

##### Existing GRADE recommendation (adapted)<sup>15</sup>

WHO recommends that in settings in which antenatal HBV DNA testing is not available, hepatitis B e antigen (HBeAg) testing can be used as an alternative to HBV DNA testing to determine eligibility for tenofovir prophylaxis to prevent vertical transmission of HBV2 (*conditional recommendation, moderate certainty of evidence*) (178).

Please see also: [WHO technical brief: preventing HIV during pregnancy and breastfeeding in the context of PrEP](#).

<sup>11</sup> Recommendations related to prevention of vertical transmission of HIV, syphilis and HBV have been reworded to be more gender inclusive.

<sup>12</sup> Ibid.

<sup>13</sup> Ibid.

<sup>14</sup> Recommendations related to prevention of vertical transmission of HIV, syphilis and HBV have been reworded to be more gender inclusive.

<sup>15</sup> Ibid.



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## Essential for impact: health interventions

### Prevention of STIs, HIV and viral hepatitis (cont.)

#### Hepatitis B vaccination

**Existing WHO position** WHO recommends hepatitis B vaccination of persons at high risk of HBV infection.<sup>16</sup>

Please find further details in [WHO position paper: Hepatitis B vaccines: – July 2017](#)

**Existing GRADE recommendation** It is suggested to offer people who inject drugs the rapid hepatitis B vaccination regimen<sup>17</sup> (*conditional recommendation, very low certainty of evidence*) (168).

#### Addressing chemsex



#### New good practice statement

Addressing chemsex\*, especially for key populations and their sexual partners, requires a comprehensive, non-judgemental and person-centred approach. This can include integrated sexual and reproductive health, mental health, access to sterile needles and syringes and OAMT services, with linkages to other evidence-based prevention, diagnostic and treatment interventions.

\*Chemsex, for the purpose of these guidelines, is defined as when individuals engage in sexual activity, while taking primarily stimulant drugs, typically involving multiple participants and over a prolonged period.

Further details on evidence, decision-making, implementations, considerations and research gaps related to this new recommendation can be found in [Chapter 9](#).

#### Diagnosis

##### HIV testing services

**Existing guidance statement** In high and low HIV-burden settings, HIV testing should be offered to all key populations and their partners in all services as an efficient and effective way to identify people with HIV (175).

**Existing guidance statement** It is recommended to offer retesting at least annually to all people from key populations. Depending on individual risk behaviours, more frequent voluntary retesting can be offered (175).

Mathematical modelling among key populations in Viet Nam shows that retesting for key populations is cost effective. Bi-annual testing for key populations may be considered in similar settings, and should prioritize those at higher risk (179).

<sup>16</sup> Including key populations, persons with chronic liver disease, including those with hepatitis C, persons with HIV infection, and sexual contacts of persons with chronic HBV infection, as well as health care workers and others who may be exposed to blood, blood products or other potentially infectious body fluids.

<sup>17</sup> While this recommendation includes only people who inject drugs, this approach may be appropriate for all key populations receiving HBV vaccination.



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## Essential for impact: health interventions

### Diagnosis (cont.)

#### HIV testing services (cont.)

**Existing GRADE recommendation** Community-based HIV testing services for key populations linked to prevention, treatment and care services are recommended, in addition to routine, facility-based HIV testing services in all settings (*strong recommendation, low certainty of evidence*) (175).

**Existing GRADE recommendation** Lay providers who are trained can, using rapid diagnostic tests, independently conduct safe and effective HIV testing services (*strong recommendation, moderate certainty of evidence*) (175).

**Existing GRADE recommendation** HIV self-testing should be offered as an approach to HIV testing services (*strong recommendation, moderate certainty of evidence*) (175).  
*Please note that self-testing means an individual performing a test on themselves in private or under observation of a professional if they so desire. It should be voluntary and cannot be forced or coerced by anyone. Importantly, people who have self-tested should not be forced to disclose the results of that test to anyone, and should only do so on a voluntary basis.*

**Existing GRADE recommendation** Social network-based approaches can be offered as an approach to HIV testing key populations as part of a comprehensive package of care and prevention (*conditional recommendation, very low certainty of evidence*) (175).

**Existing GRADE recommendation** Provider-assisted referral should be offered for all people with HIV as part of a voluntary comprehensive package of testing and care (including key populations) (*strong recommendation, moderate certainty of evidence*) (175).  
*Please note that particularly for sex workers, the risks associated with disclosing an HIV diagnosis to either clients or regular partners must be carefully considered and should always be voluntary. People who are experiencing intimate partner or other violence need assessment, support, documentation, treatment of any injuries and referral to appropriate services (162).*

**Existing guidance statement** Dual HIV/syphilis RDTs may be considered for use among key populations and can increase access to both HIV and syphilis testing services (181).  
Further testing to confirm syphilis diagnosis or offer of treatment depends on local epidemiology, past treatment history, available resources and confirmatory testing capacity, and national protocols.  
Mathematical modelling among key populations in Viet Nam shows that using dual HIV/syphilis RDT is cost-saving compared to separate HIV and syphilis tests at current coverage (179).

For detailed guidance on HIV testing, please see [Consolidated guidelines on HIV testing services](#).





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## Essential for impact: health interventions

### Diagnosis (cont.)

#### STI testing

<b>Existing guidance statement</b>	Screening and diagnosing STIs for key populations is a crucial part of a comprehensive response to HIV and STIs (3).
<b>Existing GRADE recommendation</b>	Offering periodic testing for asymptomatic urethral and rectal <i>N. gonorrhoeae</i> and <i>C. trachomatis</i> infections using nucleic acid amplification tests (NAAT) is suggested over not offering such testing for men who have sex with men and trans and gender diverse people ( <i>conditional recommendation, low certainty of evidence</i> ) (79).
<b>Existing GRADE recommendation</b>	Offering periodic serological testing for asymptomatic syphilis infection to men who have sex with men and trans and gender diverse people is strongly recommended over not offering such screening ( <i>strong recommendation, moderate certainty of evidence</i> ) (79).
<b>Existing GRADE recommendation</b>	WHO suggests offering periodic screening for asymptomatic sexually transmitted infections* to sex workers ( <i>conditional recommendation, low certainty of evidence</i> ) (84).  *Chlamydia, gonorrhoea and syphilis
<b>Existing GRADE recommendation</b>	Self-collection of samples for <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> should be made available as an additional approach to deliver STI testing services ( <i>strong recommendation, moderate certainty of evidence</i> ) (182).
<b>Existing GRADE recommendation</b>	For people with symptoms of: 1) urethral discharge from the penis or 2) anorectal discharge and report receptive anal sex, management is recommended to be based on the results of quality-assured molecular assays. However, in settings with limited or no molecular tests or laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the same day of the visit ( <i>strong recommendation, moderate certainty of evidence</i> ) (183).
<b>Existing GRADE recommendation</b>	For people who present with genital ulcers (including anorectal ulcers), WHO recommends treatment based on quality-assured molecular assays of the ulcer. However, in settings with limited or no molecular tests or laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the same day of the visit ( <i>strong recommendation, moderate certainty of evidence</i> ) (183).
	For detailed guidance screening and diagnosis of different STIs please see: <a href="#">Guidelines for the management of symptomatic sexually transmitted infections</a> <a href="#">WHO guidelines for the treatment of <i>Neisseria gonorrhoeae</i></a> <a href="#">WHO guidelines for the treatment of <i>Treponema pallidum</i> (syphilis)</a> <a href="#">WHO guideline on syphilis screening and treatment for pregnant women</a> <a href="#">WHO guidelines for the treatment of <i>Chlamydia trachomatis</i></a> <a href="#">WHO guidelines for the treatment of genital herpes simplex virus</a>



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## Essential for impact: health interventions

### Diagnosis (cont.)

#### Hepatitis C testing

##### Existing GRADE recommendation

In all settings (and regardless of whether delivered through facility- or community-based or self-testing testing), it is recommended that serological testing for HCV antibody (anti-HCV) be offered, with linkage to prevention, confirmatory diagnosis, care and treatment services, to the following individuals (184):

- adults and adolescents from populations most affected by HCV infection (i.e., who are either part of a population with high HCV seroprevalence or who have a history of exposure and/or high-risk behaviours for HCV infection)<sup>18</sup>; and
- adults, adolescents and children with a clinical suspicion of chronic viral hepatitis C (i.e., symptoms, signs, laboratory markers).

(*strong recommendation, low certainty of evidence*).

For detailed guidance on HCV testing: how to test, how to confirm viraemic HCV infection and which assays to use, please see [Guidelines on hepatitis B and C testing](#).



##### New GRADE recommendation

People at ongoing risk and a history of treatment-induced or spontaneous clearance of HCV infection may be offered 3–6-monthly testing for presence of HCV viremia (*conditional recommendation, very low certainty of evidence*).

Remarks:

- Testing should be voluntary and not be used to further stigmatize any populations at ongoing risk.
- Testing should be offered alongside primary prevention services that are evidence-based and reduce transmission risks, and in combination with appropriate treatment access and linkage.
- To detect presence of viremic infection, the use of quantitative or qualitative nucleic acid testing (NAT) for detection of HCV RNA, or alternatively an assay to detect HCV core antigen, can be performed.

Further details on evidence, decision-making, implementation considerations and research gaps related to this new recommendation can be found in [Chapter 9](#).

##### Existing GRADE recommendation

HCV self-testing should be offered as an additional approach to HCV testing services (*strong recommendation, moderate certainty of evidence*) (185).

<sup>18</sup> Includes those who are either part of a population with higher seroprevalence (e.g., some mobile/migrant populations from high/intermediate endemic countries, and certain indigenous populations), or who have a history of exposure or high-risk behaviours for HCV infection (e.g., people who inject drugs, people in prisons and other closed settings, men who have sex with men and sex workers, and HIV-infected persons, children of mothers with chronic HCV infection, especially if HIV-coinfected).



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## Essential for impact: health interventions

### Diagnosis (cont.)

#### Hepatitis B testing

##### Existing GRADE recommendation

In all settings (and regardless of whether delivered through facility- or community-based testing), it is recommended that HBsAg serological testing and linkage to prevention, care and treatment services be offered to the following individuals (184):

- adults and adolescents from populations most affected by HBV infection (i.e., who are either part of a population with high HBV seroprevalence or who have a history of exposure and/or high-risk behaviours for HBV infection);
- adults, adolescents and children with a clinical suspicion of chronic viral hepatitis (i.e., symptoms, signs, laboratory markers);
- all pregnant women (at least once and as early as possible, ideally at the first ANC visit); and
- sexual partners, children and other family members, and close household contacts of those with HBV infection.

*(strong recommendation, low certainty of evidence)*

For detailed guidance on HBV testing and diagnosis, please see [Guidelines on hepatitis B and C testing](#).

### Treatment

#### HIV treatment

##### Existing GRADE recommendation

ART should be initiated in all adults living with HIV, regardless of WHO clinical stage and at any CD4 cell count (*strong recommendation, moderate certainty of evidence*) (171).

For detailed guidance on HIV treatment, please see [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#).

Please also see the service delivery [chapter](#) for details of differentiated service delivery for ART.



##### New guidance statement

Successful ART with viral suppression prevents HIV transmission to sexual partners: there is no transmission when viral load is undetectable or suppressed (less than or equal to 1000 copies/ML) (186–188).



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## Essential for impact: health interventions

### Treatment (cont.)

#### HIV-associated TB

**Existing GRADE recommendation** People living with HIV should be systematically screened for TB disease at each visit to a health facility (*strong recommendation, very low certainty of evidence*) (189).

**Existing GRADE recommendation** ART should be started as soon as possible within two weeks of initiating TB treatment, regardless of CD4 cell count, among people living with HIV\* (*strong recommendation, low-moderate certainty of evidence for adults and adolescents, very low certainty of evidence for children*).

\*Except when signs and symptoms of meningitis are present

**Existing GRADE recommendation** WHO recommends ART for all people with HIV and drug-resistant TB, requiring second-line anti-TB drugs irrespective of CD4 cell count, as early as possible (within the first eight weeks) following initiation of anti-TB treatment (*strong recommendation, very low certainty of evidence*) (190, 191).

**Existing GRADE recommendation** Adults and adolescents living with HIV who are unlikely to have active TB should receive TB preventive treatment as part of a comprehensive package of HIV care. Treatment should also be given to those receiving ART, to pregnant women and to those who have previously been treated for TB, irrespective of the degree of immunosuppression, and even if TB infection testing is unavailable (*strong recommendation, high certainty evidence*) (192).

**Existing GRADE recommendation** Routine co-trimoxazole prophylaxis should be given to all people living with HIV with active TB disease regardless of CD4 cell count (*strong recommendation, high certainty of evidence*) (190).

For detailed guidance on TB/HIV, please see [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#).

WHO guidelines on TB can be accessed [here](#).

#### STI treatment

STIs disproportionately affect key populations and should be diagnosed and treated in a timely manner following WHO guidelines.

For detailed guidance on treating different STIs please see:

[Guidelines for the management of symptomatic sexually transmitted infections](#)

[WHO guidelines for the treatment of \*Neisseria gonorrhoeae\*](#)

[WHO guidelines for the treatment of \*Treponema pallidum\* \(syphilis\)](#)

[WHO guideline on syphilis screening and treatment for pregnant women](#)

[WHO guidelines for the treatment of \*Chlamydia trachomatis\*](#)

[WHO guidelines for the treatment of genital herpes simplex virus](#)



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## Essential for impact: health interventions

### Treatment (cont.)

#### HCV treatment

**Existing GRADE recommendation** WHO recommends offering treatment to all individuals diagnosed with HCV infection who are 12 years of age or older, irrespective of disease stage (*strong recommendation, moderate certainty of evidence*) (193).

**Existing GRADE recommendation** WHO recommends the use of pan-genotypic direct-acting antiviral (DAA) regimens for treatment of all adults, adolescents and children aged 3 years and above with chronic hepatitis C virus infection, regardless of stage of disease.

Adults (18 years and above): (*strong recommendation, moderate certainty of evidence*).

Adolescents (12–17 years): (*strong recommendation; moderate-low certainty of evidence*).

For detailed guidance on HCV treatment, please see:

[Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection](#) and,

[Updated recommendations on treatment of adolescents and children with chronic HCV infection and HCV simplified service delivery and HCV diagnostics](#)



#### **New GRADE recommendation**

Pan-genotypic DAA-HCV treatment should be offered without delay to people with recently acquired HCV infection and ongoing risk (*strong recommendation, very low certainty of evidence*).

Remarks:

- Individuals with recently acquired infection must have the option to make an informed choice about starting treatment immediately or delaying treatment initiation.
- Treatment for recently acquired infection should be offered alongside additional, evidence-based interventions to reduce HCV risk and primary prevention services.

Further details on evidence, decision-making, implementation considerations and research gaps related to this new recommendation can be found in the [Chapter 9](#).



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## Essential for impact: health interventions

### Treatment (cont.)

#### HBV treatment

**Existing GRADE recommendation** As a priority, all adults, adolescents and children with chronic hepatitis B and clinical evidence of compensated or decompensated cirrhosis (or cirrhosis based on APRI score >2 in adults) should be treated, regardless of ALT levels, HBeAg status or HBV DNA levels (194) (*strong recommendation, moderate certainty of evidence*).

**Existing GRADE recommendation** Treatment is recommended for adults with chronic hepatitis B who do not have clinical evidence of cirrhosis (or based on APRI score ≤2 in adults), but are aged more than 30 years (in particular), and have persistently abnormal ALT levels and evidence of high-level HBV replication (HBV DNA >20 000 IU/mL), regardless of HBeAg status (194) (*strong recommendation, moderate certainty of evidence*).

**Existing GRADE recommendation** Where HBV DNA is not available: Treatment may be considered based on persistently abnormal ALT levels alone, regardless of HBeAg status (194) (*conditional recommendation, low certainty of evidence*).

For detailed guidance on HBV treatment, please see [Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection](#).

## Essential for broader health: health interventions

#### Anal health



#### New guidance statement

WHO does not have specific recommendations about anal health or anal cancer, but people infected with HIV are at least 20 times more likely to be diagnosed with anal cancer than uninfected people (195). Like cancer of the cervix, anal cancer is associated with human papillomavirus (HPV) and HPV is vaccine-preventable for all people.<sup>19</sup>

Cytological screening can be performed for anal cancer and its precursors, known as anal high-grade squamous intraepithelial lesions, particularly for men who have sex with men, trans and gender diverse people and other people who are more likely to engage in anal sex.

#### Conception and pregnancy care

**Existing guidance statement (adapted)<sup>20</sup>** It is important that all members of key population groups have the same support and access to services related to conception and pregnancy care as pregnant people who are not members of key population groups, as indicated by WHO guidelines (3).

WHO has various guidelines on conception and pregnancy. Please see the [WHO maternal health webpage](#).

For specific recommendations related to pregnancy and HIV, please see [Consolidated guideline on sexual and reproductive health and rights of women living with HIV](#).

<sup>19</sup> Achieving high HPV vaccination coverage in girls (>80%) reduces the risk of HPV infection for boys. Vaccination of secondary target populations, e.g., females aged ≥15 years or males, is recommended only if this is feasible, affordable, cost-effective, and does not divert resources from vaccination of the primary target population or from effective cervical cancer screening programmes (196).

<sup>20</sup> This guidance statement has been reworded to be more gender inclusive.





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## Essential for broader health: health interventions

### Contraception

WHO does not have an overarching recommendation related to contraception for key populations, but publishes medical eligibility criteria for contraceptive use (MEC), which provides guidance on the safety of various contraceptive methods for use in the context of specific health conditions and characteristics (197).

#### Existing guidance statement

All hormonal contraceptive methods and intrauterine devices (IUDs) now fall into Category 1 of the MEC for women at high risk of HIV. Thus, women at high risk of HIV can use all methods of contraception without restriction.

For detailed guidance on contraception, please see:

[Medical eligibility criteria for contraceptive use](#)

[Selected practice recommendations for contraceptive use](#)

[Contraceptive eligibility for women at high risk of HIV](#)

Please see also the [service delivery chapter](#) for details of integrating HIV, family planning and STI services.

### Gender-affirming care<sup>21</sup>

#### Existing guidance statement

Trans and gender diverse individuals who self-administer gender-affirming hormones require access to evidence-based information, quality products and sterile injection equipment (182).

The principles of gender equality and human rights in the delivery of quality gender-affirming hormones are critical to expanding access to this important intervention and reducing discrimination based on gender identity (182).

### Mental health

#### Existing guidance statement

Routine screening and management for mental health issues (particularly depression and psychosocial stress) should be provided for people from key populations in keeping with the principles of consent, confidentiality and evidence-based quality (3).

WHO does not have overarching recommendations related to preventing or treating mental health issues for key populations. Instead, specific mental health issues and recommendations and a practical guide on addressing mental health issues in non-specialized health settings is provided by the mental health gap action programme (MhGAP):

[MhGAP Evidence Resource Centre](#)

[MhGAP intervention guide](#)

<sup>21</sup> WHO guidelines on health services for trans and gender diverse people are under development at the time of writing. They should be available in 2023.



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## Essential for broader health: health interventions

### Prevention, assessment and treatment of cervical cancer

**Existing WHO position** WHO recommends that all countries proceed with nationwide introduction of HPV vaccination.

For the prevention of cervical cancer, the WHO-recommended primary target population for HPV vaccination is girls aged 9–14 years, prior to becoming sexually active. Vaccination strategies should initially prioritize high coverage in this priority population (196).

**Existing GRADE recommendation** HPV self-sampling should be made available as an additional approach to sampling in cervical cancer screening services for individuals aged 30–60 years (*strong recommendation, moderate certainty of evidence*) (182).

**Existing guidance statement** All people with a female reproductive system are at risk for cervical cancer. Recommendations for cervical cancer prevention, screening and treatment can be found in the WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, which includes 16 new and updated recommendations and good practice statements for women living with HIV (198, 199).

For detailed guidance on cervical cancer prevention, screening and treatment, please see:

[WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention](#)

[New WHO recommendations on screening and treatment to prevent cervical cancer among women living with HIV](#)

### Safe abortion

**Existing guidance statement** Abortion laws and services should protect the health and human rights of all women, including those from key populations (3).

**Existing GRADE recommendation** WHO recommends the full decriminalization of abortion; recommends against laws and other regulations that restrict abortion by grounds; recommends that abortion be available on the request of the woman, girl or other pregnant person; and recommends against laws and other regulations that prohibit abortion based on gestational age limits (*strong recommendations*) (200).

For detailed guidance on safe abortion, please see [Abortion care guideline](#).

### Screening and treatment for hazardous and harmful alcohol and other substance use

**Existing GRADE recommendation (adapted)<sup>22</sup>** All key populations with hazardous and 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 certainty of evidence*) (3, 201, 202).

For details on recommended, evidence-based interventions for the screening and treatment of hazardous and harmful drug and alcohol use please see:

[MhGAP Evidence Resource Centre](#)

[MhGAP intervention guide](#)

[The Alcohol, Smoking and Substance Involvement Screening Test \(ASSIST\)](#)

[International standards for the treatment of drug use disorders](#)

<sup>22</sup> The original wording of the recommendation was: 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.



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## Essential for broader health: health interventions

### TB prevention, screening, diagnosis and treatment

**Existing GRADE recommendation** Systematic screening for TB disease should be conducted in prisons and penitentiary institutions (*strong recommendation, very low certainty of evidence*) (189).

**Existing GRADE recommendation** Systematic screening for TB disease may be conducted among subpopulations with structural risk factors for TB. These include urban poor communities, homeless communities, communities in remote or isolated areas, indigenous populations, migrants, refugees, internally displaced persons and other vulnerable or marginalized groups with limited access to health care (*conditional recommendation, very low certainty of evidence*) (189).

**Existing GRADE recommendation** Systematic TB infection testing and treatment may be considered for people in prisons, health workers, immigrants from countries with a high TB burden, homeless people and people who use drugs (*conditional recommendation, low to very low certainty in the estimates of effect*) (192).

### TB prevention, screening, diagnosis and treatment

**Existing GRADE recommendation** In settings where the TB prevalence in the general population is 100/100 000 population or higher, systematic screening for TB disease may be conducted among people with a risk factor for TB\* who are either seeking health care or who are already in care (*conditional recommendation, very low certainty of evidence*) (189).

\*Substance use disorders and alcohol use disorders are considered risk factors.

Additional guidance on TB prevention, screening, diagnosis and treatment is available:

[Consolidated guidelines on tuberculosis Module 1:](#)

[Prevention: Tuberculosis preventive treatment](#)

[Consolidated guidelines on tuberculosis Module 2:](#)

[Screening – Systematic screening for tuberculosis disease](#)

[Consolidated guidelines on tuberculosis Module 3:](#)

[Diagnosis – Rapid diagnostics for tuberculosis detection](#)

[Consolidated guidelines on tuberculosis Module 4:](#)

[Treatment – Drug-resistant tuberculosis treatment](#)



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## Supportive interventions

Behavioural interventions, counselling, demand creation, information and education can all support the interventions listed above. In the development of this guideline, we did not find evidence for the effectiveness of counselling behavioural interventions that aim to change risk behaviours (see below).

While we did not review evidence related to other types of behavioural or supportive interventions, and there is limited WHO guidance on these interventions, they may be helpful depending on the context and population. These include:

- information and education which support key populations to understand their health, health risks, available services and legal rights;
- interventions which aim to increase demand (demand creation) for evidence-based HIV, viral hepatitis and STI services;
- supportive counselling which does not aim to change behaviours; and
- counselling for mental health issues.

In general, the structural barriers which are described in the previous [chapter](#) make changing behaviours and improving uptake and retention in services for key populations difficult, and these should be addressed as a priority.

### Behavioural interventions



#### New good practice statement

When planning and implementing a response for HIV, viral hepatitis and STIs, policy-makers and providers should be aware that counselling behavioural interventions that aim to change behaviours to reduce risks associated with these infections for key populations have not been shown to have an effect on HIV, viral hepatitis and STI incidence nor on risk behaviour such as condom use and needle sharing. Counselling and information-sharing, not aimed at changing behaviours, can be a key component of engagement with key populations, and when provided it should be in a non-judgmental manner, alongside other prevention interventions and with involvement of peers.

Remarks:

- Addressing structural and social barriers is critical to create environments which permit supportive and impactful counselling.
- Counselling interventions which promote abstinence from drug use, rehabilitation or cessation of sex work or drug use, or a so-called cure for homosexuality or gender incongruence (for example, so-called conversion therapy)\* are not recommended, and create barriers to key population service access.

\* Compulsory, or involuntary, treatment for drug dependence, so-called conversion therapy or rehabilitation of sex workers is against human rights and medical ethics principals of consent, freedom from arbitrary arrest, access to quality health, freedom from torture and cruel, inhuman and degrading treatment.

Further details on evidence, decision-making, implementation considerations and research gaps related to this new practice statement can be found in [Chapter 9](#).



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# CHAPTER 5

Packages by key population





## Introduction

This chapter presents the above-recommended interventions as packages per key population. It should be noted that there is much cross over between key populations; for example, sex workers who inject drugs and men who have sex with men who sell sex, and for those people, additional interventions to the ones presented below may be needed. Person-centred care means assessing each person's health needs and providing evidence-based interventions in an integrated and accessible way. The tables of packages below are provided as guidance only.

## Sex workers

### Background

Sex workers include female, male, trans and gender diverse 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 (3, 84). Increasingly, sex workers are meeting and staying in contact with their clients online.

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 (203, 204). (Please see [Chapter 7](#) on young key populations.)

Sex workers in many places are highly vulnerable to HIV and STIs due to multiple factors, including large numbers of sex partners, unsafe working conditions, barriers to the negotiation of consistent condom use, and intersecting social determinants of poor health. These include lack of social protection and housing, food insecurity, reduced education opportunities and disability. Moreover, sex workers often have reduced control over these factors due to structural barriers that increase their risk of unprotected sex and reduce access to health services (please see the [chapter on critical enablers](#)). In particular, sex workers may be harassed by law enforcement officers, including the practice of officers confiscating and using condoms and mobile phones as evidence of sex work; be subjected to violence from law enforcement officers, clients and intimate partners; and experience stigma and discrimination in health and other settings. As a result, sex workers are disproportionately affected by HIV and STIs. For the most recent data related to HIV, syphilis and sex workers, please access UNAIDS [Key Populations Atlas](#).

The recommended package of interventions for sex workers includes enabling interventions that should be implemented as a priority, including the decriminalization of sex work (namely, removing all offences that criminalize sex workers, clients and third parties). Addressing these barriers would not only ensure sex workers' human rights, but also have an impact on HIV, STIs and viral hepatitis in all settings where sex work is criminalized and sex workers experience stigma, discrimination and violence (68, 75). Other essential interventions are health interventions related to HIV and STI prevention, testing and treatment.

The majority of participants in the key populations values and preferences qualitative research (for the detailed report, please see [Web Annex B](#)) were opposed to the periodic presumptive treatment (PPT) of STIs, citing both health and ethical concerns. Participants noted an array of potential health risks associated with prolonged antibiotic use, including antibiotic resistance, kidney damage, depression and impacts on vaginal health. Additionally, participants expressed concerns surrounding the ethical implications of PPT and its role in perpetuating stigma and vulnerability. Others attested to the role of PPT in reinforcing stereotypes of sex workers as vectors of disease. Rather than offering sex workers PPT for STIs, participants stressed the need for increased access to STI testing and evidence-based prevention methods. For these reasons, the recommendation to provide PPT for STIs for sex workers is not included in these guidelines. If sex workers wish to prevent STI acquisition through PPT, this should always be voluntary, in full understanding of the potential complications, only in settings where aetiological diagnosis is not possible, and in consultation with health care providers.





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WHO recommends expanding access to aetiological diagnosis of STIs for sex workers as a priority, as well as suggesting offering periodic screening for asymptomatic STIs to sex workers. Offering voluntary periodic screening for HIV and the other main curable STIs, such as syphilis, gonorrhoea and chlamydia, is particularly relevant for sex workers, due to the severe consequences of STIs, including infertility. In cases of pregnancy, untreated STIs can also lead to severe adverse pregnancy outcomes, such as prematurity, neonatal death, low-birth weight and congenital anomalies. WHO has specific recommendations for the treatment of the main STIs, suppressive therapy for genital herpes, and for the management of syndromes when the aetiology cannot be investigated for the most appropriate treatment (183).

While evidence of increased prevalence of HCV and HBV in men who have sex with men is clear (12), concerns about viral hepatitis in female and trans and gender diverse sex workers are new and emerging, and there is little data available to understand global prevalence of HBV and HCV among these populations. For female and trans and gender diverse sex workers who are living with HIV, there may be an increased risk of HCV and HBV (205), although evidence is scarce, and additional small studies have shown increased risk for mono-infections (18). However, HCV prevalence is high in people who inject drugs (206) and in people in prisons (207), and there is considerable intersection between female and trans and gender diverse sex workers and these other key populations, indicating a need to ensure access to viral hepatitis prevention, testing and treatment for these groups. For this reason, viral hepatitis prevention, testing and treatment are included in the package of essential health interventions for all sex workers.

Other health issues are of particular concern to sex workers, including: those related to sexual and reproductive health (safe abortion, contraception, conception and antenatal care); those related to cervical and anal cancer prevention; and those related to screening and treatment for mental health issues, and for hazardous or harmful alcohol and substance use. In particular, the results of qualitative research undertaken by four global networks of key populations showed that addressing mental health was a priority for key populations. While global data on TB among sex workers is not available, sex workers who live and work in cramped conditions may be at increased risk of TB. These are essential interventions to address broader health beyond HIV, STIs and viral hepatitis, and access for key populations should be ensured.

The package of essential interventions for sex workers does not include those that are specifically related to HIV and viral hepatitis prevention for people who inject drugs (namely, NSPs, OAMT and naloxone for overdose management), or to gender-affirming care for trans and gender diverse people. However, for sex workers who inject drugs or who are trans and gender diverse, these are relevant interventions that should be made available, as outlined in the specific packages for these key populations.



# Recommended package for sex workers

These interventions are not in order of priority.

## Essential for impact: enabling interventions

- Removing punitive laws, policies and practices
- Reducing stigma and discrimination
- Community empowerment
- Addressing violence

## Essential for impact: health interventions

### Prevention of HIV, viral hepatitis and STIs

- Condoms and lubricant
- Pre-exposure prophylaxis for HIV
- Post-exposure prophylaxis for HIV and STIs
- Prevention of vertical transmission of HIV, syphilis and HBV
- Hepatitis B vaccination
- Addressing chemsex

### Diagnosis

- HIV testing
- STI testing
- Hepatitis B and C testing

### Treatment

- HIV treatment
- Screening, diagnosis, treatment and prevention of HIV associated TB
- STI treatment
- HBV and HCV treatment

## Essential for broader health: health interventions

- Anal health
- Conception and pregnancy care
- Contraception
- Mental health
- Prevention, assessment and treatment of cervical cancer
- Safe abortion
- Screening and treatment for hazardous and harmful alcohol and other substance use

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## People who inject drugs

### Background

People who inject drugs refers to people who inject psychoactive substances for non-medical purposes. These drugs include, but are not limited to, opioids, amphetamine-type stimulants, cocaine and hypno-sedatives including new psychoactive substances.<sup>23</sup> 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. While these guidelines focus on people who inject drugs because of their specific risk of HIV and HCV transmission, due to the sharing of blood-contaminated injection equipment, much of this guidance is also relevant for people who use substances through other routes of administration, such as snorting, smoking and ingestion (3).

In many countries drug use or possession is criminalized, and in almost every country it is considered immoral and significant stigma and discrimination is experienced by people who use drugs (please see the [critical enablers chapter](#)). At the time of writing there is extremely low coverage of the evidence-based package of NSPs and OAMT (208). As a direct result, people who inject drugs are disproportionately affected by HIV and viral hepatitis. For most recent data related to HIV, viral hepatitis and people who inject drugs, please access UNAIDS [Key Populations Atlas](#), the [World Drug Report](#) and the [Global state of harm reduction](#).

For impact on HIV and viral hepatitis, structural barriers for people who inject drugs need to be addressed, including decriminalizing drug use and possession for personal use, ending forced detention in compulsory drug treatment centres, addressing violence, stigma and discrimination, and empowering communities of people who use drugs. People who use drugs in particular face additional barriers to accessing health services where cessation of drug use is a condition for eligibility. Women who inject drugs may be more stigmatized than their male counterparts, and many sell sex to pay for both their and their partner’s drugs. Fear of losing custody of their children may make mothers who inject drugs less likely to access reproductive and other health services (209). They may experience more police harassment and violence than men who inject drugs. The impact of these barriers on HIV and viral hepatitis acquisition is clear (64, 73, 210), and for this reason the enabling interventions listed in the table below are considered essential for impact for people who inject drugs.

Harm reduction is one of the key elements of a public health promotion framework (or response) that has been proven highly effective in reducing and mitigating the harms of injecting drug use for individuals and communities. WHO defines harm reduction as a comprehensive package of evidence-based interventions, based on public health and human rights, including NSPs, OAMT and naloxone for overdose management. Harm reduction also refers to policies and strategies that aim to prevent major public and individual health harms, including HIV, viral hepatitis and overdose, without necessarily stopping drug use.

High prevalence and incidence of HIV and viral hepatitis B and C in people who inject drugs call for countries to prioritize the provision of HIV and viral hepatitis prevention (particularly NSPs, OAMT and naloxone for overdose management), testing and treatment interventions.

Pre-exposure prophylaxis (PrEP) is an evidence-based HIV prevention intervention. Although there is strong evidence that PrEP is highly protective for sexual HIV transmission, evidence is more limited for the prevention of parenteral HIV transmission. PrEP services for people who inject drugs and their sexual partners can provide benefits both in the prevention of sexual transmission, and likely in the prevention of HIV, acquired through unsafe injection practices. PrEP services should

<sup>23</sup> UNODC uses the term “new psychoactive substances” which are defined as “substances of abuse, either in a pure form or a preparation, that are not controlled by the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, but which may pose a public health threat” (2).

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not replace NSPs. NSPs have the greatest impact in preventing the transmission of HIV and other bloodborne infections, including HCV associated with injecting drug use.

More research is needed on the values and preferences of people who inject drugs on PrEP as part of comprehensive HIV prevention approaches, and on how to best deliver PrEP services for this population to improve uptake and effective use (including through comprehensive and integrated community-based delivery models).

While global estimates of STIs among people who inject drugs are not known, people who inject and use drugs may be at increased risk of STIs, particularly those engaging in chemsex or those using stimulants. Values and preferences research showed a strong preference for STI services among women who inject drugs. For this reason, people who inject drugs should have access to STI testing, diagnosis and treatment.

People who inject drugs are at increased risk of TB, irrespective of their HIV status, and TB is a leading cause of HIV-related mortality among people who inject drugs (211, 212). For this reason, TB prevention, screening, diagnosis and treatment are included in the package of interventions essential for broader health of people who inject drugs. Other common health issues related to unsafely injecting drugs include nerve and vein damage, abscesses and skin infections.





# Recommended package for people who inject drugs

These interventions are not in order of priority.

## Essential for impact: enabling interventions

Removing punitive laws, policies and practices

Reducing stigma and discrimination

Community empowerment

Addressing violence

## Essential for impact: health interventions

### Prevention of HIV, viral hepatitis and STIs

Harm reduction (NSPs, OAMT and naloxone for overdose management)

Condoms and lubricant

Pre-exposure prophylaxis for HIV<sup>24</sup>

Post-exposure prophylaxis for HIV and STIs

Prevention of vertical transmission of HIV, syphilis and HBV

Hepatitis B vaccination

Addressing chemsex

### Diagnosis

HIV testing

STI testing

Hepatitis B and C testing

### Treatment

HIV treatment

Screening, diagnosis, treatment and prevention of HIV associated TB

STI treatment

HBV and HCV treatment

## Essential for broader health: health interventions

Conception and pregnancy care

Contraception

Mental health

Prevention, assessment and treatment of cervical cancer

Safe abortion

Screening and treatment for hazardous and harmful alcohol and other substance use

TB prevention, screening, diagnosis and treatment

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<sup>24</sup> Please note, results of qualitative research found that people who inject drugs prioritize access to harm reduction (NSPs, OAMT and naloxone for overdose management) over PrEP.





## Men who have sex with men

### Background

Men who have sex with men refers to all men who engage in sexual relations with other men. The words **men** and **sex** can be 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.

Men who have sex with men are disproportionately affected by HIV, hepatitis C (12), hepatitis B (213) and STIs (28, 31, 214). Hepatitis A outbreaks among men who have sex with men are common (215–219) and could be prevented with vaccination. This heightened risk is in part due to greater efficiency of transmission of the three disease groups through unprotected anal sex and syndemic features, such as increased risk of HIV acquisition in those with STIs (221), or increased risk of HCV acquisition in men who have sex with men who live with HIV (12).

Some men who have sex with men may also engage in chemsex – defined as when individuals engage in sexual activity while taking primarily stimulant drugs, typically involving multiple participants and over a prolonged time, which increases risk to all three infectious disease groups when there is no access to, and use of, prevention, diagnosis and treatment services.

Persistent structural barriers, such as criminalization of male-to-male consensual sex, stigma, discrimination and violence against men who have sex with men, reduces access to prevention, testing and treatment services, contributing to increased risk of infection (please see the [critical enablers chapter](#)).

The essential package of interventions for men who have sex with men includes enabling interventions to address structural barriers as a priority, including the decriminalization of same-sex intimacy. Essential health interventions for impact on HIV, STIs and viral hepatitis include prevention, such as PrEP, diagnosis and treatment for the three disease groups. Men who have sex with men who inject drugs also need access to harm reduction interventions (NSPs, OAMT and naloxone for overdose management).

Those interventions essential for broader health, and to which access for men who have sex with men should be ensured, include screening and treating mental health, and hazardous or harmful alcohol and drug use. Additionally, given the disproportionate rates of anal cancers among men who have sex with men, screening and treatment for anal cancer should be considered for men who have sex with men.

For most recent data related to HIV, syphilis and men who have sex with men, please access UNAIDS [Key Populations Atlas](#).

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# Recommended package for men who have sex with men

These interventions are not in order of priority.

## Essential for impact: enabling interventions

Removing punitive laws, policies and practices

Reducing stigma and discrimination

Community empowerment

Addressing violence

## Essential for impact: health interventions

### Prevention of HIV, viral hepatitis and STIs

Condoms and lubricant

Pre-exposure prophylaxis for HIV

Post-exposure prophylaxis for HIV and STIs

Prevention of vertical transmission of HIV, syphilis and HBV

Hepatitis B vaccination

Addressing chemsex

### Diagnosis

HIV testing

STI testing

Hepatitis B and C testing

### Treatment

HIV treatment

Screening, diagnosis, treatment and prevention of HIV associated TB

STI treatment

HBV and HCV treatment

## Essential for broader health: health interventions

Anal health

Mental health

Screening and treatment for hazardous and harmful alcohol and other substance use

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## Trans and gender diverse people

### Background

Trans and gender diverse people is an umbrella term for those whose gender identity, roles 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 nonconforming or gender incongruent. Trans and gender diverse people may self-identify as transgender, female, male, transwoman or transman, trans-sexual or one of many other gender nonconforming identities. They may express their genders in a variety of masculine, feminine and/or androgynous ways. The high vulnerability and specific health needs of trans and gender diverse people necessitates a distinct and independent status in the global HIV response (3, 222).

Trans and gender diverse people experience structural barriers such as criminalization, stigma and discrimination, as do all key populations, but experience very high rates of sexual and physical violence (223–226). High levels of stigma and discrimination against trans and gender diverse people in health care settings have been widely reported (100). Violence and stigma and discrimination increase vulnerability to substance use disorders, eating disorders, depression, suicide attempts, HIV and other sexually transmitted infections, among others, and compromise trans and gender diverse people's access and utilization of health services (101, 102, 222). Depression, for example, has been reported to affect more than half of the trans and gender diverse population in certain settings (222), and their quality of life has been shown to be significantly poorer than that of the general population prior to receiving hormonal treatment, when desired (227). Additionally, there are specific barriers caused by the lack of legal recognition of other gender identities and expressions, which hinder access to health and other services, and limit entry into both public and private health insurance schemes. In particular, gender-sensitive care for trans and gender diverse people is often not available, with health care providers untrained regarding the specific needs of trans and gender diverse people (228).

Trans and gender diverse people are disproportionately affected by HIV and STIs (30, 229). While data are limited, studies have also shown high prevalence of viral hepatitis B and C in trans and gender diverse people (20). For the most recent data related to HIV, syphilis and trans and gender diverse people, please access UNAIDS [Key Populations Atlas](#).

Gender-affirming care can include any of the following: hormone therapy; upper (for example, face, chest, breast) surgery; and/or lower (for example, vaginoplasty, phalloplasty, metoidioplasty, etc.) surgery. Gender affirmation is often a priority intervention for the trans and gender diverse community, but access is often hindered by poor availability, high cost and exclusion of gender-affirming interventions from national health service packages. Administration of industrial-grade silicone or other illicit subcutaneous injections, as well as non-medical-grade fillers, are reported to be common, especially in low- and middle-income countries (LMICs) (231, 232). These interventions can cause body disfigurement, skin damage, allergic reactions, thrombosis, pulmonary silicone embolism and severe autoimmune and connective tissue disorders, among others (233). Likewise, the use of unsafe and unregulated hormones was reported to be very common among trans and gender diverse people (234).

It is important that hormones administered for gender affirmation remain within appropriate physiological levels to avoid negative health consequences, and trans and gender diverse people who self-administer hormones need access to evidence-based information, products and sterile injection equipment (182, 235). Moreover, other non-medical body modification strategies are often used by both youth and adult trans and gender diverse people, including genital tucking and chest binding; little research has described either the prevalence or health risks and benefits of these methods of gender affirmation (235).

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The recommended package of interventions for trans and gender diverse people includes enabling interventions that should be implemented as a priority to address barriers, in particular, recognizing gender diversity in laws, policies and practices.

The health intervention package reflects the complex and varied needs of trans and gender diverse people. Trans and gender diverse people need access to the entire range of HIV, viral hepatitis and STI prevention, testing and treatment interventions for greatest impact. These interventions include access to prevention of vertical transmission of HIV, HBV and syphilis for pregnant trans and gender diverse people; and include harm reduction (NSPs, OAMT and naloxone for overdose management) for trans and gender diverse people injecting drugs, including the injection of hormones and other products, such as silicon gel, for gender affirmation. Interventions for broader health include sexual and reproductive health interventions; screening for and treating hazardous or harmful drug and alcohol use and mental health issues; and preventing, assessing and treating cervical and anal cancers. Access to safe and evidence-based gender-affirming care should be seen as central to trans and gender diverse people's broader health, as well as an important entry point for HIV, STI and viral hepatitis health services, and other health services in general.

The international classification of diseases (ICD-11) has redefined gender identity-related health as gender incongruence, and has reclassified gender incongruence as a condition related to sexual health rather than a mental and behavioural disorder (236). This reflects evidence that trans and gender diverse identities are not conditions of mental ill health and classifying them as such can cause enormous stigma. Inclusion of gender incongruence in the ICD should ensure trans and gender diverse people's access to gender-affirming health care, as well as adequate health insurance coverage for such services.



# Recommended package for trans and gender diverse people

These interventions are not in order of priority.

## Essential for impact: enabling interventions

Removing punitive laws, policies and practices

Reducing stigma and discrimination

Community empowerment

Addressing violence

## Essential for impact: health interventions

### Prevention of HIV, viral hepatitis and STIs

Condoms and lubricant

Pre-exposure prophylaxis for HIV

Post-exposure prophylaxis for HIV and STIs

Prevention of vertical transmission of HIV, syphilis and HBV

Hepatitis B vaccination

Addressing chemsex

### Diagnosis

HIV testing

STI testing

Hepatitis B and C testing

### Treatment

HIV treatment

Screening, diagnosis, treatment and prevention of HIV associated TB

STI treatment

HBV and HCV treatment

## Essential for broader health: health interventions

Anal health

Conception and pregnancy care

Contraception

Gender-affirming care

Mental health

Prevention, assessment and treatment of cervical cancer

Safe abortion

Screening and treatment for hazardous and harmful alcohol and other substance use

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## People in prisons and other closed settings

### Background

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; included are adult and juvenile males, and females and trans and gender diverse people, who are detained 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, including people who use drugs and sex workers. Nonetheless, most of the considerations in these guidelines may apply to these populations as well (3). Prison staff are also affected by HIV, viral hepatitis, STIs and other health issues, and may lack access to health services, particularly if they live in prison compounds without health services (237).

People in prison are disproportionately affected by HIV (212), hepatitis B and C (207, 238) and TB (11, 212). This is, in part, due to the crossover between other key populations, particularly considering the criminalization of behaviours such as drug use, drug possession and sex work, and their overrepresentation in prison populations. Besides this, there is the transmission of HIV and viral hepatitis within prison through unprotected sex, sexual violence, sharing injection equipment, tattooing or parent-to-child transmission. HIV and hepatitis prevention interventions are often unavailable in prisons, although the risks persist (239). There is a frequent intersection with people in prisons and those who are poor, have little education, and come from socioeconomically deprived sectors of the population, and in many prisons there is an overrepresentation of racial minorities. In particular, the prevalence of substance use and dependence in prison populations is much higher than in the community, particularly for women (240–242).

People in prisons also have high exposure to TB, including multi-drug resistant TB, because of factors including overcrowding, poor ventilation and poor infection control practices. Assuring equitable access to TB services for all people in prisons, regardless of HIV status, is critical for reducing increased burden of HIV-associated TB among people in prisons. Contributing to poor health of people in prisons are: limited access to health care, with delays in diagnosis (due to insufficient laboratory capacity and diagnostic tools); inadequate treatment; frequent transfer of people in prisons between prisons, without continuity of treatment; and poor nutrition. Additionally, after release from prison there is often little support for ongoing health and social care.

For most recent data related to HIV and people in prisons and other closed settings, please access UNAIDS [Key Populations Atlas](#).

The right to equivalent health services for people in prisons (namely, equivalent to that available outside of prisons) is enshrined in several internationally recognized documents (243), and respect for these should be reflected in prison policies and practices. Violence in prisons is common and often clandestine because of the fear of reprisal when it is reported, therefore it is easily overlooked or underestimated (244). Structural barriers within prisons, in particular regarding violence, where it is also important to develop measures for safe reporting and protection of victims, need to be urgently addressed, and are essential and priority interventions for impact.

People in prisons are adolescents, adults, male, female, trans and gender diverse and have urgent, varied and complex health needs. For impact on HIV, viral hepatitis and STIs, the package of interventions which prevent, diagnose and treat these diseases is essential, and should be provided within prisons and other closed settings, with continuity during inter- and intra-prison transfers and after release. This package should include condoms and lubricant and harm reduction

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interventions (NSPs, OAMT and naloxone for overdose management), given that drug use is prevalent in prisons.

People in prisons have broader health needs, and the package of interventions includes mental health and hazardous or harmful drug and alcohol use screening and treatment; sexual and reproductive health interventions; and prevention, screening and treatment of cervical and anal cancers. Importantly, TB prevention, screening and treatment should be implemented in all prisons and closed settings.

UNODC recommends a package of 15 interventions for HIV prevention, diagnosis and treatment for people in prisons (245). These guidelines address multiple disease areas and present a different package, although almost all the 15 UNODC recommended interventions are included here.<sup>25</sup>

<sup>25</sup> Interventions included in the UNODC package which are not included here are: Prevention of transmission through medical and dental services and Protecting staff from occupational hazards.





# Recommended package for people in prisons and other closed settings

These interventions are not in order of priority.

## Essential for impact: enabling interventions

Removing punitive laws, policies and practices

Reducing stigma and discrimination

Community empowerment

Addressing violence

## Essential for impact: health interventions

### Prevention of HIV, viral hepatitis and STIs

Harm reduction (NSPs, OAMT and naloxone for overdose management)

Condoms and lubricant

Pre-exposure prophylaxis for HIV

Post-exposure prophylaxis for HIV and STIs

Prevention of vertical transmission of HIV, syphilis and HBV

Hepatitis B vaccination

Addressing chemsex

### Diagnosis

HIV testing

STI testing

Hepatitis B and C testing

### Treatment

HIV treatment

Screening, diagnosis, treatment and prevention of HIV associated TB

STI treatment

HBV and HCV treatment

## Essential for broader health: health interventions

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Conception and pregnancy care

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Mental health

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Screening and treatment for hazardous and harmful alcohol and other substance use

TB prevention, screening, diagnosis and treatment

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# CHAPTER 6

## Service delivery





## Background

Based on the principal of the human right to health, health services for key populations (as for all populations) should be:

**Available** – There needs to be sufficient number of functioning health care facilities, goods and services that can, in coordination, provide a package of interventions as described in these guidelines for all key populations.

**Accessible** – Health facilities, goods and services must be accessible to all key populations. This means they should be physically accessible, affordable and non-discriminatory.

**Acceptable** – Health services must respect medical ethics, be culturally and developmentally appropriate, sensitive to gender, and non-judgemental. Acceptability requires that health facilities, goods, services and programmes are people-centred, and cater for the specific needs of key population groups, and do so in accordance with international standards of medical ethics of confidentiality and informed consent.

**Quality** – Quality health services are: evidence-based, safe, effective, people-centred, timely, equitable, integrated and efficient.

The coronavirus disease (COVID-19) pandemic highlighted deficiencies in health systems, with most countries unprepared and experiencing considerable disruptions to health services, including HIV, viral hepatitis and STI services for key populations. This is due in part to divergence of funds from essential health services and barriers to health service access, such as restricted movement, reduced ability to pay and fear of infection. The inequities experienced by key populations increased their vulnerability to COVID-19 as well as HIV, viral hepatitis and STIs. At the same time, there are positive examples of resilience from key population communities to help their peers to continued access to life-saving services, such as ART and harm reduction.

To strengthen health systems to respond to the current and potential future pandemics, WHO recommends: investment in essential public health functions; building a strong primary health care foundation; increased domestic and global investment in health system foundations; involving communities (including key population communities) and societies; and addressing pre-existing inequities and the disproportionate impact of COVID-19 on marginalized and vulnerable populations, including key populations (1).

The service delivery and enabling interventions recommended in these guidelines will not only increase accessibility, availability and acceptability of HIV, viral hepatitis and STI services for key populations, but will strengthen systems to provide universal health coverage and mitigate the impact of health emergencies.

The majority of health interventions included in these guidelines are relevant for all populations, but key populations experience particular structural barriers to access health services, as described in the [chapter on enabling interventions](#). In combination with the recommended enabling interventions, service delivery strategies described in this chapter, particularly community and key population-led delivery of services, can address these barriers, as well as contribute to person-centred care and UHC, ensuring key populations' right to health.

While different in every country, key populations access health interventions through a range of services. Traditional, facility-based services, which may not be targeted towards key populations, offer a range of health interventions, including for HIV, STI and viral hepatitis prevention, testing and treatment, which should be able to be accessed by key populations. However, stigma, discrimination and restrictive policies often deter key populations from accessing these services.

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Other services include community-based services, which may or not be key population led. Youth-friendly services can be accessed by young key populations. Often these services also conduct regular outreach and can provide mobile prevention, testing and/or treatment services as well. Some of these community-based services provide integrated HIV, STI and viral hepatitis interventions, as well as other health and social interventions, such as family planning, additional reproductive health and cancer screening, and sometimes legal services; these are often referred to as “one-stop-shops”. Methadone and buprenorphine are often provided by specialized services, which may or may not integrate HIV, viral hepatitis, TB and/or STI services as well.

This chapter describes a range of service delivery strategies: integration; decentralization; online services; self-care; involvement of peers and task sharing.

## Community-led services, task-sharing and involvement of key population peers

Key populations have a central role to play in leading programmes and services: reaching groups; providing prevention, testing and treatment services; as well as helping their peers navigate and remain in treatment services. Qualitative research conducted by four key population networks (for detailed report, please see [Web Annex B](#)) found that community-led services were unanimously endorsed and preferred by participants. Key populations described community-led services as being critical to promoting the health and human rights of marginalized groups, especially as a counterbalance to stigma experienced by some in traditional health care environments. Accordingly, participants across all population networks advocated for the scale-up of community-led interventions, as well as resources to support community-led services.

UNAIDS defines community-led organizations, groups and networks as those that are led by and for the constituencies they serve. They are self-determining and autonomous entities: for which the majority of governance, leadership, staff, spokespeople, membership and volunteers reflect and represent the experiences, perspectives and voices of their constituencies, and who have transparent mechanisms of accountability to their constituencies (246).

UNAIDS further defines community-led responses as the actions and strategies undertaken by these groups to improve the health and human rights of their constituencies. These responses are informed and implemented by and for communities themselves and the organizations, groups and networks that represent them. Community-led responses are determined by and respond to the needs and aspirations of their constituents, and include a range of activities, such as advocacy, campaigning and holding decision-makers to account; monitoring of policies, practices, and service delivery; participatory research; education and information-sharing; capacity-building; and funding of community-led organizations, groups and networks. Community-led organizations and responses must be understood as distinct from those that are community-based. “Community-based” refers to where a response happens, regardless of who is implementing it, while “community-led” refers to who leads and implements the response (246).

Community-led services with peers as providers have a positive impact on HIV, STI and viral hepatitis, with increased access, availability and acceptability of services (247–252). Peers have an important role in reaching other key populations through outreach (253), giving information, providing commodities (such as condoms, lubricants, needles/syringes, PrEP, PEP and naloxone) and providing services, including testing and treatment.

As well as key population peers, other non-specialist health care providers and lay people can provide health interventions, including nurses and outreach workers, which can reduce the workload of doctors and increase access and equity.





This guideline includes a new GRADE recommendation specific to key population peers.

## Peer navigation

### ★ NEW RECOMMENDATION

**Peer navigators are recommended to support people from key populations to start HIV, viral hepatitis or STI treatment, and to remain in care** (*conditional recommendation, moderate certainty of evidence*).

Remarks:

- A peer navigator's role is to assist key population members to access health services, navigate these services and stay in care.
- Peer navigators require adequate remuneration, recognition, training and other support to fulfil their role.
- Peer navigators are often highly valued by their peers.

Further details on evidence, decision-making, implementation considerations and research gaps related to this new recommendation can be found in [Chapter 9](#).

Relevant WHO guidelines include those related to task sharing and peer navigation for:

- HIV treatment. See [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#);
- HIV testing. See [Consolidated guidelines on HIV testing services](#);
- Hepatitis testing. See [Guidelines on hepatitis B and C testing](#);
- For general recommendations related to task sharing, please see [Task shifting: global recommendations and guidelines](#);
- For guidance for task sharing in family planning services, please see [Task sharing to improve access to family planning/contraception](#);
- [Updated recommendation on treatment of adolescents and children with chronic HCV infection and HCV simplified service delivery and HCV diagnostics](#)



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## Integration

Integration is the management and delivery of health services so that people receive a continuum of prevention, testing and treatment services, according to their needs, over time and across different levels of the health system. This is particularly relevant for people, such as some key population members, who have complex health needs and who are affected by health issues. Health systems organized around the needs of people and communities perform more effectively, cost less, improve health literacy, increase patient engagement, and are better prepared to respond to health crises (254). Health service integration includes the development of referral systems and networks, and empowering patients and communities to participate in their own care, as well as the provision of multiple interventions at one site.

[Table 1](#) provides one way of classifying health service integration, and how these can be applied to the recommendations and implementation of prioritized packages as outlined in these guidelines (255).

Table 1. Types of health service integration

Type of health service integration	Definition	Application to these guidelines
<b>Organizational</b>	Organizations and departments within organizations plan and budget together	National programmes for HIV, STIs and viral hepatitis and other relevant health programmes review these guidelines, and use them to inform the development of integrated strategies, plans, budgets, guidelines and protocols for key populations.
<b>Service</b>	Different clinical services integrated at organizational level, through coordinated referral or linkage	Clinical service managers at different levels and for different clinical services review these guidelines, and work together to ensure key population members' access to the comprehensive package of health interventions across health services, through referral or linkage.
<b>Site level</b>	Provision of multiple interventions at one site	Site level managers of primary health care, community-based or other clinics, which serve key populations, are supported to provide multiple, appropriate, evidence-based interventions, as included in the WHO recommended package.

WHO recommends the integration of HIV, viral hepatitis and STI services, and also the integration of these with a range of other relevant clinical services, such as those for TB, maternal and child health, mental health, sexual and reproductive health services, and drug dependence treatment.

The following WHO guidelines related to integration are particularly relevant to key populations. However, this is not an exhaustive list of integration strategies, and programmes should endeavour to integrate services based on the needs of their clients.

- For guidance on HIV and TB integration, sexual reproductive health and HIV integration, ART and OAMT integration, please see [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#).



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- For guidance on integrating hepatitis C services, please see [Updated recommendation on treatment of adolescents and children with chronic HCV infection and HCV simplified service delivery and HCV diagnostics](#)
- [Integration of HIV testing and linkage in family planning and contraception services: implementation brief](#)

## Decentralization

Decentralization is the transfer of formal responsibility and power to make decisions regarding the management, provision and/or financing of health services to geographically or organizationally separate actors. In effect, this moves services out of tertiary health care facilities, physically and managerially, and means that health interventions can be provided and managed at different lower-level sites, including community-based services. Key populations may feel less comfortable and may experience stigma and discrimination in tertiary hospitals, and so the provision of health services outside of hospital settings in community-based and key population-targeted services can increase acceptability and accessibility. Decentralizing health services can also reduce barriers such as transport costs and long waiting times in central hospitals. However, decentralization of services for key populations may not always be appropriate or acceptable, and people may prefer to receive services in tertiary facilities where there is greater anonymity.

- For guidance on decentralized HIV testing, please see [Consolidated guidelines on HIV testing services](#)
- For guidance on decentralized HIV treatment, please see [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#).
- For guidance on decentralized HCV testing and treatment, please see [Updated recommendation on treatment of adolescents and children with chronic HCV infection and HCV simplified service delivery and HCV diagnostics](#)

## Differentiated service delivery

Differentiated service delivery can be defined as a client-centred approach that simplifies and adapts services, in ways that both serve the needs of affected people better and reduce unnecessary burdens on the health system (256). Differentiated service delivery for key populations considers where, when and by whom relevant interventions are provided, with the goal of increasing access to health services, increasing equity and increasing efficiencies in health systems. For example, to achieve these goals, service planners may decide to reduce the frequency at which people need to collect methadone doses for OAMT and support community-based distribution.

WHO has several recommendations related to differentiated service delivery for ART, including rapid ART initiation, reduced frequency clinical visits and ART pick-up and adherence support, as well as recommendations for differentiated HIV testing services.

- Please see [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#) for more details.

## Virtual interventions

Increasingly, services designed for key populations are using virtual platforms, conducting outreach to reach people at risk; providing information about available services; providing self-test information and tests; booking appointments for testing; and linking people diagnosed with HIV, viral hepatitis or STIs with treatment service providers (257–259). This approach to service delivery may be of particular relevance and importance to complement and enhance existing health



infrastructure and service delivery for the younger key population community, always under the condition that potential concerns about sensitive content and data privacy can be addressed (257).

Different interventions are implemented online. Common categories include the following.

- 1. Online outreach** to potential key populations service users through online platforms. This involves reaching out to those who had not been reached before, by using systems and structures like websites and social media apps, where key populations can communicate, access information and socialize.
- 2. Online case management** for key populations diagnosed with HIV, HCV or STIs who need to engage in services to assess risk and adhere to necessary treatment. Providing case management through online systems can potentially reduce loss to follow-up, provide helpful prompts (such as reminders to book an appointment or take a medication) and support for key populations.
- 3. Targeted health information** uses internet sites and social networking apps to allow for communication to be targeted, based on user demographics and characteristics. For example, social media advertisements can target users of certain ages, political profiles, geographic locations, etc. Population segmentation may allow for more specific targeting of key population audiences to provided tailored information or linkage to health services.

The potential advantages of online services include reaching a broader audience, reaching people who are geographically isolated, targeting information to specific people, improved efficiencies and convenience for clients.

Online services should be complementary to face-to-face services and not replace them. Online services may not reach all key populations, and some key population members may prefer face-to-face services, or have concerns about privacy when accessing online. Some key population members, often the most vulnerable, have additional barriers, such as the cost associated with network data, illiteracy, language barriers and limited access to phones, tablets or computers.

Online platforms can provide a safe space for key populations to access information and services; however, efforts to protect the safety of users and eliminate online mistreatment need to also be implemented and monitored closely. The engagement and involvement of key populations, in all their diversity and ages, in the development of apps or online tools and services will increase the likelihood of apps being culturally and age-appropriate and friendly, and ensure the information is age-appropriate (257, 260). Lastly, it is important to ensure trustworthy platforms, with staffing by trained operators, counsellors, and key populations themselves, to provide developmentally appropriate health and welfare information to young key populations, as well as the opportunity for referrals to relevant services (257).

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## Online interventions

### ★ NEW RECOMMENDATION

**Online delivery of HIV, viral hepatitis, and STI services to key populations may be offered as an additional option, while ensuring that data security and confidentiality are protected** (*conditional recommendation, low certainty of evidence*).

Remarks:

- Choice is important, and online services should form a part of a menu of interventions, not stand-alone interventions, and should not be a replacement for face-to-face services.
- Efforts should be made to increase equitable access to the internet, improve literacy and provide appropriate training for key population members where needed.
- Consideration should be given to the preferences of different key population groups, given the current lack of published evidence from sex workers and people who inject drugs.

Further details on evidence, decision-making, implementation considerations and research gaps related to this new recommendation can be found in [Chapter 9](#).

## Self-care

WHO uses the following working definition of self-care: Self-care is the ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health worker (182). The scope of self-care as described in this definition includes health promotion; disease prevention and control; self-medication; self-testing; providing care to dependent persons; seeking hospital/specialist/primary care if necessary; and rehabilitation, including palliative care. It includes a range of self-care modes and approaches. While this is a broad definition that includes many activities, it is important for health policy to recognize the importance of self-care, especially where it intersects with health systems and health professionals.

For key populations, who may feel a lack of control of their health in the face of persistent structural barriers, engagement in self-care can be empowering, as well as increasing accessibility and availability of health interventions.

Relevant, recommended approaches that can be self-administered or managed include:

- emergency contraception;
- abortion and post-abortion contraception;
- HPV, chlamydia, and gonorrhoea self-sampling;
- self-care after sexual assault and violence;
- pregnancy testing; and
- HIV and HCV self-testing.

For more details on self-care, please see [WHO guideline on self-care interventions for health and well-being](#).

For more details on HIV self testing, see WHO [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#).

For more details on HCV self-testing, see [Recommendations and guidance on hepatitis C virus self-testing](#).



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# CHAPTER 7

Programme and service considerations  
for young key population groups





*“The barriers that impede our access to high-quality health services also affect us uniquely. We know the solutions to these barriers, but we need spaces to engage in mitigating them.”*

Fahe Kerubo, Y+ Global

This chapter summarizes and updates information from four WHO HIV technical briefs for young key population groups published in 2015<sup>26</sup> (261–264). WHO did not publish a technical brief on HIV and young people in juvenile detention and prison, but many considerations for young people who sell sex, young men who have sex with men, young trans and gender diverse people, and young people who inject drugs will also apply to this population. This chapter aims to catalyse and inform discussions about how best to provide health services, programmes and support for young key populations. While the focus is on health for young key populations, the considerations will be relevant to other programmes: welfare, justice, protection, education and social protection (261–264).

## Background

Attention is growing globally on the importance of addressing the specific health needs of young people (those aged from 10 to 24 years). Adolescence and young adulthood are periods with significant physiological changes, and a time where young people establish identities and sexual preferences and explore new life experiences (265). Structural factors and the vulnerabilities of youth (power imbalances in relationships; evolving identity and capacity; restricted access to sexual and reproductive health; effective prevention interventions; and, sometimes, alienation from the school system, family and friends) reduce young people’s access to prevention, harm reduction, and reproductive health services, and put them at higher risk of infection from HIV, STIs and viral hepatitis (261–264, 266–268).

Epidemiological data on the global status of HIV, STIs and viral hepatitis among young people remain limited, with significant gaps for young key populations (265, 269, 270). Available data show that young key populations are disproportionately vulnerable to, and affected by, HIV (270) and STIs compared to their peers and older key populations (183, 271–276). For HCV infection, data show that rates are high and rising among young people who inject drugs and young men who have sex with men (277–280). Transmission of HBV mainly occurs in early childhood, from mother to child, and many countries have high HBV immunization programme coverage. Despite this, young people born before the initiation of the infant immunization programme, or not vaccinated, will remain susceptible to HBV infection (19, 281). Young people remain at higher risk for STIs, and may be biologically more susceptible to STIs, particular younger women (183, 282).

The global response to HIV, STIs and viral hepatitis has not reached adequate numbers of young key populations (269). Young key populations’ lower access to prevention, diagnosis and treatment is due to a range of factors (282–290):

- misconceptions about risks;
- lack of knowledge and accurate age-appropriate information;
- lack of comprehensive sexuality education (CSE);
- low awareness of available, friendly health services; and
- barriers to access and uptake of services (including legal and policy barriers around consent requirements).

In addition, social determinants, such as wealth, race and gender inequality, and access to education greatly impact health behaviour and outcomes for this population (269, 291).

<sup>26</sup> Young trans and gender diverse people, young men who have sex with men, young people who sell sex and young people who inject drugs.

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Services and providers are often poorly equipped to provide services for young key populations, and staff frequently lack training, skills and knowledge to deliver acceptable and appropriate services for young key populations (292–294). Furthermore, inadequate investments and availability, or use of age- and sex-disaggregated data in primary research, monitoring and evaluation is a barrier to programming for young key populations (295–298).

States have a legal obligation to respect, protect and fulfil children’s right to life, health and development. Societies share an ethical duty to ensure this right for all young people. Addressing underlying structural barriers for young key populations is critical.

One of the added structural barriers specifically young key populations face that is distinct from their adult counterparts’ barriers is the requirement for parental, caregiver or guardian consent (261–264) to access services, including harm reduction services. For young people who do not wish to disclose an issue to their caregivers, this can be directly inhibitive to accessing care, resulting in missed opportunities for prevention and treatment. Countries are encouraged to examine their age of consent policies, and to consider revising them to reduce age-related barriers to access and uptake of services and interventions that are critical to the health and wellbeing of this population.

## Changes to the legal and policy environments

The United Nations Convention on the Rights of the Child (CRC) obliges the state to protect the rights of all young people under 18 years of age. The treaty includes protection from sexual exploitation and sexual abuse; it emphasizes four guiding principles: non-discrimination; the best interests of the child; the right to life, survival and development; and respect for the young person’s views (299). Commitment to the CRC includes lowering the risk of infectious diseases and strengthening protective systems to reduce vulnerabilities for young people. The rights of children are contravened when those young people under 18 years of age are excluded from effective HIV, STI and viral hepatitis prevention and life-saving prevention, testing, treatment, care and support services (261–264).

## Elements of successful programming for young key populations

WHO recommended interventions and service delivery strategies for all key population groups also apply to young key populations ([See Chapters 4–7](#)).

Fig. 4. Summary of key characteristics of effective young key population services



Informed by WHO and UN partner publications, the elements of successful programming for young key populations update the 2015 WHO policy briefs (261–264). Services must be designed and delivered to consider the differing needs and rights of young people according to their age, gender identity, sexual orientation, specific behaviours, the complexities of their social and legal environment and the epidemic setting, while simultaneously respecting the CRC.



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## Meaningful involvement of young people

The WHO global consensus statement on meaningful adolescent and youth engagement states that meaningful adolescent and youth engagement requires a mutually-respectful partnership between adolescents, youth and adults. Power is thereby shared; respective contributions are valued; and young people's ideas, perspectives, skills and strengths are integrated into the design and delivery of programmes, strategies, policies, funding mechanisms and organizations that affect their lives and their communities, countries and world (300). Meaningfully and ethically involving young key populations in the planning, design, implementation, monitoring and evaluation of services requires acknowledging and building upon the strengths, competencies and evolving capacities of young key populations, especially their ability to express their views and articulate what services they need (301).

- [Global consensus statement: meaningful adolescent and youth engagement](#). Geneva: WHO; 2020.

## Work with trusted partners and existing infrastructure to design and deliver services

It is important to partner with community-led youth and key population organizations, build upon their experience and credibility, and use appropriate, effective and efficient approaches to design and provide services for young people.

- UNAIDS. [Young people's participation in community-based responses to HIV — from passive beneficiaries to active agents of change](#). Geneva: WHO; 2019.

## Provide quality, comprehensive and adolescent-friendly services

It is crucial to ensure that health (including immunization), welfare, justice, protection, education and social protection services are integrated, linked and multidisciplinary in nature, with a strong system for referral along the continuum of care. Provision of a comprehensive range of services with online delivery options (see the service delivery [chapter](#)) can help to address the overlapping vulnerabilities and intersecting behaviours of different young key populations. The WHO adolescent-friendly health services principles guide adolescent-friendly health services (302). WHO and UNAIDS have also published global standards that define the quality in delivering of health services for adolescents (303).

- [Adolescent-friendly health services for adolescents living with HIV: from theory to practice](#). Geneva: World Health Organization; 2019.
- United Nations Children's Fund (UNICEF). [Improving HIV service delivery for infants, children and adolescents: a framework for country programming](#). Geneva: WHO; 2020.
- UNAIDS, WHO. [Global standards for quality health-care services for adolescents: a guide to implement a standards-driven approach to improve the quality of health care services for adolescents](#). Geneva: WHO; 2015.
- [Youth-centred digital health interventions: a framework for planning, developing and implementing solutions with and for young people](#). Geneva: WHO; 2021.

## Improve access to and retention in services

It is essential to ensure that young key populations have access to the necessary health services and information regardless of their marital status and caregiver consent. Medical treatment without caregiver consent is possible and should be considered when in the individual's best interests. Making services accessible includes ensuring that service locations are easy, affordable, confidential and safe for young key populations to access, and are provided at times that are convenient to young people. Providers have discretion to provide services to young people and should not be prosecuted for doing so. Adolescents, irrespective of age, should be permitted access to counselling and advice without the consent of a parent or guardian (303). Young people should be made aware of their rights to confidentiality, and any limits of confidentiality made clear by those with mandatory reporting responsibilities (304).



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## Provide developmentally appropriate information and education

Services for young key populations must provide developmentally appropriate, accurate and inclusive information and education. Prevention of HIV, STI and viral hepatitis prevention, in addition to comprehensive sexuality education for young key populations and their partners (including for adolescents and young people out of school) should focus on skills-based risk reduction. Information can be shared using various media platforms, such as online, mobile phone technology and participatory approaches (261–264, 305–307).

## Build capacity in the health sector and beyond

Sufficient capacity amongst professionals, particularly in the health, social welfare, justice and education sectors, to work with young key populations and apply rights-based approaches and evidence-informed practice is critical. Capacity-building involves expanding knowledge on the health needs and rights of different young key populations, and relevant overlapping vulnerabilities (namely, injecting drugs, sexual exploitation or selling of sex) (308, 309). Training is needed on providing respectful, non-judgemental services that consider sexual and gender diversity, gender and power relations, gender-affirming care, and further development of communication and negotiation skills – as they relate to key populations (310).

- [Assessing and supporting adolescents' capacity for autonomous decision-making in health care settings](#). Geneva: WHO; 2021.
- [Core competencies in adolescent health and development for primary care providers](#). Geneva: WHO; 2015.
- [How to plan and conduct telehealth consultations with children and adolescents and their families](#). Geneva: WHO; 2021.
- [Guidelines to strengthen social service workforce for child protection](#). UNICEF; 2019.

## Implement peer-driven models

Adolescent and youth peer-driven models and support are key implementation strategies towards the global standard of adolescent participation (311, 312). Young people highly value peer support programmes. Peer navigators are crucial in bridging online information and offline action, such as accessing testing and treatment services (313). Appropriate training, support and mentoring are essential to help young key populations advocate within their communities to support them in accessing services (204, 261, 263, 264). The WHO technical brief *Adolescent-friendly health services for adolescents living with HIV* (302) provides implementation considerations for adapting and scaling-up peer-based, adolescent-friendly models.

- [Adolescent friendly health services for adolescents living with HIV: from theory to practice](#). Geneva: WHO; 2019.

## Strengthen protection and welfare for families

Helping parents and families to fulfil their responsibilities to protect, care for and support young key populations effectively is critical. For adolescents aged between 10 and 17 years old, it is important to try to reintegrate them with their families when appropriate, if in their individual best interests, or to provide other appropriate living arrangements and care options in line with the 2010 *UN Guidelines for Alternative Care* (314).

## Update national policies

To ensure harmonized implementation across programmes, evidence-informed services for young key populations must be clearly stated in national policies; that is, the National Strategic Plans (NSPs). (See [Chapter 9](#).)



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- WHO, UNAIDS, UN WOMEN, UNFPA, WORLD BANK GROUP, UNICEF. [Accelerated Action for the Health of Adolescents \(AA-HA!\) A manual to facilitate the process of developing national adolescent health strategies and plans](#). WHO; 2019.
- [Online toolkit for adolescents and young key populations](#). UNICEF; 2021.
- This toolkit is a collection of online resources to help plan and scale-up HIV prevention programmes with adolescents and young key populations (ayKP) – people aged 10–24 years.

## Monitoring and evaluation

Programming for young people needs to consider the population size, demographics and epidemiology; data disaggregation should be done by sex or gender and age group (298). Collect and collate baseline measurements, monitoring and evaluation systems into programmes to strengthen quality and effectiveness and develop a culture of learning and evidence-based practice to better inform future policies and programmes. (See [Chapter 9](#).)

- [Strengthening the adolescent component of national HIV programmes through country assessments](#). UNICEF; 2016.
- [Collecting and reporting of sex- and age-disaggregated data on adolescents at the sub-national level](#). UNICEF; 2016.

## Addressing the additional needs and rights of young key populations

Ensuring that the needs of young key populations are met will improve health outcomes and overall wellness for these populations. The following particular needs should be considered when designing and implementing programmes and services (261–264).

- Protection is needed from all forms of physical, emotional and sexual violence and exploitation, whether by law enforcement officials or other perpetrators (315–320).
- Access to information on the harm that early marriage and early pregnancy can cause is needed.
- Young people who become pregnant need access to health services sensitive to their rights and needs. This includes providing access to sexual and reproductive health services, including family planning, contraception and information and access to youth friendly safe abortion services, adequate and comprehensive obstetric care, and counselling (321–323).
- Psychosocial support services are called for; namely, therapy, counselling, peer support groups and networks to address the impact of self-stigma, discrimination, social exclusion, coming out, gender-affirming care, and to address mental health issues (312, 324).
- Support is critical to remain in or to access education or vocational training, and opportunities to return to school need to be offered, and access to preventative strategies for bullying, stigma and discrimination (307, 315, 317, 325, 326).
- Independent living and group housing shelter are necessities as immediate or long-term accommodation arrangements (327, 328).
- Food security, including nutritional assessments, is all-important (329, 330).
- Livelihood development, economic strengthening, and support to access social services and state benefits are needed (331).
- Access to free or affordable legal information and services is critical, including information about their rights, reporting mechanisms and access to legal redress.
- Counselling for families when requested to facilitate access to services is essential, especially where parental/guardian consent is required.



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# CHAPTER 8

Developing the response:  
the decision-making, planning  
and monitoring process





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

## Situational analysis

Data and a strong evidence base should guide the response, but lack of this information is not a reason to stop or not initiate a response to improve the health of key populations and work towards the elimination of HIV, viral hepatitis and STIs as public health threats.

Particularly when programmes and services are first being developed, it is important to undertake a situational analysis. For a local response to be appropriate, acceptable and most effective, risks and needs must be examined locally, and local key population members must be consulted and actively involved in this situational analysis. Local people from key populations should ideally be drawn from networks, where they exist, or people acknowledged as community leaders who can represent community opinions.

It is critical to understand the dynamics of local epidemics; the characteristics of the populations affected; the physical, social and political environments that influence risk and vulnerability; the specific 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-informed plan can be developed and implemented.

As already described, people from key populations face elevated HIV, viral hepatitis and STI risk and burden, and have specific and sometimes complex health-related needs. While many of these risks and needs may be common across key populations in different settings, some factors will differ among key populations, and some will be specific to a particular context.

It is also important to recognize the diversity and varying levels of risk within each key population. In many settings, 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. 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, impoverished, educationally disadvantaged, disabled, experience mental health conditions, or have other acute or chronic health concerns.

Key population size and location (that is, where people live or congregate) can vary from place to place, with some constants, such as the overall proportion of adult men who have sex with other men (332). To determine the required scale of the response, the appropriate balance and cost effectiveness among different interventions and where interventions should be targeted, it is important to appreciate the size and concentration of key populations, among other factors. (See [Box 2](#) and Section 3.) It is important to note the difficulty in conducting key population size estimates and the lack of reliable data about key population size (333). Efforts should be made to validate key population size estimates and limitations recognized.





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### Box 1. Stakeholders to include in the planning process

- Key population-led community organizations and key population community representatives, including young key population members;
- Managers and health care workers from the following fields in both the public and private sectors: HIV programmes and clinics, hepatology service providers, sexual and reproductive health programmes and clinics, including family planning and STIs, maternal and child health, mental health, TB services, drug dependence, NSPs, OAMT services and prison health programmes;
- Civil society, including people living with HIV and viral hepatitis, women's and youth groups, religious leaders and people with disabilities;
- Technical specialists in specific areas, such as laboratory services, pharmacology, drug resistance, toxicity management, supply chains and community health;
- Government partners, including representatives of relevant ministries, such as health, justice and law enforcement, internal affairs, finance, planning and regional (such as provincial) authorities;
- Non-governmental 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;
- International donors and implementers;
- Human rights institutions; and
- Professional associations of various cadres of health workers (such as physicians, nurses and community health workers).

The makeup, characteristics and needs of key populations change over time, as do various contextual and environmental factors. Updating a situational analysis through ongoing monitoring and evaluation 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.



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## Box 2. Key information required for decision-making and planning

Information required	Source of information
Key population size	Population size estimation
Prevalence of HIV, viral hepatitis B and C and priority STIs among key populations	Sero-surveillance
Key population location/geographic distribution; identification and mapping of key populations accessible online	Mapping exercises (including online mapping)
Key population characteristics, risk behaviours and health concerns	<ul style="list-style-type: none"> <li>• Demographic surveys</li> <li>• Behavioural surveys</li> <li>• General health surveys</li> </ul>
Important structural factors, barriers to implementing a response to HIV, viral hepatitis and STIs, and the needs of key populations	<ul style="list-style-type: none"> <li>• Audit of current legislation, policy and practice</li> <li>• Consultation with community members, community-led organizations and other stakeholders</li> <li>• Behavioural surveys</li> </ul>
Accessibility, coverage, quality, outcome and impact of interventions	<ul style="list-style-type: none"> <li>• Programmatic data</li> <li>• Disease notification registries</li> <li>• Integrated bio-behavioural surveys</li> </ul> <p>(See <a href="#">Box 3</a> for further description of national programme monitoring and evaluation framework)</p>

In settings where services for key populations are not well established, and where much of the information listed above has not been previously compiled, undertaking a rapid assessment may be appropriate. 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. These guides focus largely on HIV, and were developed earlier in the HIV epidemic, but the principles and methods described remain relevant to gathering information on HIV, as well as viral hepatitis and STIs:

- [Rapid assessment and response adaptation guide on HIV and men who have sex with men](#). Geneva: WHO; 2002
- [The rapid assessment and response guide on injecting drug use \(IDU-RAR\)](#). Geneva: WHO; 1998
- [The rapid assessment and response guide on psychoactive substance use and sexual risk behaviour \(SEX-RAR\)](#). Geneva: WHO; 2002
- [Rapid assessment and response adaptation guide for work with especially vulnerable young people](#). Geneva: WHO; 2004
- [HIV in prisons: Situation and needs assessment toolkit](#). Vienna: UNODC; 2010



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## Planning and implementing the response

The effectiveness of the interventions included in the essential health interventions package is well established. Experience in multiple countries has demonstrated the generalizability of these interventions in diverse settings. While national strategies should be guided by the health intervention packages recommended in these guidelines, local factors do have a bearing on intervention effectiveness and impact, and have a bearing on how an intervention is implemented to optimize access and effectiveness. With the information gathered on the local setting, as described above, planning processes should be taken forward with participation of stakeholders, particularly key populations, and decisions can be made on how interventions should be implemented.

The following are some of the decisions that need to be taken while developing and implementing a national response to HIV, viral hepatitis and STIs among key populations. Guidance on planning and implementing the response is listed in [Box 3](#).

### Targeting the response

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

### Implementation

- Are key populations' members effectively leading the response?
- Which interventions need to be implemented and where, and how should implementation be prioritized?
- How can services addressing HIV, viral hepatitis, STIs and broader health be integrated at the organizational, service and site levels (see the service delivery [chapter](#)) to optimize accessibility and impact for key populations?
- Where and at what scale do interventions need to be provided?
- 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

- 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 (including key population peers) 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 interventions save on costs and improve service provision?
- What resources are available from donor organizations and what resources will need to be mobilized from national sources? Greater funding for HIV may be available through The Global Fund and PEPFAR, but funds for STIs and viral hepatitis may need to be integrated in national plans.

### 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?



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## 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.

### Box 3. Guidance on planning and implementing the response to HIV, viral hepatitis and STIs for key populations

- [Considerations in planning and budgeting for a key population trusted access platform](#). Global HIV Prevention Coalition; 2020
- [Establishing community-led monitoring of HIV services – Principles and process](#). UNAIDS; 2021

## Monitoring and evaluating the responses

**Monitoring and evaluation** is an essential part of the HIV, viral hepatitis and STI response for key populations

A monitoring and evaluation system is needed to assess both structural and health sector components of the response to HIV, viral hepatitis and STIs 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 while adhering to human rights principals as described previously.

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:

- [Tool to set and monitor targets for HIV prevention, diagnosis, treatment and care for key populations](#). Geneva: WHO; 2015;
- [Consolidated strategic information guidelines for viral hepatitis: planning and tracking progress towards elimination](#). Geneva: WHO; 2019;
- [Consolidated guidelines on person-centred HIV patient monitoring and case surveillance](#). Geneva: WHO; 2017;
- [Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management](#). Geneva: WHO; 2020;
- [Strategies and laboratory methods for strengthening surveillance of sexually transmitted infection](#). Geneva: WHO; 2012.

These frameworks recommend sets 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 4). The indicators can also be used when preparing proposals or reporting progress to donor organizations.

The M&E process requires data from a variety of sources, including behavioural and sero-surveillance surveys, programmatic and administrative data, community-led monitoring as well as information gathered through reviewing policy documents and legislation, and consultation with experts and stakeholders (Box 5). The quality and limitations of these data should be assessed and considered when undertaking analysis and interpretation.



## Ongoing planning and development of the response

Setting clear, achievable but ambitious targets is crucial when planning to scale-up interventions to have an impact on HIV, viral hepatitis and STIs. Targets concretely define what a successful national programme or project should achieve within a specified timeframe. Targets can be set for both intervention-specific indicators and cross-cutting outcome and impact indicators ([Box 4](#)).

**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, viral hepatitis and STI risk, sufficiently to reduce transmission and ensure the adequate provision of appropriate treatment and care for those living with HIV, viral hepatitis 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, viral hepatitis or STI epidemics; for example, reductions in incidence of HIV, viral hepatitis or STIs ([Box 4](#)).

Like planning overall, the target-setting process should be collaborative, involving a 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 epidemics.

**Baseline assessment** – initial assessment should measure the scale of the current response, assessing the availability, coverage and quality of current interventions, and appraise current environmental enablers and barriers using agreed indicators. This information serves as a baseline for tracking progress. Also, currently available resources and technical capacity must be determined to estimate what more is needed, and how to scale the intervention appropriately. From this information, realistic, achievable targets can be set and the timeframe specified.

**Estimating cost** 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 for HIV and STI programming. It comprises several software apps, 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: [https://www.unaids.org/sites/default/files/media\\_asset/QuickStartGuide\\_Spectrum\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/QuickStartGuide_Spectrum_en.pdf).

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 LMICs. 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 (Avenir Health, 2021) at: <https://www.avenirhealth.org/software-onehealth.php>.

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 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](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](http://www.unaids.org/en/media/unaids/contentassets/documents/document/2012/The_HRCT_User_Guide_FINAL_2012-07-09.pdf).

WHO commissioned Avenir Health to develop the Syphilis Interventions Towards Elimination (SITE) tool which is a dynamic transmission model to evaluate and project the impact, cost and cost-effectiveness of syphilis interventions (screening, treatment and prevention) to support national control programmes: <https://avenirhealth.org/software-site.php>.

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#### Box 4. 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 to set and monitor targets for HIV prevention, diagnosis, treatment and care for key populations](#). Geneva: WHO; 2015
- [Consolidated strategic information guidelines for viral hepatitis: planning and tracking progress towards elimination](#). Geneva: WHO; 2019

Specific impact indicators related to validating elimination of viral hepatitis in people who inject drugs can be found in:

- [Interim guidance for country validation of viral hepatitis elimination](#). Geneva: WHO; 2021

#### **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;
- achievement of meaningful involvement of people from key populations in policy and strategy formulation;
- legal support services for key populations have been established;
- support services for people from key populations who experience violence are functioning;
- sensitization training on key populations is regularly conducted for law enforcement officers; and
- sensitization training on key populations is regularly conducted 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 each intervention is available, including availability of online interventions;
- 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; and
- geographic mapping of key populations in relation to where interventions are provided.





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#### Box 4. Indicators for monitoring and evaluating the response (cont.)

##### **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; and
- 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); and
- 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 HIV, viral hepatitis and STI infections in key populations;
- prevalence of infection in key population;
- incidence of HIV-related mortality in key population;
- prevalence in key population of experiencing stigma or discrimination; and
- incidence of violence against people from key population.



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### Box 5. Data sources

**Behavioural and sero-surveillance surveys.** These 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 and viral hepatitis epidemics. 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 requires programme data to be disaggregated by key population, where information on key population status and behaviours can be collected safely and securely and where feasible. 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.



# CHAPTER 9

## Additional information on the development of new recommendations

### Introduction

As highlighted in previous chapters, this updated guidelines contains seven new recommendations or new practice statements that are included in the overall framework of health interventions and service delivery.

### Methodology

WHO developed seven PICO questions. In an online survey, the Guideline Development Group members ranked the importance of each outcome to those affected by the intervention using the GRADE rating scale of 1–9 (0–3: not important; 4–6: important; 7–9: critical). Once the PICO question and priority outcomes were agreed, external researchers, supported by the WHO team, conducted a systematic review of the evidence.

The systematic review teams developed protocols and conducted a systematic review of the relevant scientific evidence. The appointed independent methodologist assessed and reviewed the protocols, as did the Steering Group, key population networks and WHO technical officers. The methodologist advised the review team on analytical decisions and synthesis and the grading of evidence. Studies providing information on feasibility, values and preferences, and cost-effectiveness were also included and summarized. The scientific evidence supporting the recommendations was evaluated using the GRADE approach, and the effectiveness and overall certainty of evidence for each intervention was determined.

The risk of bias for studies included in systematic reviews were assessed using the Cochrane Collaboration’s risk of bias tool for randomized controlled trials (RCTs) (334) and the ROBINS-I tool for non-randomized studies (335).

WHO also commissioned four global networks of key populations (men who have sex with men, sex workers, trans and gender diverse people, and people who inject drugs) to undertake new qualitative research on values and preferences among their networks. The results formed part of the evidence synthesis. Further details are provided in the next section.

Table 2. Domains considered when assessing the strength of recommendations

Domain	Rationale
<b>Benefits and harm</b>	When a new recommendation is developed, desirable effects (benefits) need to be weighed against undesirable effects (risks or harm), considering any previous recommendation or an 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.
<b>Certainty of evidence</b>	High certainty of evidence is likely to lead to a strong recommendation.
<b>Values and preferences</b>	If the recommendation is likely to be widely accepted or highly valued, it is likely that a strong recommendation will be made. If there is a great deal of variability or strong reasons why the recommended course of action is unlikely to be accepted, it is more likely that a conditional recommendation will be made.
<b>Cost and financial implications</b>	Lower costs (monetary, infrastructure, equipment or human resources) or greater cost-effectiveness contribute to a strong recommendation.
<b>Feasibility</b>	If an intervention is achievable in a setting where the greatest impact is expected, a strong recommendation is appropriate.
<b>Equity and human rights</b>	If the recommendation is likely to increase access to an intervention for those most in need, a strong recommendation is likely.
<b>Acceptability</b>	The greater the acceptability to all or most stakeholders, the greater the likelihood of a strong recommendation.



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The GRADE approach specifies four levels of certainty of evidence (Table 3.) The certainty of evidence is a key determinant of the strength of a recommendation, which can be either strong or conditional.

Table 3. Interpretation of the four GRADE levels of evidence

Certainty of evidence	Rationale
<b>High</b>	We are very confident that the true effect lies close to the estimate of effect.
<b>Moderate</b>	We are moderately confident in the estimate of effect. The true effect is likely to be close to the estimate of effect, but it could be substantially different.
<b>Low</b>	Our confidence in the estimate of effect is limited. The true effect may be substantially different from the estimate of effect.
<b>Very low</b>	We have very little confidence in the estimate of effect. Any estimate of effect is very uncertain.

Good practice statements are sometimes appropriate for use when the supporting evidence is indirect and therefore difficult to collect and summarize, but the certainty or confidence surrounding an intervention’s impact is high, and when the desirable consequences of an intervention clearly outweigh the undesirable ones. Often data is not disaggregated by key population group and there is a lack of supporting evidence related to key populations, meaning that good practice statements were appropriate in the development of these guidelines. Good practice statements are, by nature, strong recommendations (56).

Following the WHO guideline development process (56), the Guideline Development Group formulated recommendations according to the GRADE approach to appraise evidence. The Guideline Development Group also made good practice statements. The evidence was synthesized and incorporated into an evidence-to-decision framework to help inform the discussions at the Guideline Development Group meeting. WHO convened a virtual Guideline Development Group meeting that occurred over six days between 30 August and 8 September 2021, chaired by two members of the Guideline Development Group. All conflicts of interest were managed. The methodologist assisted by the chairs facilitated the Guideline Development Group’s judgements on the potential benefits and harms of the intervention, stakeholder values and preferences, acceptability, feasibility, resource use and considerations of human rights and equity. Taken together, these judgements contributed to determining the strength and direction of the recommendation (334). All the recommendations were arrived at through consensus. Voting was not required, but the group agreed a priori that two thirds of the votes would be required for a decision. The draft guidelines were circulated for review to members of the Guideline Development Group and the External Review Group in November 2021.

## Evidence and decision-making for new recommendations

### Behavioural interventions

#### Background and rationale

Behavioural interventions are widely used in programmes which aim to reduce transmission of HIV, STI and viral hepatitis. There are a range of different behavioural interventions, including those that focus on providing information and education and those that take a counselling approach, but all aim to increase health-seeking behaviours and/or reduce behaviours that increase risk of HIV, STIs and viral hepatitis, including needle and syringe sharing and unprotected sex. Counselling behavioural interventions can be provided by health care workers or by peers, can be a single session or multiple sessions, can be brief or long, can be provided in groups or individually, and can be online or face-to-face.

The 2014 and 2016 WHO *Consolidated key population guidelines* (3) included recommendations related to behavioural interventions that were based on low certainty of evidence and lack of standard comparators. During the scoping exercise to review which recommendations required updating and the community and expert consultation in 2019–2020 (see methods), these recommendations were identified as in need of an update. To inform the decision-making process, the evidence review focused on behavioural interventions with a counselling component, in particular whether provision of counselling behavioural interventions impacts HIV, STIs and viral hepatitis acquisition and transmission for key populations.

#### Evidence review

A systematic review was commissioned by WHO to update existing recommendations, to answer the PICO question of whether counselling behavioural interventions reduces risk behaviours associated with transmission or acquisition of HIV, STIs and viral hepatitis. The primary outcomes were HBV, HCV, HIV or STI incidence and the secondary outcomes were unprotected sex (for example, condomless sex, sex without lubricant, sex without PrEP), needle and syringe sharing and mortality.



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A systematic review of published articles from 1 January 2010 to 1 March 2021 identified nine eligible randomized control trials (see [Web Annex C](#)). Five studies were among adult key populations and two studies were among young men who have sex with men (16–25 years old) (336) and young females (13–17 years old) released from juvenile detention (337). Together these indicated that counselling behavioural interventions probably make little to no difference on HIV (336, 338–343), viral hepatitis (341) or STI (337–340, 342–344) incidence in key populations. This was also true for unprotected sex (336–342) and needle and syringe sharing (340, 341). There was moderate certainty in the lack of effect across outcomes.

Moderate certainty evidence from six randomized controlled trials (RCTs) among men who have sex with men, transgender women, people who inject drugs and sex workers in China, Kazakhstan, Kenya and the USA showed counselling behavioural interventions had probably no effect on *HIV incidence* in meta-analysis (combined risk ratio (RR): 0.700, 95% CI: 0.409–1.197), with no important benefit or harm (336, 338–342). Low certainty evidence from one RCT among sex workers who inject drugs in Mexico showed no impact on HIV/STI incidence when findings were meta-analysed across study sites (RR: 0.663; 95% CI: 0.224 to 1.960) (343).

Moderate evidence from six RCTs among people in prisons, men who have sex with men, transgender women, people who inject drugs and sex workers in China, Kazakhstan, Kenya and the USA showed probably little to no difference in *STI incidence* in meta-analysis (RR: 0.985; 95% CI: 0.741–1.308), with no statistically significant heterogeneity ( $Q=2.120$ ,  $p=0.832$ ,  $I^2=0.000$ ).

Moderate certainty evidence from one RCT among people who inject drugs in Kazakhstan showed probably little to no difference in *HCV incidence* when calculated as an unadjusted RR directly (RR: 0.447; 95% CI: 0.158–1.267), but there was a reduction in HCV incidence when calculated by the study authors as a rate ratio adjusting for a baseline measure of unsafe injection in the past 90 days (rate ratio: 0.31, 95% CI: 0.10–0.90).

There was very low certainty evidence from seven RCTs among people in prisons, men who have sex with men, people who inject drugs and sex workers in China, Kazakhstan, Kenya and the USA on the impact of counselling behavioural interventions on *unprotected sex* (using various measures of condomless sex; RR: 0.821, 95% CI: 0.663–1.018). This meta-analysis showed statistically significant heterogeneity ( $Q=22.015$ ,  $p=0.001$ ,  $I^2=72.746$ ), which was not clearly explainable by subgroup analyses or other reasons, and it is uncertain whether counselling behavioural interventions reduce unprotected sex.

Low certainty evidence from two RCTs among people who inject drugs in the USA and Kazakhstan showed that there may be no impact on *needle and syringe sharing* in meta-analysis (RR: 0.719; 95% CI: 0.317–1.628), with no statistically significant heterogeneity ( $Q=1.135$ ,  $p=0.287$ ,  $I^2=11.909$ ).

### Feasibility, cost and cost effectiveness

A systematic review identified two studies with cost data on counselling behavioural interventions for key populations, both from the USA. Costs ranged from US\$ 682 to US\$ 782 for a single session and from US\$ 1823 to US\$ 3890 annually (345, 346).

One cost-effectiveness analysis of an intervention among sex workers along the Mexican and USA border that included multiple components was identified (346). For a hypothetical 1000 sex workers, receiving a once-only intervention, they calculated an incremental cost of US\$ 78 200, 33 HIV cases prevented and 5.7 months of quality-adjusted life-years (QALYs) gained, compared to no intervention. Additional cost per QALY gained was US\$ 183. For sex workers receiving the intervention annually, they calculated an incremental cost of US\$ 389 000, 29 additional HIV cases prevented and 4.5 additional months of QALY compared to the once-only intervention. The additional cost per QALY was US\$ 1075.

There is little evidence of cost or cost effectiveness of counselling behavioural interventions in different settings or for different modalities.

### Values and preferences

Two studies from the USA, one with men who have sex with men and one with transgender women, both focused on HIV, found that participants generally viewed specific counselling behavioural interventions favourably (347, 348).

Qualitative research conducted by four global networks of key populations found that key population members (see [Web Annex B](#) for full report) value peer-led education information, counselling and outreach as it is more likely to be non-judgemental and is provided by people who understand key populations' needs. They indicated a preference for multiple, consistent interventions, rather than one-off interventions and interventions delivered through a variety of mechanisms.

People who inject drugs appreciate access to information and education, but adequate access to evidence-based harm reduction approaches, such as NSPs, OAMT, and overdose management, remains a priority, in order to put health education into practice.

The focus of comments from all four key population networks in relation to other factors impacting access to behavioural interventions (including education and counselling) overwhelmingly related to structural issues, including: negative community and service-provider attitudes; problematic approaches and messaging; stigma and discrimination; and the need for law reform and education to change the way that key populations are perceived and treated.



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## Equity and acceptability

Provision of counselling behavioural interventions may increase access if a wide range of different interventions are available with tailored content that focuses on increasing access to health services and empowering key populations. However, the key population networks research identified a lack of formal education and literacy as barriers to HIV, STI and HCV prevention education. It noted the need for more specific, ongoing, peer-based and community-led HIV, STI and HCV education. When delivered through a variety of mechanisms and formats to account for different levels of access, knowledge and literacy, and when combined with counselling and other psychosocial supports, it leads to maximum effectiveness.

Key populations reported that behavioural interventions that promoted abstinence from drug use, or rehabilitation or cessation of sex work would reduce equity by creating barriers to service usage and should be avoided. Methods claiming to so-called cure homosexuality, such as conversion therapy, or other alleged methods to change gender identity or sexual orientation are harmful, are human rights violations and should never be conducted (349). Potential individual harm may occur when counsellors or counselling behavioural interventions promote abstinence from drug use, rehabilitation, cessation of sex work or advocate so-called cures for homosexuality, which can discourage key population members from accessing services. Moreover, diversion of funds to these forms of interventions can limit the availability of evidence-based interventions.

## Evidence assessment and decision-making

Following the WHO guideline development process, the Guideline Development Group considered the evidence and concluded that it was not possible to recommend counselling behavioural interventions to reduce HIV, viral hepatitis and STI incidence, given that there was no evidence of impact of the intervention on the outcome. However, the Guideline Development Group felt strongly that counselling and information sharing can enable informed consent and decision-making to initiate and continue certain interventions such as PrEP, ART, OAMT and NSPs. Counselling can enhance relationships between providers and clients and may encourage service access. The group determined to develop a good practice statement to make policy-makers and providers aware that while counselling interventions have other potential positive effects, there is moderate certainty of evidence that they probably do not reduce HIV, viral hepatitis or STI incidence.

## Implementation considerations

Given that a systematic review did not find any effect of counselling behavioural interventions on the incidence of HIV, viral hepatitis or STI, the choice to include counselling behavioural interventions in standard and minimum packages of interventions for key populations should be made with an understanding of the potential limitations on incidence outcomes.

If behavioural interventions are implemented, ongoing training for peers and health care workers is needed, and stigmatizing attitudes within the health system and structural barriers to care should be addressed urgently.

If implemented, behavioural interventions should be developed and implemented in collaboration with key population groups. These interventions should be tailored to specific key population groups and individuals, recognizing that people are in different stages of life and have different priorities and needs. Some people may be currently unable to change their risk behaviours, or may not want to make changes, and this should be accepted without judgement. Interventions which focus on cessation of drug use, rehabilitation, ending employment as a sex worker and purported cures for homosexuality create barriers to service usage, are not recommended and should be avoided.

## Research gaps

While further research to measure the impact of counselling behavioural interventions on HIV, STIs and viral hepatitis is not required, future research may allow us to better understand the effect of different aspects of counselling interventions on building client and provider relationships, psychosocial improvements and mental health. Research is required across a range of settings and for each of the key population groups. For young people, peer-based counselling has been shown to be a strategy that improves ART adherence, but more research is required on its impact on PrEP adherence for HIV prevention (350).

For the detailed evidence profile, please see [Web Annex C](#).

## Chemsex

### Background and rationale

Chemsex is a growing phenomenon where individuals engage in sexual activity while taking stimulant drugs such as methamphetamine, mephedrone or gamma-hydroxybutyrate (GHB). Chemsex typically involves multiple participants, the use of multiple drugs (including injecting drug use), and occurs over a prolonged time, for example, in group sex or orgy parties (351–353). Chemsex is also known by other names, such as slam sex (associated with injecting drug use), party and play, or sexualized drug use. There have been increasing reports of chemsex in some communities of men who have sex with men (352), most often in high income settings in Europe and North America, though a recent qualitative scoping review of sexualized drug use and chemsex among men who have sex with men and transgender women found it to be increasingly common in Asia (354, 355). The associate editor of The New England Journal of Medicine *Journal Watch Infectious Diseases* commented in 2018 that the “markedly high rate” of HIV infections among men who have sex with men participating in chemsex in a London study (356) “identifies a high-priority (but often challenging) population for





prevention efforts (including pre- and postexposure prophylaxis, mental health, chemical health, health promotion, and harm minimalization interventions)” (357).

Chemsex may be associated with unprotected sex and unsafe injecting, as well as hazardous drug use, overdose, drug dependence and adverse mental health outcomes (358), with one systematic review finding inconsistent evidence of increased HIV and HCV prevalence in those engaging in slam sex (injecting drugs before or during planned sexual activity) (351).

During the scoping exercise for the development of these guidelines, there was a request from key stakeholders for WHO to investigate further whether behavioural interventions can help increase uptake of services among people engaging in chemsex, reduce harms, and have an impact on HIV, viral hepatitis and STIs.

A systematic review did not identify any articles meeting the inclusion criteria for effectiveness or cost-effectiveness. Five articles assessing values and preferences were identified in the review (359–363) and qualitative values and preferences research on the topic (see [Web Annex C](#)) was undertaken by four key population networks. Overall, the values and preferences research revealed a preference for:

- specialist chemsex services (for example, specialized counselling with a single professional about both drug and sex-related issues);
- tailored, non-judgemental, peer-led services focusing on the principles of harm reduction rather than cessation of drug use;
- integrated sexual health and HIV, STI and viral hepatitis services; and
- more chemsex specific information and education to be available through various modalities that include explanations of potential risks.

Qualitative values and preferences research (see [Web Annex B](#)) showed that perceptions surrounding chemsex and its relevance varied both across and within the four key population networks. Although chemsex is most widely recognized and practiced among gay, bisexual and other cis men who have sex with men, participants beyond these communities also noted that they engage in drug use to enhance or prolong sexual experiences or both. Some participants described this activity without using the term chemsex. Some sex workers reported engaging in chemsex due to pressure from clients and from financial necessity.

The key population groups highlighted the need to promote awareness and education surrounding chemsex, as well as to address stigma and discrimination towards those who engage in chemsex. People who inject drugs stressed the importance of expanding the understanding and changing the framing of chemsex to the concept of “sexualized drug use” to help reduce judgement and rather encourage and support people to engage in “cultures of care”, including ideas such as “hosting packs” or “safety kits” that are harm-reduction focused and encourage people to “plan to be safe”.

WHO recommends various HIV, STI and viral hepatitis prevention options, which are relevant for those engaging in chemsex, including recommendations for condoms and lubricant for the prevention of sexual transmission of HIV and STIs, pre-exposure prophylaxis and post-exposure prophylaxis for HIV prevention, and provision of sterile needles and syringes for the prevention of HIV and viral hepatitis (3). Despite this guidance, communities and clinicians are increasingly concerned about the low uptake of these prevention interventions before, during and after engaging in chemsex, and about the ongoing risk. Interventions which aim to increase the uptake of these evidence-based prevention interventions, as well as the linkage to testing and treatment services and the integration of services, could have an impact on transmission among people engaging in chemsex. Referral to other relevant services for those reporting instances of non-consensual sex or drug use is essential.

Based on the available preferences of the key population community, the experience gained from implementation and from the evidence-based interventions already recommended by WHO, the Guideline Development Group made a good practice statement. The group recognized the importance of highlighting this phenomenon to HIV, STI and hepatitis programmes to ensure people engaging in chemsex are linked to the appropriate services in a non-judgemental manner.

## Online interventions

### Background and rationale

Increasingly, services designed for key populations are going online, conducting outreach to identify people at risk, providing information about available services, providing self-test information and tests, booking appointments for testing, and linking people diagnosed with HIV, viral hepatitis or STIs with service providers. The potential advantages of online services include: reaching a broader audience, reaching people who are geographically isolated, targeting information to specific people, improved efficiencies and convenience for clients.

Different forms of interventions are implemented online, the most common of which are:

- 1) **Online outreach** to potential key populations service users through online platforms involves reaching out to those who previously hadn’t been engaged, by using systems and structures like websites and social media apps, where key populations communicate and learn information and socialize.
- 2) **Online case management** for key populations who have tested positive and need to engage in services. Providing case management through online systems could potentially reduce loss to follow-up and provide helpful nudges (such as reminders to book an appointment or take a medication) and support for key populations.



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- 3) Targeted health information** uses internet sites and social networking apps to allow for messages to be targeted at user demographics and characteristics. For example, Facebook advertisements can target users of certain ages, political profiles, geographic locations, etc. Population segmentation may allow for more specific targeting of key population audiences to provide tailored information or linkage to health services.

## Evidence review

A systematic review was commissioned by WHO to answer the question of whether providing services online improves uptake of HIV, viral hepatitis, STI prevention, testing, linkage to treatment and treatment retention for key populations, compared to standard care .

Given the range of online interventions, the evidence review was split to consider the following separately: online outreach, online case management and targeted health information. The outcomes tested were for the following:

- online outreach – number or proportion of previously unreached people reached, use of prevention services, PrEP adherence, PEP uptake, PEP adherence, counselling, condoms, uptake of testing services for HIV, viral hepatitis and STIs, and treatment initiation for HIV, viral hepatitis and STIs;
- online case management – use of prevention services, uptake of testing services for HIV, viral hepatitis and STIs, treatment initiation for HIV, viral hepatitis and STIs, treatment retention or completion for HIV, viral hepatitis and STIs, viral load (for example, HIV and HCV), cure (for curable STIs, for instance HCV, syphilis and gonorrhoea) and mortality; and
- targeted online health information – use of prevention services, uptake of testing services for HIV, viral hepatitis and STIs, treatment initiation for HIV, viral hepatitis and STIs, treatment retention/completion for HIV, viral hepatitis and STIs, viral load (for example, HIV and HCV), cure and mortality.

Two RCTs (364, 365) and one serial cross-sectional study (366), all among men who have sex with men, were included in a review of online outreach; four RCTs (367–370) among men who have sex with men, transgender women and people in prisons, and three observational studies (371–373) among men who have sex with men, transgender women and people in prisons were included in the review of online case management; and two RCTs (374, 375) and one observational study (376), all among men who have sex with men, were included in the review of targeted online health information.

## Online outreach

A stepped-wedge cluster RCT among men who have sex with men (aged 16 years and older) in China found comparable (little or no difference) in self-reported condom use between clusters who received the online HIV testing intervention compared to conventional HIV testing programmes, routinely provided by local centres of disease control and community-based organizations (RR: 1.00, 95% CI: 0.86–1.17). There was high certainty that the estimated lack of effect is close to the true effect (364). Another RCT of men who have sex with men in China found that online outreach may make little or no difference to self-reported condom use, regardless of partner type, with low certainty evidence (RR: 0.90, 95% CI: 0.39–2.06) (377).

Moderate certainty evidence from a meta-analysis of the same two RCTs showed a probable increase in HIV testing (RR: 1.39, 95% CI: 1.21–1.60) (364, 377). Moderate certainty evidence from one of these RCTs showed probably no difference in syphilis testing (RR: 0.92, 95% CI: 0.70–1.21) (364).

Moderate certainty evidence from one serial cross-sectional study among men who have sex with men in the USA showed probably more previously unreached people getting reached (366). When only traditional outreach methods were used (October 2011 to March 2012) the local public health department had contact with 60 men who have sex with men. After implementing outreach via Grindr (from October 2013 to March 2014), the department made contact with 816 men who had had sex with men. There was no denominator to calculate rates, only number of contacts (which may include duplicates), and possible confounding from other factors, creating the potential risk of bias.

## Online case management

In terms of PrEP adherence, low certainty evidence from one RCT among young men who have sex with men and transgender women (from 15 to 19 years old) in Thailand showed that there may be no difference in use of PrEP services when comparing those who used an online case-management application (provided alongside standard youth-friendly services) to no application, but with the same youth-friendly services (RR: 1.12, 95% CI: 0.78–1.59) (370).

One RCT among men who have sex with men in the USA showed no difference in uptake of repeat HIV testing (RR: 1.24, 95% CI: 0.78–1.95) (367), but due to the very low certainty there is limited confidence in this estimate.

A cohort study among people in prisons living with HIV in the USA found that there may be no difference in linkage to care after release from prison, when comparing those who used an online tailored or personalized website with those who only have access to an online provider directory webpage (RR: 1.09, 95% CI: 0.92–1.29) (low certainty) (373). Another cohort study among men who have sex with men and transgender women in the USA found that there may be a modest increase in the proportion who received primary HIV care in the last six months, when comparing those who completed a six-month digital HIV care navigation intervention with those who did not (RR: 1.20, 95% CI: 1.01–1.42) (low certainty) (372).

One RCT with moderate certainty among 90 stimulant-using men who have sex with men living with HIV in the USA found probably higher overall ART adherence in the intervention than the control arm at 4 months: 89.0% (95% CI: 83.4–94.6)



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intervention versus 77.2% (95% CI: 66.7–87.7) control, giving a difference in ART adherence of 11.8% (95% CI: 0.34–23.2;  $p=0.04$ ). However, two months after the intervention the improvements in adherence had probably dissipated: 85.3% (95% CI: 80.0–90.6) intervention versus 89.0% (95% CI: 83.2–94.9) control, giving a difference of -3.7% (95% CI: -11.4–4.0;  $p=0.34$ ) (368).

One RCT with low certainty among 110 soon-to-be or recently released people in prisons living with HIV in the USA found that online outreach may make little or no difference in engagement in HIV care, measured by having seen an HIV care provider in the community at least once in the past 24 weeks (RR: 0.98, 95% CI: 0.85–1.12) (369). A cohort study with low certainty among 120 men who have sex with men and transgender women living with HIV in the USA found online case management may make little to no difference in the proportion of people in each group self-reporting currently taking ART (RR: 1.19, 95% CI: 0.97–1.45) (372).

The RCT with low certainty among people in prisons living with HIV in the USA found that being in an intervention group that received a computerized motivational interview and individual risk reduction plan pre-release, plus text messaging about care navigation post-release, made little or no difference to viral suppression (lab-assessed viral load < 200 copies/ml) (RR: 0.97, 95% CI: 0.69–1.36) (369). A cohort study among men who have sex with men and transgender women living with HIV in the USA also found that using online case management makes little or no difference to viral suppression (self-reported viral load < 200 copies/ml) (RR: 1.05, 95% CI: 0.79–1.40) (372). However, another cohort study with moderate certainty among 1201 people in prisons in the USA found probable improvement in the proportion of participants who had lab-assessed virologic suppression at any of their first six care visits (RR: 1.53, 95% CI: 1.43–1.64) (371).

No studies measured our other outcomes of cure (for example, HCV, syphilis or gonorrhoea) or mortality.

### Targeted health information

One RCT with low certainty among men who have sex with men in the USA found that targeted health information may make little or no difference in testing for HIV (measured by following up for HIV test result after requesting a HIV self-test kit and returning the kit) (RR: 2.19, 95% CI: 1.20–4.01), though more participants in the intervention arm requested the kit than in the control arm (375). A serial cross-sectional study among men who have sex with men in Canada with low certainty determined with GRADE methodology also found little or no difference in the number of people who ordered a syphilis test before, during or after a syphilis testing advertisement campaign (RR: 1.00, 95% CI: 0.94–1.07) (376). Another RCT was conducted among young men who have sex with men (aged from 15 to 24 years old) in the USA. Based on these results, it is uncertain whether virtual targeted health information improves testing rate for HIV or STIs (RR: 1.46, 95% CI: 0.72–2.94) because the sample size was very small (374).

Based on evidence from one RCT among men who have sex with men in the USA, it is uncertain whether targeted health information improves uptake of prevention services (STI vaccination) because the certainty of evidence is very low (374). No studies measured our other outcomes of interest: treatment for HIV, viral hepatitis and STIs, treatment retention or completion for HIV, viral hepatitis and STIs, viral load (for example, HIV and HCV), cure (for STIs, for example, syphilis and gonorrhoea) or mortality.

### Feasibility, cost and cost effectiveness

Access to the internet and social media apps has grown exponentially in recent years, even in low-income settings. Many government and community-based programmes are already using online services for key populations, suggesting it is a feasible intervention in many settings (378).

Only one study was included in the cost review (379). This study among men who have sex with men in Canada found that syphilis testing campaign advertisements released over one month over four platforms had the lowest cost-per-click ratio on the hook-up platforms Grindr and Squirt, compared to more traditional social media platforms like Facebook and the Gay Ad Network. No studies measured cost effectiveness.

Indirect evidence from FHI360 *Going online budgeting guide* (380) shows a wide range of costs for programmes, depending on scope of work, including, but not limited to: country or regional costs, connectivity level, programme intensity or scale, vendors, in-person trips or training needs and equipment needs.

### Values and preferences

Related to online outreach, in Spain, men who have sex with men thought it acceptable to receive unsolicited messages about rapid HIV, syphilis or HCV testing on social media or hook-up apps (381). In Kenya, Rwanda, South Sudan, Tanzania and Uganda, almost half of respondents who self-identified as a sexual or gender minority were “very likely” to engage in a sexual health programme if outreach was conducted online using either text messages or emails (382). In China, men who have sex with men stated high interest and willingness to use a “men who have sex with men-friendly physician finder function” within gay mobile on-line applications (383).

Related to online case management, men who have sex with men in China expressed interest in features or functions related to sexual health that could be embedded in existing smartphone apps or developed as standalone apps (384). Men who have sex with men in the USA were strongly in favour of a smartphone app developed for online case management (385). Positive features of such apps were their ease of use (easy to navigate, fast and convenient), the ability to set reminders or alarms to take medication at a certain time each day, trackers for adherence and communication with providers, which helped users feel supported in their care process. Several studies mentioned concerns regarding ensuring confidentiality in the online environment (368, 385, 386).



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When asked about targeted online health information specifically, men who have sex with men expressed a diverse range of acceptability; however, most were comfortable interacting with health services online (376).

Qualitative research conducted by four key population networks (see [Web Annex B](#)) showed that, overall, participants across key population groups and regions supported the use of online services and platforms to augment in-person services. At the same time, many participants described challenges associated with varying levels of internet access, digital competencies, as well as the broader implications of poverty.

It was stressed across all key population groups that online services and platforms cannot replace in-person health services. Participants emphasized the importance of maintaining in-person, face-to-face services as a gateway to broader health and support services, as well as a means to foster personal connections and trust. Participants raised security concerns associated with leaving a digital footprint.

## Equity and acceptability

In a qualitative, questionnaire-based study among frontline outreach workers, managers or public health volunteers who worked with men who have sex with men in Canada (387, 388), it was noted that online technologies have reshaped the “gay or queer community”, changed norms for social and sexual interactions, and that these online technologies can help reach out to hard-to-reach people. They found that, generally, online outreach allowed for more non-intrusive and anonymous communication (beneficial for clients), yet quick feedback helped them be responsive to user needs. They also outlined some barriers to online outreach, such as quality of service, collaboration between outreach service agencies and companies that own apps and websites, budgetary and staff or volunteer capacity constraints, and data security and safety. From their own experiences, service providers mentioned four ethical dilemmas as outreach moved to online platforms: 1) managing personal and professional boundaries with clients; 2) disclosing personal and identifiable information to clients; 3) maintaining client confidentiality and anonymity; and 4) security and data storage measures of online information.

While noting that online platforms can be particularly impactful amongst harder-to-reach sub-populations, such as migrant sex workers or young men who have sex with men, participants in the key population networks’ values and preferences research also highlighted the role that digital inequality plays in mediating access to, and uptake of, online services. Concerns, including reduced access to technology or electricity, high data costs and differing levels of digital competencies, were all cited as factors affecting the use and impact of online tools and platforms. Those with limited or controlled access to mobile devices, particularly women and adolescents, were particularly vulnerable to digital inequality (378). These issues can be exacerbated by criminalization and law enforcement actions.

## Evidence assessment and decision-making

Overall, the evidence indicates that online service delivery is at least as effective as face-to-face services in terms of reaching new people, use of HIV and STI prevention services, linkage to and retention in HIV care. While the evidence of effect was modest or small for some outcomes, and for other outcomes there was no effect found, the evidence did not show worse outcomes when employing any online service delivery method. These interventions are feasible, acceptable and may increase equity. The resource requirements will vary depending on setting and intervention, and cost effectiveness is uncertain.

For some people who are unable to attend face-to-face services, online services may offer the only means of receiving information, support, referral and case management. But while the use of online services is increasing, there are still limitations related to reach. Furthermore, key populations said they value online services, but felt strongly that these services should complement and not replace face-to-face services. Potential harms related to data security and confidentiality was of particular concern for key populations who may engage in criminalized and stigmatized activities and experience discrimination, arrest or harassment if confidentiality is breached. For these reasons a conditional recommendation was made in favour of online services.

## Implementation considerations

Online services complement but do not replace face-to-face interactions and should be part of larger HIV, STI and viral hepatitis programmes for key populations. Systematic planning of the ways in which online services can complement other services and target audiences should be conducted with key populations playing a central role in their design, implementation and monitoring. Content development should be informed by appropriate and accurate health content and information aligned with recommendation practices (for example, from health programme guidelines or evidence-based normative practices) (389). Demand creation plans, service delivery packages and approaches need to be customized, based on country contexts and priorities. Online services can effectively be managed and implemented by key population peers.

Efforts should be made to make access to the internet equitable, improve literacy and provide appropriate training where needed. Where barriers to key populations accessing online services remain, this needs to be taken into consideration when planning and implementing online programmes.

Safety and security in online services need to be maintained by the following means: monitoring for harm, explicitly stating and using de-identified information as much as possible; maintaining data protection and storage, and training all staff in data security measures; thinking about the setting and using broad branding that does not lead to identifying certain groups of key populations; training staff in client confidentiality; verifying health worker licenses and credentials



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where applicable; using secured internet, devices and apps; and providing services only with informed consent from clients (390).

WHO has further guidance and recommendations on general population digital health, as well as a framework for planning, developing and implementing solutions with and for young people (180, 389).

## Research gaps

Available published research about online services for key populations is mainly among men who have sex with men in high income countries and related to HIV. Further research is needed on the accessibility, safety and effectiveness of online services for other key populations, the various experiences and preferences of different key populations in low- and middle-income settings, and their effect on outcomes related to STIs and viral hepatitis. Continuing monitoring and evaluation and publishing the implementation results will also support and help to refine future guidance.

More research is needed on the cost effectiveness of different types of online services by key population groups.

## Peer navigators

### Background

Peer navigation is rooted in the concept of *patient navigation*, where vulnerable patients are directly assisted to help find their way through complex health care systems to obtain timely diagnoses and treatment. Instead of formal health workers, lay staff members who are peers of the participants and therefore could promote trust among the population fill this role (391). While lay providers, including key populations, are recommended to provide HIV testing and ART distribution (190), the role of a peer navigator is different. Key population peer navigators are often employed at community-based services, primary health care settings and testing and treatment facilities that are designed to serve people from key population groups. Their role is to support key populations, after screening positive, to access confirmatory diagnosis and treatment services; to support the early stage of treatment with regular peer support, as well as to accompany key populations to appointments; and support navigation to other related health services. This is important as key population members are often under-represented in treatment programmes, and can be reticent to access treatment due to their fear of discriminatory attitudes among health care providers and other staff in health care settings, and due to their lack of experience with traditional, facility-based programmes.

### Evidence review

WHO commissioned a systematic review to answer the question of whether peer navigators improve initiation and retention in HIV, viral hepatitis and STI treatment programmes for people from key populations. The outcomes tested were: time to diagnosis or linkage to care, treatment initiation, treatment retention and completion, viral load, cure and mortality.

Four studies (two RCTs and two observational studies) were included in the systematic review designed to find the effect of peer navigators on time to diagnosis, linkage to care, treatment retention or completion, and viral load or disease cure. All these studies measured HIV outcomes, and none measured STI or viral hepatitis outcomes.

One RCT in the USA, with high certainty evidence, found no difference in probability of HIV care visits after release from jail for people in prisons with involvement of peer navigators (RR 0.95, 95% CI: 0.81–1.12) (391), one RCT among sex workers in Tanzania found there may be improvements in linkage to care (RR 1.44, 95% CI: 1.15–1.80), but there was low certainty of this effect (128), and one observational study among transgender women in the USA found improvements in linkage to care when people were assisted by peer navigators (regression coefficient 0.38; 95% CI: 0.09–0.67) with moderate certainty that the true effect was close to this estimate (392).

The employment of peer navigators was found to result in modest improvements in current ART use in one RCT in Tanzania (RR 1.28, 95% CI: 1.05–1.55) (128) and one observational study in the Dominican Republic (RR 1.11, 95% CI: 1.03–1.19) (393), both with low certainty of evidence. The RCT among people in prisons found no difference in ART use with peer navigation (RR 0.97, 95% CI: 0.87–1.08) and there was moderate certainty that the true effect was close to this estimate (391).

One RCT showed improvements in undetectable viral load with peer navigation (RR 1.38, 95% CI: 1.03–1.85) with high certainty indicating that this estimate is very close to the true effect (391), but the other studies found no difference (128, 392, 393), all with moderate certainty. No studies measured the outcomes of treatment initiation, cure or mortality.

### Feasibility, cost and cost effectiveness

Peer navigators have been employed at community and facility-based services in several different settings, and it is feasible to introduce this role to new or existing programmes.

A systematic review did not identify any research on the cost or cost effectiveness of key population peer navigators in HIV, STI or viral hepatitis programmes. Guideline Development Group members judged that as peer navigators work to support existing programmes, the cost associated with their employment may be considered to be moderate and related to salary, training, transport and tools such as mobile phones.





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## Values and preferences

Key population network-led qualitative research was undertaken to assess values and preferences associated with peer navigation in all key population groups, except for people in prisons (for detailed report, please see [Web Annex B](#)). Although the term “peer navigators” was not universally recognized by all participants, the practice of peers assisting with health service access, information, education and referral was greatly valued by participants across all four key population groups. Participants both supported the concept of peer navigators, as well as their capacity to “act as a bridge between two different worlds”. In some settings, peer navigators were described as one of the only available tools for reaching communities. Peer navigators were considered as facilitators throughout the testing and treatment cascade – including treatment linkage, continuity and re-engagement.

## Equity and acceptability

Key population peer navigators improve linkage to care and retention in treatment programmes for populations who may otherwise be excluded due to structural barriers, including stigma, poor literacy and poverty. In this respect, peer navigators have an important role in improving equity by assisting those with inequitable access to health care to enter testing and treatment programmes.

A systematic review identified two studies of acceptability related to key population peers, which found overloaded health workers welcomed assistance from peer navigators and suggested appropriate tasks for them. However, concerns were expressed about clients becoming too dependent on peer navigators (that they are not able to self-manage), and there were some negative and discriminatory community reactions to support groups for men who have sex with men (394). In Mexico, staff at a community-based organization felt peer navigators could address stigma and social support. However, they discussed concerns about police interference with peer navigators, and whether it put peers and their clients at risk of harassment and arrest (395).

## Assessment of evidence and decision-making

The benefits of using peer navigators include, as described above, the prospect of them improving linkage to care and retention in treatment. Key population members highly value services provided by their peers, and community empowerment is an evidence-based intervention (122, 127). It was noted that support from peer navigators is not always desired by all key population members, particularly when people do not wish to disclose their disease status to a peer.

Peer navigators increase equity, and peer navigation is a feasible intervention. The costs vary greatly depending on setting, and cost effectiveness is unknown.

The evidence included in the systematic review was only relevant to HIV programmes, although STI and viral hepatitis programmes also employ peer navigators. It was decided that there was adequate indirect evidence to make a recommendation that applies to the three disease areas. Based on the moderate certainty of evidence supporting peer navigators, the value placed on peer navigators by key populations, and the likely beneficial effect on equity, the Guideline Development Group made a conditional recommendation in favour of peer navigation.

## Implementation considerations

Key population peer navigators are increasingly employed at health services, along with key population peers who undertake different roles (including planning, mapping, management, education, adherence support, outreach, testing, distribution of medicines, overdose management, condoms and needles/syringes, etc). All peers who work within HIV, STI and viral hepatitis services need to be recognized as part of the health workforce, be fairly remunerated and receive ongoing training and development to fulfil their roles. Peer navigators can be subject to additional risks, such as arrest and violence, because they can be identified by police or others as members of the key populations; therefore, efforts should be made to protect peer navigators, in particular young key population peers, from any additional risks.

According to participants in the key populations’ values and preferences research, the key traits of successful peer navigators include: passion for the community and the health issue, communication, compassion, supportive listening skills, first-hand experience, trustworthiness, empathy and dedication. Participants also stressed the importance of having peer navigators with appropriate age, gender, cultural and linguistic backgrounds.

While valued by key populations in general, not all key population members need or want the support of a peer navigator. Concerns about confidentiality may mean that some people prefer not to disclose their infectious disease status to a peer; therefore, they will not be comfortable using the services of a peer navigator, which highlights the importance of informed choice when implementing this intervention.

## Research gaps

While there is considerable research about the effectiveness of peers as treatment support staff and patient navigators, there is far less research that is specific to key populations. More studies are needed to understand the effectiveness of different approaches for various key population groups of all ages, as well as for STIs and viral hepatitis. Overall, better research on what works to improve treatment outcomes among key populations is needed.





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## HCV recommendations: introduction

Effective and affordable diagnostics and treatment are available for HCV and recommended by WHO (184, 185, 193, 396), but a rapid increase in the availability and accessibility of HCV testing and treatment for all populations, including those at increased risk and those with HCV reinfection, will be needed to reach the elimination targets.

HCV causes both acute and chronic infection. Acute HCV infections are usually asymptomatic, and most do not lead to a life-threatening disease. Following recently acquired HCV infection, approximately 30% (15–45%) of infected persons spontaneously clear the virus within 6 months of infection without treatment (15), with a median time to clearance of 16.5 weeks. Spontaneous clearance is more likely to occur in women, genotype 1 infection, and people with clinical evidence of acute hepatitis, but less likely to occur in people with HIV (397). The remaining 70% (55–85%) will develop chronic HCV infection. Of those with chronic HCV infection, the risk of cirrhosis ranges from 15% to 30% within 20 years (193). Importantly, individuals that clear HCV infection spontaneously or after treatment are not immune to the virus, and those with ongoing risk and exposure can become reinfected.

“Treatment-as-prevention” is becoming a key part of a multifaceted public health approach to HCV elimination. Early identification of primary and recurrent HCV infections, as well as timely treatment, is vital for a treatment-as-prevention approach, in order to reduce transmission and liver disease-related morbidity and mortality (398) – especially in countries where many of the new HCV infections are among key populations.

## HCV retesting after resolved HCV infection

### Background and rationale

After HCV infection and DAA treatment or spontaneous clearance of HCV, ongoing risk behaviours, poor access to prevention interventions, and persistent structural barriers for groups such as people who inject drugs and men who have sex with men may lead to HCV reinfection, which often goes undiagnosed. The potential for HCV reinfection remains a major obstacle to achieving the HCV elimination goals. From a patient perspective, concern for HCV reinfection remains a major driver for provider and health system-level barriers to HCV treatment of persons perceived to be at high risk for reinfection after cure (399). From a population perspective, elimination is dependent on diagnosing and treating enough infected individuals, so as to reduce overall population prevalence, and thereby reduce the pool of individuals who can sustain the epidemic by transmitting infections to others. If people with high risk of transmission do not receive HCV diagnosis and treatment in a timely manner, this may present an ongoing challenge to community-wide and global HCV elimination (220).

To address missed diagnoses of HCV reinfection among priority groups, to offer continued care and to increase access to treatment, several national and international guidelines, including WHO’s, suggest serial testing for hepatitis C reinfection in priority groups, but do not state a specific testing frequency (184, 400). Determining this optimum frequency will assist in a treatment-as-prevention approach to reduce HCV incidence and prevalence, notably among most-affected populations.

### Evidence review

A systematic review was commissioned by WHO to answer the question of how often people with ongoing risk of HCV infection should be retested for evidence of viremia (using NAAT) for HCV RNA or HCV core antigen after treatment-induced or spontaneous HCV clearance. The primary outcome tested was the detection rate of HCV reinfection and the secondary outcomes were testing uptake for viremia (RNA or HCV core antigen) testing; linkage to clinical assessment or treatment initiation following reinfection or both; risk behaviour and adverse events or social harm.

No RCTs or comparative studies were identified. Thirty-five other studies were included in the review; 33 were single-armed observational studies and two were modelling studies. The 33 observational studies comprising 10 857 participants (key population groups included in the literature were people who inject drugs, people in prison or closed settings and men who have sex with men) at risk of HCV reinfection reported HCV reinfection incidence per 100 person-years (py), hence were included in a meta-analysis. The included studies did not report results for any of the secondary outcomes.

The studies had varying testing intervals; in order to answer the research question, the most meaningful comparison was between studies testing at 3–6-monthly intervals versus studies testing at greater than 6-monthly intervals.

The overall pooled HCV reinfection incidence estimate was 4.73 per 100 py (95% CI: 3.68, 5.78). The pooled incidence estimate among people who inject drugs was 3.94 per 100 py (95% CI: 2.83, 5.05), among men who have sex with men 7.11 per 100 py (95% CI: 4.16, 10.06) and among people in custodial settings 6.00 per 100 py (95% CI: 0.00, 12.31). Very low certainty evidence showed that among studies that reported a testing interval of 3–6 months, the pooled incidence estimate of 5.88 per 100 py (95% CI: 4.14, 7.61) was higher than studies reporting testing less frequently than every 6 months (up to every 12 months) at 3.08 per 100 py (95% CI: 1.81, 4.35). Additionally, among the people who inject drugs population, very low certainty evidence showed that pooled reinfection incidence was higher in those tested every 3–6 months at 5.39 per 100 py (95% CI: 3.47, 7.31) compared to those tested less frequently than every 6 months (up to every 12 months) at 1.84 per 100 py (95% CI: 0.64, 3.05). Given the very low certainty, confidence in these results is limited. Differences in incidence were not reported in other population groups from the studies included.

Two modelling studies were also identified that directly compared more and less frequent HCV testing regimes. A modelling study in India used a closed Markov model of reinfection among people who inject drugs in India. They



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assumed 6.2 million chronic HCV patients, 10% infections diagnosed/year, a reinfection rate 1.0/100 py, baseline DAA efficacy off 90%, the cost of DAAs US\$ 900 for a 3-month course, and standard Indian costs for hepatitis C treatment. In a sensitivity analysis post successful treatment, the authors compared a one-off testing strategy at 1 year post-SVR compared to a regular annual testing strategy. They found that ongoing annual testing was more effective (0.4 QALY/person treated), cost-saving (US\$ 993 per person), and very cost effective, with a negative incremental cost-effectiveness ratio (401).

A modelling study in France used a deterministic dynamic compartment model among HIV-positive men who have sex with men in France, assuming a baseline HCV prevalence of 3.6%. Their baseline scenario involved DAA treatment of all patients and 12 monthly population testing, and projected that HCV incidence would fall from 0.98 to 0.24/100py. The authors found that more frequent testing (3, 3–6 or 6-monthly) was associated with further reductions over baseline in overall HCV incidence by 2030. The reinfection incidence in these scenarios was also modelled, and demonstrated that 3, 3–6 and 6-monthly testing reduced HCV reinfection incidence by 2030 significantly more than baseline (12 monthly testing, though there was little difference between reductions from 6-monthly (18.5%), 3–6-monthly (21.5%), and 3-monthly testing (23%) (402).

Overall, there is very low certainty evidence that more frequent testing may identify more infections, and therefore be beneficial in contributing to preventing onward transmission if individuals are linked to treatment and care. Some of the differences between testing intervals may have been found because researchers and clinicians were more likely to frequently test patients at higher risk of reinfection.

### Values and preferences

Preferences regarding frequency of HCV testing varied greatly across the three key population groups who were asked this question in the key population-led values and preferences qualitative study (people who inject drugs, men who have sex with men, and sex workers) (see [Web Annex B](#)). Men who have sex with men pointed out a lack of protocols and the need for evidence to guide frequency of HCV testing recommendations. Meanwhile, sex workers had a wide range of preferred HCV testing frequencies – from once a week to once a year – with many participants considering 3–6 months as optimal. People who inject drugs suggested that individuals be tested every 3-months for the first year following viral clearance, and then subsequently every 6 or 12 months, depending on risk profile.

Sex workers and people who inject drugs preferred that regular HCV RNA testing and retesting following cure be made available, and promoted similarly to HIV “Test and Treat” approaches, whereby regular monitoring is publicly and positively promoted, widespread testing is facilitated, and immediate treatment for those diagnosed is encouraged. All groups highlighted concerns associated with criminalization, stigma, and discrimination, noting that testing should always be voluntary.

Overwhelmingly, key populations preferred HCV services to be community-led and available within community settings, in order to address concerns related to safety, confidentiality, stigma and discrimination, as well as criminalization. Increased training and resources to support community organizations in this work will be required. People who inject drugs emphasized the importance of embedding HCV testing within a broader harm reduction approach that did not focus on abstinence, including offering pan-genotypic DAA treatment and HCV prevention for people in prisons.

No additional studies on related values and preferences were identified through the systematic review.

### Resource-use: cost and cost effectiveness

The costs, both for tests confirming the presence of HCV viremia and for treatment for those identified HCV positive, vary considerably, depending on settings and countries. In particular, NAAT and HCV core antigen are relatively expensive in many lower- and middle-income settings.

More frequent testing could involve increased short-term costs of tests, costs of outpatient visits, including personnel and, if more reinfections are identified, the short-term costs of increased treatment. The approach may also entail opportunity costs for time and attention spent by medical personnel and administrators. Testing people more often after they have been successfully treated may also divert resources away from other testing programmes, such as those aiming to reach a larger population of people who have not had access to testing or treatment.

In the long-term, there may be cost savings by averting costs of advanced hepatitis disease and liver failure. There is some support from modelling evidence (401, 403), with one modelling study suggesting that more frequent annual testing for reinfection of people who inject drugs post-treatment was overall cost-saving, compared to a one-time only retest (220).

### Equity

More frequent HCV testing could potentially increase early diagnosis and treatment of HCV reinfection in priority groups, thus reducing HCV infection and improving health equity. However, increased testing frequency could also potentially increase the burden of medical interventions for patients who may have multiple comorbidities and a high treatment and investigation burden. Testing should be voluntary, and streamlining medical visits and investigations should always be considered.

### Feasibility and acceptability

NAAT and HCV core antigen testing accessibility and cost vary widely across settings. Thus, feasibility is dependent on the context, availability of resources and health system capacities. In settings with existing point-of-care solutions or



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well-developed linkage services, frequent retesting may be a feasible approach. For some people though, offers of more frequent testing based on risk may be stigmatizing and create barriers to accessing services. Also, it may be difficult to correctly assess ongoing risk, particularly in settings where key populations are criminalized and stigmatized, as people may choose not to disclose risk behaviours, and equally it will not always be possible to know about individuals' history of treatment or clearance. Moreover, increased frequency of testing, especially in the 3–6-monthly range, may be a significant time and resource burden, which may influence acceptability among providers and policy-makers.

### Assessment of evidence and decision-making

The review found very low certainty evidence, from one-armed observational studies and limited modelling studies, in favour of more frequent retesting in people at ongoing high risk for HCV reinfection, particularly in people who inject drugs. Overall, the Guideline Development Group determined the certainty of evidence to be very low. While evidence of effect was small across the principal outcome, the Guideline Development Group highlighted that testing for presence of viremia in people with ongoing risk and previously cleared infection may be beneficial at both the individual and population level.

The main physical harms of more frequent blood testing for HCV are relatively minor, such as short-lived discomfort and bruising. The very rare risk of false positives should also be considered.

Considering the evidence of benefits for 3–6-monthly testing for reinfection; the relatively strong support from community values and preferences; the potential for expanding patient choices; the feasibility to implement; as well as potential for cost-effectiveness and improved equity, the Guideline Development Group deemed that the overall benefits outweigh the potential harms and risks. More frequent testing of people at ongoing risk can identify more people with viraemic HCV; the potential benefits of this include population-level ones, such as reduced HCV incidence and prevalence over time, due to more infections being treated and accordingly less potential for community transmission, and better individual patient outcomes related to early diagnosis. Patients may also benefit from better engagement in the health care system for other interventions, such as OAMT.

The Guideline Development Group recognized that testing frequency for reinfection should be contextualized and adapted to the reinfection incidence of a population. Furthermore, short-term costs and accessibility of diagnostics for presence of viremia (NAAT and HCV core antigen testing) may be a limitation to scaling-up the recommendation in some settings. Given the range consideration, the Guideline Development Group agreed to make a conditional recommendation.

### Implementation considerations

In general, a successful response to HCV requires available, accessible, affordable and coordinated prevention, testing and treatment services, with well designed integrated service delivery and referral pathways. It is important to highlight that the frequency of retesting needs to be contextualized, and that the recommendation is meant to orientate programmes towards a potential testing frequency. Planning country-level testing frequency needs to factor in resource needs and evolving epidemiological patterns in certain populations and settings. Additionally, HCV management should include screening for HIV, STIs and voluntary partner notification for HCV testing where appropriate. Importantly, testing approaches and policies need to be developed with support from, and in exchange with, affected communities.

One of the major objectives of extending testing, referral and linkage to treatment to people with ongoing risk is the potential of population level benefits and a reduction of HCV transmission. Frequent testing for viremia should be offered alongside additional, evidence-based interventions to reduce HCV risk, and primary prevention services, such as harm reduction (NSPs and OAMT), which remain a priority and should be offered alongside testing for reinfection and not be de-prioritized. This new recommendation is particularly relevant for countries and settings where the reduction of HCV incidence is a major aim of the programme, and includes approaches such as micro-elimination in certain population groups.

Given that NAAT for occurrence of HCV RNA and HCV core antigen testing accessibility varies widely across settings and is often centralized, with the majority of tests requiring processing at central laboratories, decentralized models of care – with increased availability of point of care testing – are needed to make more frequent retesting feasible. It is important that frequent retesting is implemented in a way that does not reduce the number of people assessed for longstanding chronic HCV infection.

It is important to differentiate between HCV reinfection and treatment relapse in people with past DAA treatment. Evidence of HCV clearance and cure is evaluated 12 weeks after end of treatment (sustained virological response at 12 weeks post-treatment (SVR12)). SVR12 is widely considered to be equivalent to virologic cure. In the oral DAA era, rates of virologic relapse after the achievement of SVR12 are very low (399) and, when it occurs, it is usually within the first four weeks after end of treatment. Thus, a diagnosis of HCV reinfection can be made when HCV viremia is detected in persons who achieved SVR12 following completion of treatment with an effective oral DAA combination regimen, notably in persons who also have probable or definite risk factors for reinfection. In people with viremia between treatment completion and SVR12 assessment, or people for whom SVR12 is unknown, a further differentiation between relapse and reinfection may be useful and needed to orientate treatment decisions.

Monitoring and reporting systems are critical for all approaches to viral hepatitis testing and treatment, and it is essential for programmes to utilize or adapt existing systems to monitor and report on adverse events, in order to address harm if and when it occurs.



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## Research gaps

Current research about HCV testing and detection of viraemic infections in people with ongoing risk comes largely from high-income countries.

Therefore, more research, ideally through comparative longitudinal studies comparing 12 monthly testing with more frequent testing or modelling, is needed to answer the question of whether more frequent testing after reinfection, followed by immediate treatment (namely, test and treat), would support a treatment-as-prevention strategy and micro-elimination of HCV with population-level benefits. There is a need for more research from LMICs. Real-world studies in different settings are needed to further establish cost-effectiveness and assess resource needs, feasibility and acceptability.

## HCV treatment for recently acquired infection

### Background and rationale

WHO currently recommends HCV therapy with pan-genotypic DAAs for all persons with chronic infection over the age of 18 years and irrespective of disease's stage. DAAs can cure most persons with chronic HCV infection, and treatment duration is short (usually from 12 to 24 weeks), depending on the absence or presence of cirrhosis (193). However, DAA treatment is not currently approved by certain regulators for the treatment of recently acquired hepatitis C (404). The rationale for this policy is to avoid unnecessary treatment and costs, since around 30% of people will clear the virus without treatment. This argument may become less important in contexts in which the costs of treatment is reducing. More recently, clinical guidelines from umbrella organizations in Europe and the USA recommend the treatment of recently acquired infection, recognizing the benefits, such as reductions in loss to follow-up, avoiding chronic infection and reducing ongoing transmission (405, 406).

### Evidence review

A systematic review was commissioned by WHO to determine the benefits and harm of immediate treatment of recently acquired hepatitis C in people at ongoing risk, and to update the current body of evidence informing the timing of HCV treatment. The outcome measures were hepatitis C incidence, treatment initiation, engagement in care (adherence), overtreatment, adverse events, treatment completion and SVR12.

A post-hoc review of the search results was conducted to identify modelling studies evaluating the effectiveness of treating recently acquired HCV infection, and any studies that reported on values and preferences of stakeholders.

No randomized controlled trials nor comparative studies were identified in the systematic review. Twelve noncomparative studies were included in the review: three single-group prospective cohort studies (407–409) five retrospective cohort studies (410–414), three cohorts embedded in open label trials (415–417) and one case series study (412). Across all these studies, all outcomes were rated as providing very low certainty evidence using the GRADE approach. In general, this was due to the noncomparative nature of these study designs and the indirectness and inconsistency of the data.

Two retrospective cohort studies and one prospective cohort (embedded within an open label trial) reported HCV incidence among men who have sex with men living with HIV, and allowed a comparison of incidence before and after the implementation of an HCV treatment policy for recently acquired infection (411, 412, 416). Two of these studies reported a decrease in HCV incidence at the end of the study period; a study set in a Swiss cohort which reported a decrease in incidence from 0.53/100 py in 2014 to 0.12/100 py in 2019 (416), and a study set in the United Kingdom, which reported a decrease from 11.28/1000 py in 2016 to 4.63/1000 py in 2018 (412). One study found an increase in incidence over the study duration, from 0.73/100 py in 2015 to 1.25/100 py in 2018 (412). These studies were in large cohorts of men who have sex with men, where most of the patients were being treated in the chronic phase of infection rather than recently acquired infections. As treating chronic hepatitis C can reduce incidence on population level as well (418), it was not possible to identify the distinct effect of treating acute infection on incidence in these cohorts. Given the very low certainty, there is limited confidence in these results.

Seven studies (three retrospective and two prospective cohorts, one open label trial and one case series), including a total of 567 participants with recently acquired hepatitis C, reported SVR12 in men who have sex with men, people living with HIV and people who inject drugs (407, 409, 410, 413, 414, 417, 419). The studies showed with a very low certainty evidence that people with ongoing risk treated for recently acquired HCV infection with DAA achieved consistently high rates of cure, consistent with the rates of cure seen for those treated with antivirals for chronic HCV in key risk groups. Pooled SVR12 across all risk groups was 95.9% (95% CI: 92.6–99.3%; I<sup>2</sup> = 61.3%). With men who have sex with men, the pooled SVR12 was 96.9% (95% CI: 93.1–100%); with people living with HIV, pooled SVR12 was 97.0% (95% CI: 90.7–100%); and with people who inject drugs, pooled SVR12 was 80.4% (95% CI: 66.1–90.6%). Overall, confidence in these results is limited due to the very low certainty.

The one case series and one open label trial reported 100% HCV treatment completion rates in 25 men who have sex with men living with HIV (419) and among 27 people living with HIV (415). Two open label trials (415, 417) reported on adherence: one found adherence of 81% amongst people living with HIV (415, 417) and another found adherence ranging from 79% to 85% among people who inject drugs, men who have sex with men and people living with HIV (417).

Adverse events were reported in four studies (409, 415, 417, 419); one serious adverse event, an episode of rhabdomyolysis (rash and raised creatinine kinase) requiring hospitalization was described (417), while all other adverse events were considered minor. Adverse event rates ranged from 22% (21/95) to 36% (9/25). However, confidence in these results and those for adherence is limited due to the very low certainty.

No studies included a comparator group, so it was not possible to assess overtreatment.



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## Values and preferences

Qualitative research carried out by key global population networks (see [Web Annex B](#)) found that awareness of and access to HCV treatment with pan-genotypic DAAs varied greatly across key populations. Of those participants who were aware of, and felt able to comment on, HCV and HCV treatment, most reported ongoing barriers to the access and utilization of HCV services, including cost, treatment delays, stigma and discrimination, and lack of research and political will. Some sex workers had not heard of pan-genotypic DAA treatments for HCV. People who inject drugs in particular noted that in certain contexts, cessation or abstinence from drug use (and sometimes OAMT) continues to be used as a criterion for HCV treatment access. This major barrier continues to occur, despite WHO recommendations to provide HCV treatment regardless of ongoing drug use.

People who inject drugs conveyed the most knowledge of pan-genotypic DAA treatment and recommended the expansion of HCV DAA treatment options and settings to maximize access and uptake, including at NSPs, OAMT clinics, drop-in centres and general health care settings. Given the high cure rates, good tolerability, low pill burden, fewer drug-drug interactions and significantly fewer side effects than the previous therapies, people who inject drugs expressed strong preferences for reducing barriers to treatment and making HCV DAA treatment as accessible as possible for people who inject drugs, including people who may have already been successfully treated and subsequently contracted a new HCV infection, as well as people with recently acquired HCV infection.

People who inject drugs did not express concern about the potential for overtreatment associated with offering treatment without delay for recently acquired infection, either among people who are treatment naïve or for retreatment. Rather, they expressed the concern that it is dangerous to deny access to treatment purely on the basis that some people will spontaneously clear (without treatment) – not only for the health of the individual concerned (and potential loss to follow-up), but also due to the potential for further transmission. People who inject drugs were more concerned about the ongoing lack of access to the highly effective HCV DAA treatments in certain countries and regions than about any hypothetical risk of overtreatment. Finally, people who inject drugs also emphasized the importance of offering HCV DAA treatment (and HCV prevention, including NSPs and OAMT, as well as management overdose) for people in prisons. This is particularly important in the context of an overwhelming lack of access to sterile injecting equipment and other harm-reduction measures in most prisons globally, coupled with high levels of incarceration associated with drug-related offences.

Most participants from other key population groups expressed limited knowledge about treatment with pan-genotypic DAAs, and the implications of treating recently acquired infection without delay or not. Nonetheless, most participants were open to this treatment, provided that they receive adequate information on its efficacy and side effects, as well as sufficient education and research to guide treatment implementation.

No additional studies on related values and preferences were identified through the systematic review.

## Resource-use: cost and cost effectiveness

None of the studies identified from the systematic review and meta-analysis directly addressed resource requirements or cost-effectiveness.

A post-hoc modelling search to identify additional cost-effectiveness models in both high- and low-income settings (420–423) supported the value of treatment without delay of recently acquired HCV infection and potential population-level benefits. For example, in a Dutch model, earlier treatment of recent infection will cost €68.3 million over 40 years, compared to €75.1 and €98.4 million to delay treatment – either waiting for spontaneous clearance or delaying treatment until F2 stage<sup>27</sup>, respectively. This study model also reported treatment of recent infection will prevent 7070 new infections and gain 3419 QALYs compared to F2 treatment, with resulting cost saving incremental cost effectiveness ratio (ICER) (423). Other modelling studies from China (421) and the USA (420) also showed that treating acute HCV is cost effective and cost saving compared to deferring treatment to the chronic stage; however, there were increased costs associated with HCV treatment for recent infection in patients who were not at risk of transmitting HCV (420).

One modelling study demonstrated a potential reduction in HCV incidence as a result of immediate treatment (423). This study modelled treatment scenarios in a Dutch cohort of HIV-positive men who have sex with men, and found that treatment of recently acquired HCV infection lowered incidence from 1.2/100 py to 0.2/100 py, an 88% reduction in incidence compared to treatment at liver fibrosis stage F2.

The Guideline Development Group was of the view that overall costs in the short term for treatment and testing could be increased if people are treated for recently acquired infection with significant uncertainty due to variation in costs of testing and treatment between settings, including low-, middle- and high-income countries, changes in DAA and other medication costs over time, and the variable opportunity cost of diverting staff and attention.

## Equity

No studies assessing equity were identified in the systematic review.

It can be argued that providing DAA treatment to people with recently acquired hepatitis C expands choice (namely, by providing a second option to deferral of treatment until chronic infection) for key populations, and may reduce loss to follow-up, thereby increasing the number of people accessing treatment. It is important that there are no restrictions

<sup>27</sup> METAVIR liver biopsy scoring system which ranges from 0 to 4.





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related to treatment of chronic or acute HCV infection and concurrent ongoing drug use, or drug dependence treatment or ongoing sexual risk.

In settings where access to DAAs is limited, implementing treatment for people with recently acquired infection without increasing overall DAA supply may have a negative health equity impact if DAAs are re-allocated from people with chronic hepatitis C, who are beyond the point of spontaneous clearance, and require treatment to prevent future morbidity and mortality. People with recently acquired hepatitis, on the other hand, may not necessarily require treatment, due to the remaining possibility of spontaneous clearance. Increased availability of affordable HCV treatment is needed to achieve elimination goals and ensure equity.

### Feasibility and acceptability

None of the identified studies from the systematic review and meta-analysis directly addressed feasibility or acceptability.

Overall, it could be argued that feasibility will depend greatly on context and health systems' capacities. Offering treatment without delay to people independent of chronicity may simplify HCV treatment and care algorithms and increase patient choice, and thus be a feasible option in many different settings and countries. In settings with existing decentralized services for HCV testing and treatment, or well-developed linkages, treatment without delay may be particularly feasible. Furthermore, improving awareness of HCV and DAA among key population members will be required.

It is possible that the risk of adverse events from HCV treatment – however mild – may be unacceptable to people with recently acquired hepatitis C if the possibility of achieving spontaneous clearance has not yet been exhausted. Allowing individuals to make an informed choice between immediate and deferred treatment is therefore important. Similarly, it is unclear whether routinely prescribing a treatment to individuals with recently acquired hepatitis C without a period of observation for spontaneous clearance is acceptable to clinicians.

The Guideline Development Group judged that the intervention would probably be acceptable to most key stakeholders. There was some uncertainty around whether routinely prescribing a treatment to individuals with recently acquired hepatitis C without a period of observation for spontaneous clearance would be acceptable to clinicians.

### Assessment of evidence and decision-making

The Guideline Development Group agreed that the issue of treating recently acquired HCV infection in persons with continuous risk exposure was a priority for public health and HCV elimination, and that the benefits clearly outweighed the harm. Benefits overall were judged to be large or moderate, and the related harm was trivial or small. Overall, the Guideline Development Group determined the certainty of evidence to be very low.

While evidence of effect was small across all outcomes, the Guideline Development Group highlighted that HCV treatment without delay for recently acquired HCV infection for those with ongoing risk can be beneficial, at both the individual and population level. Improved identification and treatment of recently acquired HCV may bring the benefit to the individual of being cured as soon as possible after diagnosis, rather than having to wait to access treatment and the associated risk of loss-to-follow-up, and thus would increase patient choices. The Guideline Development Group acknowledged the potential broader population-level benefit from curing an individual as soon as possible; namely, reducing the period of time during which they are infectious, and thereby reducing HCV incidence in certain population networks.

The group acknowledged that, following infection with hepatitis C, approximately one third of individuals will spontaneously clear the virus (that is, cure without any medical intervention). Therefore, treating all people with recently acquired hepatitis C immediately means that people who would have otherwise cleared their infection spontaneously are unnecessarily exposed to treatment. However, adverse events are very rare, and there was a clear preference for having treatment as an option.

Considering the evidence regarding good treatment outcomes of recently acquired infection in people with ongoing risk, the potential for reduction of HCV transmission in certain communities and populations, the strong support from community values and preferences, the potential for expanding patient choices and its feasibility to implement, as well as potential for cost-effectiveness and improved equity, the Guideline Development Group deemed that the overall benefits largely outweigh the potential harm and risk. The recommendation was thought to provide a potential for reduced stigma and simpler clinical care. Given all these elements, the group made a strong recommendation that applies to all populations with ongoing risk in all settings.

### Implementation considerations

Extending HCV treatment to people with ongoing risk and recently acquired infection, requires several areas to be considered in order to facilitate implementation in countries. The latest WHO HCV treatment and care guidelines should be consulted for further details on the clinical management of HCV (424).

Firstly, treatment without delay, independent of chronicity, is an additional indication for HCV treatment, and national treatment guidelines need to be amended. Furthermore, insurance policies for the treatment for recently acquired infection would ideally be streamlined with those for chronic HCV infection; this needs policy change and dialogue with funders and health insurance schemes in order to achieve this policy harmonization. Amendments to treatment guidelines or treatment policies need to provide a case definition for recently acquired infections, describe how a distinction can be made for treatment failure among people with a history of past HCV treatment, and how respective





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treatment strategies may differ. Moreover, it is important to identify and define certain subpopulations in which a treatment delay should be strongly considered, such as pregnant women. Furthermore, people at ongoing risk need to be offered adequate and frequent testing in order to be able to describe and discover recent HCV infection.

Secondly, patients need to be informed about the benefit and harm associated with both immediate and deferred treatment. Individuals with recently acquired infection must have the option to make an informed choice about starting treatment immediately or delaying treatment initiation. Key populations expressed preference for decentralization, with an expansion of treatment settings and simplified test and treat approaches.

Finally, one of the major objectives of extending treatment to people with recent infection and ongoing risk is the potential of population-level benefits and a reduction of HCV transmission. For the greatest impact, treatment for recently acquired infection should be offered alongside additional, evidence-based interventions to reduce HCV risk and primary prevention services, as outlined in these guidelines.

The Guideline Development Group discussed the importance and relevance of, in the future, expanding this new recommendation to promote treatment without delay in all populations, and not only for those people at ongoing risk.

### Research gaps

Current research about HCV treatment without delay for key populations is mainly among men who have sex with men in high income countries. Further research is needed to describe the impact and added value of extending treatment without delay to recent HCV infection on individual and population level in different settings and populations.

Real world cost-effectiveness and feasibility studies would be valuable to further strengthen the case for treatment of recently acquired HCV infection. Implementation science that evaluates feasibility and acceptability of this approach in different key populations would be beneficial.

The potential for truncated courses of DAAs administered during recently acquired HCV may prove to be a benefit to early treatment of HCV and warrants further research.

## Pooling samples from different anatomical sites for the diagnosis of *Neisseria gonorrhoeae* and *Chlamydia trachomatis*

### Recommendation

Where biologic samples are collected from multiple anatomical sites in the same individual, they may be pooled for molecular testing of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infections (*conditional recommendation, moderate certainty of evidence for men who have sex with men, and low certainty of evidence for other key populations*).

### Remarks:

- Collection of biological samples from all anatomical sites should always be voluntary.
- WHO recommends NAAT for the detection of *N. gonorrhoeae* and *C. trachomatis*.
- WHO recommends self-collection of samples for NAAT for the detection of *N. gonorrhoeae* and *C. trachomatis*.
- Community values and preferences did not include cisgender women, transgender men and non-binary people assigned female at birth, to inform this recommendation.

### Background

Key populations are disproportionately affected by STIs. Several STIs are highly transmissible and often asymptomatic. Syndromic management of STIs misses asymptomatic cases and results in overtreatment. Furthermore, overtreatment contributes to antimicrobial resistance (425). For example, inappropriate management of *N. gonorrhoeae* may accelerate the emergence of multidrug-resistant *N. gonorrhoeae* and increase onward transmission (426). This underscores the need for aetiological diagnosis to optimise STI case management, particularly among key populations who practice oral and anal sex.

*N. gonorrhoeae* and *C. trachomatis* can infect different anatomical sites. Thus, aetiological screening of all appropriate anatomical sites (oropharynx, urethra, endocervix and anorectum) is needed when an individual engages in anal or oral sex or both. Considering the high proportion of asymptomatic infections caused by these pathogens, a significant proportion of cases would be missed if only genital screening was undertaken (427). Studies have demonstrated that up to one third of gonorrhoea cases would be missed if only urethral or urine samples were tested in men who have sex with men (428, 429).

Whilst separate testing from different anatomical sites is preferable, there is an additional cost associated with testing samples from each site. This is especially relevant in LMICs where the cost of NAAT recommended for the diagnosis of these infections is a major barrier (430).

### Evidence review

A systematic review was commissioned by WHO to answer the question of whether pooling of samples from different anatomical sites should be used for STI laboratory screening of gonorrhoea and chlamydial infection, compared to individual samples from three anatomical sites (urethra, anorectum and oropharynx). The outcome of interest was diagnostic accuracy.



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For chlamydial infection, a meta-analysis of sensitivity and specificity included 15 estimates from 14 studies of 5891 patients (431). For multisite pooled testing for chlamydia infection, the review found the combined sensitivity<sup>28</sup> was probably 93.1% (95% CI: 90.5–95.0, I(2)=43.3), and combined specificity<sup>29</sup> was probably 99.4% (95% CI:99.0–99.6, I(2)=52.9) (moderate certainty evidence). This means, if 1000 people are tested with a background prevalence of 10% for chlamydial infection (100 cases), switching from single-site testing to pooled testing will probably result in seven missed cases (out of 100 true cases), and five people being overtreated.

For gonorrhoea, 14 estimates from 13 studies were used for the meta-analysis with data from 6565 patients. For multisite pooled testing for gonorrhoea, the review found the combined sensitivity using NAAT was probably 94.1% (95% CI: 90.9–96.3, I(2)=68.4) (low certainty evidence), and pooled specificity may be 99.6% (99.1–99.8, I(2)=83.6) (moderate certainty evidence). This means, if 1000 people are tested with a background prevalence of 10% for gonorrhoea, switching from single-site testing to pooled testing will probably result in six missed cases (out of 100 true cases), and four people being overtreated.

Meta-regression analyses did not show any significant impact on the accuracy of multisite pooled testing according to study population (men who have sex with men compared to men who have sex with women), study population size (<100 versus >100), country-income level, sample collection (self-collected versus clinician-collected) or publication year (before 2020 versus 2020 or after).

Four studies among men who have sex with men provided information specifically on the sensitivity of detecting oropharyngeal infections using pooled testing versus the standard of care (namely, testing individual samples from the three anatomic sites for chlamydia and gonorrhoea) (432–435). All oropharyngeal infections with *C. trachomatis* were detected using pooled testing in three out of four studies (10–12). In the remaining study, pooling samples resulted in one case missed out of six with oropharyngeal infection (433). On the other hand, overall, the sensitivities of oropharyngeal gonorrhoea testing using individual samples were found to be lower for identifying infection across all studies (432–435). The authors hypothesised that the reduced sensitivities were attributed to the lower bacterial load in the pharynx compared to other anatomic sites. Furthermore, two studies highlighted that most *N. gonorrhoeae* infections occurred in the pharynx, several of which would have been missed if this anatomical site was not sampled (9).

It is also important to note that the studies included in the systematic review were predominantly conducted in high-income countries (82.6%, 14/17) and men who have sex with men were the most frequently studied population (70.6%, 12/17).

In summary, although different methods of pooling were used across the studies (related to flow and timing, different order of pooling sample, different volumes of urine used), the consistently high accuracy of multisite pooled testing, despite diverse methodologies of pooling, suggest that accuracy was not significantly impacted by the method of pooling. Overall, the certainty of evidence was downgraded to moderate, mainly because of potential risk of bias in most studies due to patient selection bias, with moderate heterogeneity observed for studies contributing to gonorrhoea sensitivity results.

### Feasibility, cost and cost-effectiveness

No study included in the systematic review reported the feasibility to combine samples for multisite pooled testing. However, the Guideline Development Group noted that while pooling samples was generally feasible, this could vary depending on setting due to different laboratory structures, flow and technical capacities, among other things.

The systematic review identified three studies that estimated the cost savings of pooling samples from different anatomical sites for chlamydia or gonorrhoea testing. One study of 1064 men who have sex with men attending sexual health clinics and hospital sites between October 2012 and August 2013 in the United Kingdom suggested that pooled testing offers cost savings of up to two thirds of the costs of the assays alone, as well as savings in consumables, processing time and clinical pathway efficacy (433). A prospective study between February 2018 and July 2019 of 501 female sex workers in Belgium demonstrated a 35% decrease in reagent costs and lab technician time when using pooled testing (calculated using the obtained prevalence of 6.5% and 3.5% for chlamydia and gonorrhoea, respectively) (436). Finally, one study assessed the efficacy of pooled testing among 497 men who have sex with men in four West African countries, and demonstrated a 56% decrease in costs, in which unpooling of triple-site pooling was only undertaken when the pooled sample result was invalid (437).

One cost-effectiveness study was identified. For men who have sex with men attending sexual health clinics in the United Kingdom, researchers reported that using a willingness to pay threshold of £60 per person tested, pooled testing had a 100% probability of being cost-effective. Compared with individually analysed samples, pooled testing saved £13.37 to £18.22 per individual tested, depending on the symptom status or population group (namely, men who have sex with men and women from the general population) (438).

### Values and preferences

Qualitative research by key population networks of gay and other men who have sex with men and sex workers of all genders on values and preferences associated with pooled sampling for STI testing was conducted with men who have sex with men, cisgender males and transgender women sex workers, but not among people who inject drugs, cisgender

<sup>28</sup> Sensitivity is a measure of how well a test can identify true positives.

<sup>29</sup> Specificity is a measure of how well a test can identify true negatives.



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women who work as sex workers or others assigned female at birth. Most participants in the research indicated that they were not familiar with this method for chlamydia and gonorrhoea screening. Nonetheless, most participants stated that they were willing to have samples taken from three anatomical sites and pooled, particularly if this method would yield the most accurate results. There was uncertainty across all regions among men who have sex with men about how accurate these tests using pooled samples are. This would indicate that more education must be done at the clinical and community level about the efficacy of these testing choices.

Men who have sex with men noted that due to the stigma surrounding anal sampling, the practice of simultaneously collecting and pooling samples from anorectum, oropharyngeal and urethral swabs could offer a less stigmatizing way to test for STIs. Pooling samples would also reduce the need for health care providers to ask clients what kind of sex they engage in, thus decreasing judgement and potential risky disclosure on sexual practices. Caution should be taken in extending the practice of not asking clients what kind of sex they engage in to other key populations, as the other populations were not consulted. For a detailed report, please see [Web Annex B](#).

Additionally, two studies identified through the systematic review indicated that individuals (men who have sex with men and cisgender women) found self-sampling for chlamydia or gonorrhoea testing to be acceptable and easy to perform (433, 439).

### Equity and acceptability

Seven studies discussed the health equity impact pooling could bring by increasing testing coverage (434–437, 440–442), especially for asymptomatic individuals who would not otherwise have been tested in LMICs (437). A study also suggested that pooled testing should be incorporated in HIV PrEP programmes in resource-limited countries (17). In addition, cost savings via pooled testing would allow more people with infection to be detected and treated, or for those at higher risk of infection to be tested more frequently with a similar budget.

A web-based survey of clinic heads in the United Kingdom from 2018 reported that 84% (41/49) of sexual health clinicians in England considered the most significant benefit of pooling was cost savings, but were concerned about barriers such as lack of national guidance, loss of infection site information and a perceived reduction in sensitivity or specificity (441). In addition, most (77%, 40/52) clinicians requested more validation studies on diagnostic accuracy, 75% (39/52) wanted clinical guidelines of pooling and 48% (25/52) of clinicians requested further cost analysis (441).

### Assessment of evidence and decision-making

The Guideline Development Group discussed the benefits of pooling samples from three anatomical sites for gonorrhoea and chlamydia testing, based on the evidence review and the values and preferences of the communities.

Considering the high sensitivity and specificity of pooling samples for molecular testing for both chlamydia and gonorrhoea, the benefits of pooling samples include:

- 1) increased detection of extra-genital infections by using the same test for multiple anatomical sites, and an increase of test coverage, especially testing more asymptomatic individuals at higher risk of STIs, due to potentially significant cost savings;
- 2) potential decrease in the risk of HIV acquisition if more extra-genital infections and individuals are correctly diagnosed and treated; and
- 3) decreased workload for laboratories and other health services, especially when implementing testing at or near the point of care.

Furthermore, self-sampling, which is highly acceptable, does not affect the accuracy of multisite pooled sampling.

The values and preferences research among the key population communities (see [Web Annex B](#)) was limited to men who have sex with men, cisgender male sex workers and transgender women sex workers, and did not include cisgender women who work as sex workers, transgender men and other people assigned female at birth. For this reason, the Guideline Development Group felt that there was a possibly important uncertainty and variability in the assessment of key populations' values and preferences for pooled-site sampling. The Guideline Development Group member from NSW in particular expressed their concern about the omission of cisgender women and transgender men in the values and preferences survey and requested that this research be undertaken as a matter of priority.

Potential harms discussed by the Guideline Development Group were that, compared to a gold standard, single-site test, there would be small numbers of missed cases (five for chlamydia, six for gonorrhoea) and overtreated cases (five for chlamydia, four for gonorrhoea) if pooling samples from multiple anatomical sites in a population of 1000 people with a 10% background prevalence. Furthermore, there is uncertainty about the sensitivity of pooled-site sampling to detect oropharyngeal gonorrhoea, and without retesting, it is not possible to know exactly which sites are infected. However, this small loss in sensitivity was balanced by the opportunity to test the multiple anatomical sites when using pooled testing in settings where oropharyngeal sampling is not routinely performed because of cost.

The potential benefits of pooling samples from multiple anatomical sites to diagnose these two pathogens outweighed the harms of slightly lower accuracy. Thus, the Guideline Development Group decided to make a recommendation in favour of the intervention. There was overall moderate certainty evidence of sensitivity and specificity of pooled samples for both chlamydia and gonorrhoea. However, the limited data from LMICs and from other key populations, besides



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men who have sex with men, led the Guideline Development Group to downgrade the certainty for other populations to low. Based on the above considerations the Guideline Development Group made a conditional recommendation with moderate certainty of evidence for men who have sex with men and low certainty of evidence for other key populations.

## Implementation considerations

Multisite pooled-sample testing is highly sensitive and specific with potential associated cost-saving benefits and creates an opportunity to increase the detection of extra-genital infection and screening coverage, particularly in LMICs using NAAT.

Countries should consider conducting national lab validation methods for the use of pooled samples to diagnose chlamydial and gonococcal infections, and to include pooled sampling into national quality assurance and control protocols. The question of who would pool the samples has to be considered; for example, would the task be completed by self-sampling, health providers or lab technicians. Each approach will require adapting national protocols, training providers when point-of-care or near point-of-care tests are used and, when applicable, lab procedures and logistics, including the reorganization of sample flow, testing platform, and adjusting necessary supplies for sample collection.

Pooling samples from multiple anatomical sites can also have an impact on countries with national guidelines recommending different dosages and treatment schedules, depending on the anatomical site. In this case, there may be a need to retest samples from the different sites separately to prescribe the recommended treatment. If new samples need to be collected from positive individuals, it must be balanced against the risk of treatment delays and lost-to-follow-up patients. These concerns will not apply to countries following current WHO recommendations for the treatment of genital or anorectal chlamydial infection, for which doxycycline can be used in the same dosage in both cases as first line, or for gonorrhoea using dual therapy as the first line, when either no or insufficient data are available from local gonococcal antimicrobial resistance (443, 444). However, due to growing gonococcal antimicrobial resistance to ceftriaxone and azithromycin, WHO is updating the treatment guidelines for *N. gonorrhoea* infections, which may have implications for the treatment of infection at different anatomical sites.

## Research gaps

Based on the review of the evidence, a critical knowledge gap to be addressed is the accuracy of testing for *N. gonorrhoeae* – comparing oropharyngeal samples alone versus pooled with samples from other anatomical sites. Regarding the performance of pooled-sample testing, further studies are needed to define the optimal dilution of pooled samples for best accuracy, including optimal urine volume (when urine samples are used instead of swabs), and to understand the potential effects of the order of samples for pooling.

Additionally, there is a need to study the cost-effectiveness of pooling samples against different background prevalence of infections, and to model the optimal cut-off point for the utility of single-site pooled testing to maximise cost-effectiveness in different settings.

It is also critical to better understand the values and preferences of key population members who are cisgender women, transgender men and non-binary people assigned female at birth, as they were not included in the values and preferences research conducted for the development of these guidelines. Implementation research is important to support the adoption of multisite testing, including exploring the perception of those men who have sex with men interviewed as part of the values and preferences study, regarding the possibility of having biological samples collected from the three anatomical sites as a standard of care; namely, not requiring the disclosure of sexual practices to providers, has the potential to reduce perceived stigma and discrimination, and to increase access to care by men who have sex with men.

Finally, for countries using different treatment regimens for gonococcal and chlamydial infections or both based on anatomical site, it would be relevant to better understand the benefits versus harms of opening sample pools (retesting samples) after a positive result, considering potential treatment delays and lost-to-follow-up in different settings. Conducting an economic evaluation of retesting multiple sites in different contexts should also be considered.



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