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CONSOLIDATED GUIDELINES ON

HIV TESTING SERVICES

DECEMBER 2019

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Consolidated guidelines on HIV testing services

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ABBREVIATIONS

AIDS	acquired immune deficiency syndrome
AIM	UNAIDS Spectrum AIDS Impact Model
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral drugs
CDC	United States Centers for Disease Control and Prevention
CI	confidence interval
CLIA	chemiluminescence immunoassay
CROI	Conference on Retroviruses and Opportunistic Infections
DBS	dried blood spot
DNA	deoxyribonucleic acid
ECL	electrochemiluminescence immunoassay
EIA	enzyme immunoassay
EID	early infant diagnosis
EMR	electronic medical record
EMTCT	elimination of mother-to-child transmission
EQA	external quality assessment
GAM	Global AIDS Monitoring survey
GDG	Guideline Development Group
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GRC	Guidelines Review Committee

HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HCW	health-care worker
HIV	human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV testing services
IA	immunoassay
IAS	International AIDS Society
ICER	incremental cost-effectiveness ratio
IFU	instructions for use
ILO	International Labour Organization
IPV	intimate partner violence
IQR	interquartile range
IVD	in vitro diagnostic medical device
KP	key population
M&E	monitoring and evaluation
MTCT	mother-to-child transmission
NASBA	nucleic acid sequence-based amplification
NAT	nucleic acid testing
NGO	nongovernmental organization
NPV	negative predictive value
OST	opioid substitution therapy
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	United States President's Emergency Plan for AIDS Relief
PHIA	Population Health Impact Assessment

PICO	population/intervention/comparison/outcome
PITC	provider-initiated testing and counselling
PMTCT	prevention of mother-to-child transmission
PN	partner notification
PPV	positive predictive value
PrEP	pre-exposure prophylaxis
PS	HIV partner services
QA	quality assurance
QC	quality control
QI	quality improvement
RCT	randomized controlled trial
RDT	rapid diagnostic test
RMNCH	reproductive, maternal, neonatal and child health
RNA	ribonucleic acid
RR	relative risk
SG	Steering Group
SOP	standard operating procedure
STI	sexually transmitted infection
TAT	turnaround time
TB	tuberculosis
TNA	total nucleic acid
TWG	Technical Working Group
UAT	unlinked anonymous testing
UHC	universal health coverage
UIC	unique identifier code
UN	United Nations
UNICEF	United Nations Children's Fund

UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VCT	voluntary counselling and testing
VMMC	voluntary medical male circumcision
WB	western blot
WHO	World Health Organization

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EXECUTIVE SUMMARY

Purpose

These consolidated guidelines on HIV testing services (HTS) bring together existing and new guidance on HTS across different settings and populations.

The World Health Organization (WHO) first released consolidated guidelines on HTS in 2015, in response to requests from Member States, national programme managers and health workers for support to achieve the United Nations (UN) 90–90–90 global HIV targets – and specifically the first target of diagnosing 90% of all people with HIV. In 2016, based on new evidence, WHO released a supplement to address important new HIV testing approaches – HIV self-testing (HIVST) and provider-assisted referral.

Since the release of 2015 and 2016 HTS guidelines, new issues and more evidence have emerged. To address this, WHO has updated guidance on HIV testing services. In this guideline, WHO updates recommendation on HIVST and provides new recommendations on social network-based HIV testing approaches and western blotting (see box, next page). This guideline seeks to provide support to Member States, programme managers, health workers and other stakeholders seeking to achieve national and international goals to end the HIV epidemic as a public health threat by 2030.

These guidelines also provide operational guidance on HTS demand creation and messaging; implementation considerations for priority populations; HIV testing strategies for diagnosis HIV; optimizing the use of dual HIV/syphilis rapid diagnostic tests; and considerations for strategic planning and rationalizing resources such as optimal time points for maternal retesting (see box, next page).

These new guidelines seek to:

- provide comprehensive, evidence-based recommendations for HTS;
- support implementation and scale-up of a strategic mix of evidence-based HTS approaches, in both facility and community settings, to reach those undiagnosed;
- support effective linkage to appropriate prevention, treatment and care services among those tested;
- encourage integration of HIV testing with other relevant services,
- rationalize the use of retesting for HIV late in pregnancy and in the postpartum period and the use of dual HIV/syphilis rapid test as the first test in antenatal care;

- support programmes to implement quality HTS using recommended testing strategies and to stop using western blotting;
- provide guidance on how programmes can strategically plan HTS and rationalize resource use to achieve global and national goals;
- encourage greater national and global commitment to effective and efficient HTS as a key element of the national and global HIV response, which is essential to achieving and maintaining low HIV incidence.

Key definition: HIV testing services

The term *HIV testing services* (HTS) is used throughout these guidelines. This term embraces the full range of services that should be provided together with HIV testing. These include brief pre-test information and post-test counselling; linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.

These guidelines discuss issues related to offering HTS to the following population groups:

- key populations
- general population
- pregnant and postpartum women
- couples and partners
- adolescents (10–19 years old) and young people (15–24 years old)
- migrants, refugees, displaced people and other vulnerable populations.

Guideline development methodology

In response to the changing needs of Member States and the availability of new evidence, stakeholders proposed an update to WHO's guidance on HTS. As a result, from November 2017 to August 2019, the WHO HIV Department led the development of this update with a WHO Guideline Steering Group (SG) and an independent Guideline Development Group (GDG) of regionally representative external experts, comprising academics, researchers, programme managers, implementers and representatives of community networks and organizations. An external peer review group also provided support.

The SG developed the population, intervention, comparator, outcome (PICO) questions, commissioned systematic reviews to address the PICO questions and finalized the outline of the guidelines. The WHO HIV Department and the SG selected the GDG in consultation with WHO regional and country offices. The SG and GDG reviewed and finalized the PICO questions and the related outcomes and stratifications.

Then, the SG and GDG reviewed and provided input on early results from the systematic reviews, as well as the WHO background literature and policy reviews, mathematical modelling and cost-effectiveness analysis.

Based on the evidence reviewed and presented, the GDG made new recommendations on western blotting and social network-based HTS approaches, updated the recommendation on HIVST and crafted a good practice statement regarding the use of evidence-based approaches and considerations on the use of incentives for demand creation. The GDG also agreed on operational guidance building on existing WHO recommendations for HIV testing strategies, the use of dual/HIV syphilis testing in antenatal care and optimal settings and time points for maternal retesting in late pregnancy and in the breastfeeding period.

At the end of this process, the External Review Group, UN agency reviewers and WHO staff members from the Department of HIV and other WHO departments and regional offices reviewed, and provided further input into, these guidelines.

About the recommendations

The box on the previous page summarizes the existing, new and updated recommendations presented in this document. Table 1 summarizes all current WHO guidance on HTS.

The new recommendations are in line with, and build on, existing WHO recommendations. They emphasize the importance of early initiation of treatment and scale-up of prevention options, particularly for key populations – men who have sex with men, people who inject drugs, people in prison and other closed settings, sex workers and transgender people.

The GDG considered but did not make an overarching recommendation on demand creation, due to high levels of heterogeneity in the evidence reviewed and low- to very low-quality evidence for many outcomes, but considered a range of options. The GDG did develop a good practice statement on demand creation.

Implications for programming

Closing the HIV testing gap and diagnosing 90% of all people with HIV and linking them to treatment and care is critical to the success of the global HIV response. These guidelines seek to support countries to provide a strategic mix of differentiated HTS options that will effectively reach people with HIV who do not know their status and people at high risk who need HIV prevention interventions. They also seek to enable countries and programmes to expand coverage strategically in areas and among populations with greatest coverage gaps, to increase access to services and to help achieve global targets.

To accomplish these goals, countries will need to assess their specific situations and consider their epidemiological context and populations that are not being reached with HTS in their settings. All HTS approaches will need to adhere to the WHO 5Cs of HTS: **C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect results and **C**onnection. They also will need to consider how to overcome country- and population-specific social and legal barriers to access and uptake of HTS.

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing

Approach and reference	Recommendations and good practice statements
Mobilization and pre-test services	
Demand creation for HIV testing services NEW **Good practice statement** WHO (2019). Consolidated guidelines on HIV testing services.	Demand creation to increase HTS uptake and engage those in greatest need of services is a valuable tool for mitigating stigma, discrimination and criminalization. Demand creation approaches may need to be prioritized, depending on the setting, focus population and available resources, as part of a strategy to reach people with HIV who do not know their status and who have high HIV-related risk. A wide range of demand creation strategies have been rigorously tested to assess impact on HIV testing uptake and the proportion of people with HIV diagnosed, but often later outcomes related to linkage to care or prevention have not been measured. Evidence-based platforms for delivering demand creation include: • peer-led demand creation interventions, including mobilization; • digital platforms, such as short pre-recorded videos encouraging testing. Approaches that have showed evidence of increasing demand include: • advertisement of specific HTS attributes; • brief key messages and counselling by providers (less than 15 minutes); • messages during couples counselling that encourage testing; • messages related to risk reduction and economic empowerment, particularly for people who inject drugs; • motivational messages. Evidence suggests that the following approaches may be less effective for demand creation: • personal invitation letters; • individualized content messaging; • counselling focused on building relationship between the client and counsellor; • general text messages, including SMS. Some studies report increases in HTS uptake when incentives are offered, however when considering the use of incentives for demand creation, benefits and risks should be carefully weighed, such as: • resource use and sustainability, especially for providing financial incentives, which may undermine the principles of universal health coverage; • longer-term behavioural changes associating HTS and other services with incentive against short-term increases in uptake; • negative effect on equity, due to prioritization of some populations and diseases; • potential to deprioritize systematic implementation of strategies that improve service delivery, reduce barriers and disincentives, such as patient costs associated with accessing health services more broadly.

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
Service delivery approaches	
Facility-based HTS **Updated guidance** WHO (2017). Syphilis testing and treatment guidelines. https://www.who.int/reproductivehealth/publications/rtis/syphilis-ANC-screenandtreat-guidelines/en/ WHO (2016). WHO recommendations on antenatal care for a positive pregnancy experience. https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/ WHO (2015). Consolidated guidelines on HIV testing services. https://www. who.int/hiv/pub/guidelines/hiv-testing-services/en/ WHO (2015). Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. https://www.who.int/hiv/pub/ hepatitis/hepatitis-b-guidelines/en/	All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)* at least once and as early as possible *((syphilis: strong recommendation, moderate-quality evidence; HBsAg*: strong recommendation, low-quality evidence).* Dual HIV/syphilis rapid diagnostic tests (RDTs) can be the first test in HIV testing strategies and algorithms in ANC. **High HIV burden settings** HIV testing should be offered to all populations and in all services (for example, services for sexually transmitted infection (STI), hepatitis, tuberculosis (TB), children under five, immunization, malnutrition, ANC and all services for key populations) as an efficient and effective way to identify people with HIV. **Low HIV burden settings** HIV testing should be offered for : • adults, adolescents or children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection, including TB and STIs • HIV-exposed children and symptomatic infants and children • key populations and their partners • all pregnant women. In some resource-limited settings, particularly those with low HIV burden, programmes may need to prioritize resources by focusing HTS in pregnancy on geographical areas with higher prevalence or among women with high ongoing risk such as members of key populations.
Community-based HTS WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/	**High HIV burden settings** WHO recommends community-based HIV testing services, with linkage to prevention, care and treatment services, in addition to routinely offering facility-based testing, particularly for key populations *(strong recommendation, low-quality evidence).* **Low HIV burden settings** WHO recommends community-based HIV testing services, with linkage to prevention, care and treatment, in addition to facility-based testing, for key populations *(strong recommendation, low-quality evidence).*

*Particularly in settings with a ≥2% HBsAg seroprevalence in the general population.

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
HIV self-testing Updated recommendation WHO (2016). Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines HIV testing services. https://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/	HIV self-testing should be offered as an approach to HIV testing services *(strong recommendation, moderate-quality evidence).*
Provider-assisted referral (also called index testing and assisted partner notification) Updated recommendation WHO (2016). Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/	Provider-assisted referral should be offered for all people with HIV as part of a voluntary comprehensive package of testing, care and prevention *(strong recommendation, moderate-quality evidence).*
Social network-based approaches NEW Recommendation WHO (2019). Consolidated guidelines on HIV testing services.	Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention *(conditional recommendation, very low-quality evidence).*
Lay provider HIV testing WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/	Lay providers who are trained and supervised can independently conduct safe and effective HIV testing using rapid diagnostic tests (RDTs) *(strong recommendation, moderate-quality evidence).*

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
Retesting	
Retesting **Updated guidance** WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/	**All settings** Only specific groups of people in high HIV burden settings or individuals with HIV-related risks need post-test counselling messages encouraging retesting at the appropriate intervals. WHO guidance recommends annual retesting for: • **all sexually active individuals in high HIV burden settings** and; • people who have **ongoing HIV-related risks in all settings**. These include: - key populations, defined as men who have sex with men, people in prison or closed settings, people who inject drugs, sex workers and transgender people; - country or epidemic specific risk groups such as men and adolescent girls and young women in southern Africa - people with a known HIV-positive partner. **Retesting in special groups.** In certain situations, individuals who have been tested for HIV in the past can be retested. These include: - individuals presenting with a diagnosis or receiving treatment for STIs or viral hepatitis; - individuals with a confirmed or presumptive TB diagnosis - outpatients presenting with clinical conditions or symptoms indicative of HIV - individuals with recent HIV risk exposure. More frequent retesting, that is every 3–6 months, may be warranted based on individual risks factors and as part of broader HIV prevention interventions. For instance, individuals taking PrEP who require quarterly HIV testing or key populations who present to services with an STI. **Retesting in pregnant and post-partum women** **High HIV burden settings** Retest all pregnant women with unknown or HIV-negative status in late pregnancy – at **third trimester visit**. If either the first test or retest is missed or delayed, "catch-up" testing is needed. An additional retest for women of unknown or HIV-negative status in the post-partum period can be considered. Countries could consider an additional post-partum test in specific districts or provinces with high HIV burden or incidence, and among women from a key population or who have partners with HIV who are not virally suppressed. **Low HIV burden settings** Retest pregnant women with unknown or HIV-negative status who are in serodiscordant relationships, where the partner is not virally suppressed on ART, or have other known ongoing HIV risk in late pregnancy – at a **third trimester visit**. If either the first test or retest is missed or delayed, "catch-up" testing is needed. An additional retest for women of unknown or HIV-negative status in the post-partum period can be considered among women from key populations or who have partners with HIV who are not virally suppressed. Countries could also consider an additional post-partum test in specific districts or provinces with high HIV burden or incidence.

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
HIV diagnosis and testing strategies	
HIV diagnosis and testing strategies NEW **Recommendation, and** **Updated guidance** WHO (2019). Consolidated guidelines on HIV testing services. WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/	**Western blotting** Western blotting and line immunoassays should not be used in national HIV testing strategies and algorithms (strong recommendation, low-quality evidence). **Pregnant women** Dual HIV/syphilis rapid diagnostic tests (RDTs) can be the first test in HIV testing strategies and algorithms in ANC settings. **HIV testing strategy/algorithm** WHO recommends that all HIV testing algorithms achieve at least 99% positive predictive value and use a combination of tests with ≥99% sensitivity and ≥98% specificity. The first test in an HIV testing strategy and algorithm should have the highest sensitivity, followed by a second and third test of the highest specificity. Countries should consider moving to a three test strategy as HIV positivity within national HTS programmes falls below 5% – meaning all people presenting for HTS should have three consecutive reactive test results in order to receive an HIV-positive diagnosis. WHO suggests using a testing strategy for HIV diagnosis that is suitable for HIV diagnosis during surveillance and routinely returning HIV test results to participants.

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
Post-test services and linkage	
WHO (2019). Consolidated guidelines on HIV testing services. WHO (2017). Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. https://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/ WHO (2016). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: a public health approach. https://www.who.int/hiv/pub/arv/arv-2016/en/ WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/	Rapid ART initiation should be offered to all people with HIV following a confirmed HIV diagnosis and clinical assessment *(strong recommendation, high-quality evidence for adults and adolescents; low-quality evidence for children).* Following an HIV-positive diagnosis, a package of support interventions should be offered to ensure timely linkage to care for all people with HIV *(strong recommendation, moderate-quality evidence).* The following interventions have demonstrated benefit in improving linkage to care following an HIV diagnosis: • streamlined interventions to reduce time between diagnosis and engagement in care, including (i) enhanced linkage with case management, (ii) support for HIV disclosure, (iii) patient tracing, (iv) training staff to provide multiple services and (v) streamlined and co-located services *(moderate-quality evidence)*; • peer support and navigation approaches for linkage *(moderate-quality evidence)*; • quality improvement approaches using data to improve linkage *(low-quality evidence).* **Good practice statements** ART initiation should follow the overarching principles of providing people-centred care. People-centred care should be focused and organized around the health needs, preferences and expectations of people and communities, upholding individual dignity and respect, especially for vulnerable populations. It should promote the engagement and support of people and families to play an active role in their own care through informed decision-making. All people newly diagnosed with HIV should be retested to verify their HIV status prior to starting ART, using the same testing strategy and algorithm as the initial test. To minimize the risk of misdiagnosis, this approach should be maintained in settings in which rapid ART initiation is being implemented. The introduction of the "treat all" recommendation (ART for all people living with HIV regardless of CD4 cell count) supports the rapid initiation of ART, including the offer of same-day initiation where there is no clinical contraindication. People with no contraindication to rapid ART initiation should be fully informed of the benefits of ART and offered rapid ART initiation, including the option of same-day initiation. Rapid start of ART is especially important for people with very low CD4 cell counts, in whom the risk of death is high. People should not be coerced to start immediately and should be supported in making an informed choice regarding when to start ART.

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
Priority populations	
Key populations NEW **Recommendation** WHO (2019). Consolidated guidelines on HIV testing services. WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/	HIV testing services should be routinely offered to all key populations both in the community and in facility-based settings. Community-based HIV testing, with linkage to prevention, treatment and care, should be offered, in addition to routinely offering testing in facilities, for key populations in all settings *(strong recommendation, low-quality evidence)*. Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention *(conditional recommendation, very low-quality evidence)*.
Adolescents WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/	HIV testing services, with linkages to prevention, treatment and care, are recommended for adolescents from key populations *(strong recommendation, very low quality of evidence)*. Adolescents should be counselled about the potential benefits and risks of disclosure of their HIV-positive status and empowered and supported to determine if, when, how and to whom to disclose *(conditional recommendation, very low-quality evidence)*. **High HIV burden settings** In high HIV burden settings, HTS, with linkage to prevention, treatment and care, are recommended for all adolescents *(strong recommendation, very low quality of evidence)*. **Low HIV burden settings** HTS, with linkage to prevention, treatment and care, should be accessible to adolescents in low and concentrated epidemics *(conditional recommendation, very low-quality evidence)*. **Good practice statement** Governments should revisit age-of-consent policies, considering the need to uphold adolescents' rights to make choices about their own health and well-being (with consideration for different levels of maturity and understanding).

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
Couples and partners NEW **New and updated recommendations** WHO (2019). Consolidated guidelines on HIV testing services. WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/ WHO (2013). Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. https://www.who.int/reproductivehealth/publications/violence/9789241548595/en/	Social network-based approaches can be offered as part of a comprehensive package of testing and care for key populations *(conditional recommendation, very low-quality evidence).* Provider-assisted referral should be offered to all people with HIV as part of a voluntary comprehensive package of testing, care and prevention *(strong recommendation, moderate-quality evidence).* Couples and partners should be offered voluntary HIV testing services with support for mutual disclosure *(strong recommendation, low-quality evidence).* Women who disclose any form of violence by an intimate partner (or other family member) or sexual assault by any perpetrator should be offered immediate support. Health-care providers should, as a minimum, offer first-line support when women disclose violence. If health-care providers are unable to provide first-line support, they should ensure that someone else (within their health-care setting or another that is easily accessible) is immediately available to do so *(strong recommendation, indirect evidence).* Health-care providers should ask about exposure to intimate partner violence when assessing conditions that may be caused or complicated by intimate partner violence, in order to improve diagnosis/identification and subsequent care *(strong recommendation, indirect evidence).* **Good practice statements** Extending provider-assisted referral to the biological children of people with HIV may also be considered as part of a voluntary provider referral package. Mandatory or coercive testing is never warranted. In consultation with the client, the provider should assess the risk of harm, the most appropriate approach for couple and partner testing, including more supportive options such as provider assistance, and situations that make couple or partner testing inadvisable.

Table 1.1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing, continued

Approach and reference	Recommendations and good practice statements
Infants and children WHO (2019). HIV molecular diagnostics toolkit to improve access to viral load testing and infant diagnosis. https://www.who.int/hiv/pub/vct/hiv-molecular-diagnostic/en/ WHO (2016). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. https://www.who.int/hiv/pub/arv/arv-2016/en/	**All settings** For HIV-exposed infants, virological testing for HIV as early as possible is recommended so that ART can be started immediately, and morbidity and mortality, prevented. Nucleic acid testing (NAT) technologies that are developed and validated for use at, or near to, the point of care can be used for early infant HIV testing *(conditional recommendation, low-quality evidence)*. Addition of NAT at birth to existing early infant diagnosis (EID) testing approaches can be considered to identify HIV infection in HIV-exposed infants *(conditional recommendation, low-quality evidence)*. **High HIV burden settings** In high HIV burden settings, infants and children with unknown HIV status who are admitted for inpatient care or attending malnutrition clinics should be routinely tested for HIV *(strong recommendation, low-quality evidence)*. In high HIV burden settings, infants and children with unknown HIV status should be offered HIV testing in outpatient or immunization clinics *(conditional recommendation, low-quality evidence)*. **Good practice statements** In all settings biological children with a parent living with HIV (or who may have died of HIV) should be routinely offered HTS and, if found to be either infected or at high risk of infection through breastfeeding, should be linked to services for treatment or prevention and offered a broader package of voluntary provider-assisted referral. National regulatory agencies are encouraged not to delay adoption of point-of-care EID by conducting further evaluations but instead to adopt a rapid and streamlined registration and national approval process for immediate implementation.

INTRODUCTION

1

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1 INTRODUCTION

1.1 Progress and challenges

People's knowledge of their own, and their partners', HIV status is essential to the success of the HIV response. The overarching goals of providing HIV testing services (HTS) are to deliver a diagnosis and to effectively facilitate access to and uptake of HIV prevention, treatment and care. These services can include antiretroviral therapy (ART), voluntary medical male circumcision (VMMC), services for the prevention of mother-to-child transmission (PMTCT), condoms, contraception and harm reduction services for people who inject drugs, as well as pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). These high-impact interventions reduce HIV transmission and HIV-related morbidity and mortality *(1-5)*.

Globally, there has been substantial scale-up of HTS. In 2005 it was estimated that in Africa only 10% of people with HIV were aware of their HIV status and that, globally, only 12% of people who wanted to test for HIV were able to do so *(6)*. In contrast, nearly 15 years later, it is now estimated that 81% of people with HIV in Africa and 79% of people with HIV globally know their status *(7, 8)*. It is estimated that from 2010 to 2018 more than one billion people received HTS in reporting low- and middle-income countries *(8, 9)*. These achievements have largely been made possible through the availability of rapid diagnostic tests (RDTs). The growing availability and use of RDTs made it possible to increase task-sharing, which enabled trained lay providers to deliver HTS in settings outside laboratories, ranging from routine testing in health facilities to community-based outreach.

Despite these achievements, a substantial testing gap remains. While the number of HIV tests performed and HIV testing coverage have increased steadily in many settings HTS is often not sufficiently focused on those at highest risk *(8)*. Many of those unreached are men, adolescents (ages 10–19 years) and young people (ages 15–24 years) in high HIV burden settings, primarily East and southern Africa, and key populations worldwide *(8)*.

> Despite a rapid increase in access to HTS, many of those at highest risk of HIV remain unreached and untested.

1.1.1 Increasing access for key populations

HIV disproportionately affects key populations, including men who have sex with men, people who inject drugs, sex workers, transgender people, people in prisons and other closed settings, and their partners. People from key populations comprise more than half

of the 1.7 million new HIV infections that occur every year *(8)*. Although countries are increasingly including key populations in their national HTS guidelines as a priority population, implementation remains limited, and coverage continues to be low in most settings *(8, 9)*. Even in high HIV burden settings, a comprehensive HIV response must address key populations, as HIV burden continues to be very high among them, while in the general population the proportion of people with HIV who do not know their status is declining *(8, 10)*.

Poor coverage and low uptake of HTS among key populations is in part due to lack of accessible, available and acceptable services. Legal and social issues related to people from key populations and their behaviours also increase their vulnerability to HIV and impede access to HIV services including prevention, testing, treatment and care. Such issues include HIV-related stigma and discrimination, criminalization and punitive laws and practices *(11, 12)*. Indeed, HIV testing is sometimes misused in punitive or coercive ways against key populations, especially where their behaviours are criminalized *(7, 8)*. In many countries inadequate coverage and the low quality of HIV services for key populations, including HTS, undermine the national response to HIV *(10)*.

These challenges require new focus and approaches to reach people with undiagnosed HIV earlier in their infection. Many countries and programmes are looking for innovative approaches to delivering HTS to achieve national and global testing targets.

Inadequate coverage and low quality of services for key populations can undermine the national response to HIV.

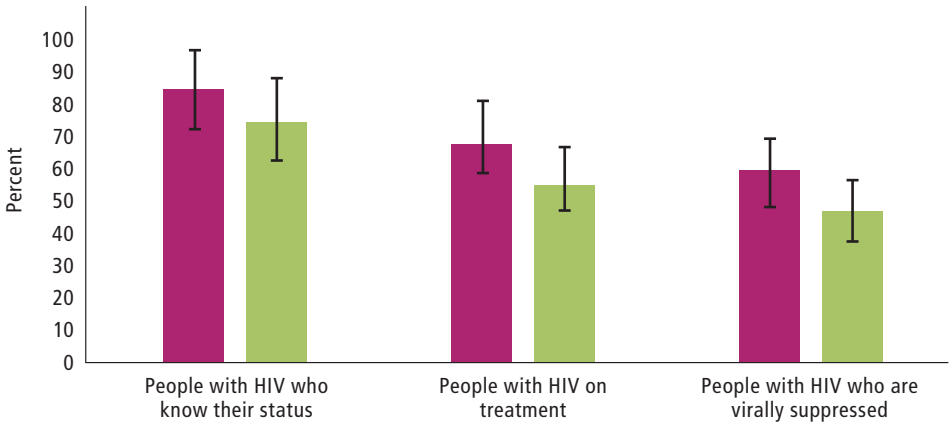
1.1.2 Men continue to lag behind

Globally, men with HIV are less likely to know their status, be on treatment and be virally suppressed than women *(8)*. Nearly 70% of HIV tests in adults were conducted for women, as reported in 76 low- and middle-income countries in 2014 *(9).* In 2018 an estimated 55% of adult men with HIV were receiving ART compared with 68% of women with HIV *(8)*. In most countries HIV testing coverage for men continues to be lower than for women *(13).* Men are overrepresented in key populations and, thus, more likely to face the barriers to access associated with membership in a key population. For example, an estimated 80% of people who inject drugs are men *(14).* Estimates suggest that, outside of Africa, men, who are primarily from key populations, account for larger number of new infections than do women *(15)*.

Barriers to HTS among men are often due to their perceptions that health services, particularly antenatal care (ANC) settings, are not friendly to men *(16).* Other sociocultural beliefs and behaviours contribute as well. For men in key populations, additional barriers to services include facility-level factors such as stigma, discrimination, confidentiality concerns and inconvenient clinic operating hours *(12, 14)*. The broader issues of punitive laws and policies, harassment by law enforcement officials and stigma and discrimination in society are also major contributors *(12)*. As a result, many men remain untested, and those with HIV continue to be diagnosed and linked to treatment and care late. Thus, in many settings males have a higher HIV-mortality rate than their female peers (Fig. 1.1) *(17).*

Strategies are needed to increase men's uptake of HTS as well as support linkage to prevention and treatment.

Fig. 1.1. HIV testing and treatment cascade, 15 years and older, global, 2018



Source: UNAIDS, 2019 *(8)*

1.1.3 Adolescents and young people, too, are underserved

Adolescents and young people, particularly young women and girls, are also at significant risk of HIV infection in high HIV burden settings in eastern and southern Africa, where nearly 90% of HIV-positive adolescents (ages 10–19 years) are estimated to be living *(8, 18).* Globally, HIV burden is often high in the young members of key populations including men who have sex with men, transgender women, young women who sell sex and young people who use or inject drugs *(8, 19).*

Despite the need for HIV testing among adolescents, coverage and uptake remain poor. It is estimated that fewer than only one in every five girls (ages 15–19 years) in the African region are aware of their HIV status *(20, 21)*. Population-based surveys in Malawi, the United Republic of Tanzania, Uganda and Zambia suggest roughly half of the young people (ages 15–24 years) with HIV were aware of their status, and only 37–46% were on treatment *(22).*

Poor access and uptake are often due to the actual or perceived poor quality of services as well because of restrictive laws and policies – for example, age-of-consent laws for testing that prevent adolescents from accessing HTS *(23)*. Greater efforts are particularly needed to improve access among adolescents where HIV incidence is high, in sub-Saharan Africa, and among young key populations in all settings.

1.1.4 Services for women can be further expanded and integrated

Globally, there are 1.4 million maternal HIV infections, 988 000 maternal syphilis infections and 65 million women of childbearing age with chronic hepatitis B virus (HBV) infections *(8, 24, 25).* Elimination of mother-to-child transmission (eMTCT) of HIV, syphilis and HBV is a global health priority *(26).* HIV and syphilis testing as early as possible in pregnancy enables affected pregnant women to benefit most from prevention, treatment and care and reduces the risk of transmission to their infants and sexual partners. Early treatment for HIV, syphilis and chronic HBV will lead to the best health outcomes for mothers and children. ART is most effective in preventing HIV transmission from mothers to infants when started before or early in pregnancy.

HTS should be routinely offered as early as possible during pregnancy *(27).* In high-burden settings, high HIV incidence is seen throughout the antenatal and postpartum period, indicating that retesting may be warranted for pregnant women who initially test HIV-negative *(28)*. Globally, syphilis and HBV testing coverage in pregnant women is considerablye lower than that for HIV *(28)*. This leads every year to adverse birth outcomes and new infections requiring treatment *(8)*.

WHO recommends testing for syphilis and HBV[1] during pregnancy. However, this recommendation often is not implemented or may not be included in national policy *(28).* In 2017 one third of countries reported antenatal syphilis testing coverage below 50% *(29)*, with even fewer testing for HBV. While WHO recommends testing at the point of care using RDTs, the majority of countries still rely on laboratory testing *(28, 30)*.

1.1.5 Children and infants are still missed

HIV testing coverage among children is also often low. Despite reports of high positivity among children tested in clinical settings in countries with a high HIV burden *(31-34),* facility-based testing is still rarely offered routinely for children in tuberculosis (TB) and malnutrition clinics *(35, 36)*. Although HIV testing coverage in PMTCT programmes has improved considerable over the past decade, rates of early infant diagnosis (EID) remain far from optimal. In 2018 only 56% of all HIV-exposed infants were tested by the second month of age *(28).* For infants who are tested, delays in obtaining results and further losses in the treatment cascade still occur. As a result, less than one third of perinatally infected infants are linked to services and initiated on ART in a timely manner *(37).*

Less than one third of perinatally infected infants are linked to services and initiated on ART in a timely manner.

Barriers to HIV testing among infants and children include mothers moving back to their homes or villages after delivery, fear of disclosure of HIV serostatus, fear of stigma and discrimination and parents' lack of knowledge of the need to enrol children in care. Other barriers that perpetuate low testing include lack of transportation, inopportune service hours and long waiting times at health facilities *(35, 36).*

1 Particularly in settings with ≥2% HBsAg seroprevalence in the general population.

1.1.6 Linkage to prevention, care, treatment and support is late or delayed

Linkage to prevention, treatment and care following HTS is a key responsibility of the testing provider and essential to programmatic impact. With the offer of immediate ART initiation and improved treatment options, access to and uptake of treatment has increased. As of 2018 approximately half of 195 reporting WHO Member States had completed or were close to completing transition to the "treat all" strategy using recommended first-line antiretroviral regimens *(28)*. According to a recent systematic review, these improvements in treatment availability have made possible higher rates of linkage *(38).* Despite this progress, gaps remain, particularly for key populations, men, young people and people with HIV who had been previously diagnosed and had not initiated ART or who had started treatment but had disengaged or been lost to follow-up.

Barriers that hinder or delay linkage to HIV treatment persist. They include transportation costs and distance to the facility, stigma, fear of disclosure, staff shortages and long waiting times *(39),* as well as policy and legal barriers that may hinder access, particularly for adolescents and key populations. In many settings the use of laboratory-based testing – particularly the use of western blotting – impedes linkage. According to a recent systematic review, testing strategies and algorithms using western blotting results in a significantly longer turnaround time, lower linkage to treatment and greater loss to follow-up than with testing strategies and algorithms that use simple tests such as rapid diagnostic tests (RDTs) and enzyme immunoassays (EIAs) *(40).* Recent studies have also highlighted the high opportunity costs for men attending services *(41)*, which also contributes to lower or delayed uptake of services.

1.1.7 Retesting among those HIV-positive and on treatment is common

At the same time, increased access to HTS and ART may be contributing to retesting among people with HIV who already know their status, including those on treatment *(42-45).* A systematic review reported retesting rates ranging from 13.2% to 68.1% among people with HIV who already knew their status *(46)*. Across studies, retesting was more common among those tested through routine offer of testing in clinical sites (often called provider-initiated testing and counselling [PITC]) and home-based (door-to-door) HTS than among those testing in stand-alone sites (often called stand-alone voluntary counselling and testing [VCT] sites), where individuals come specifically for HTS *(47, 48).*

Motivations for retesting vary among people who know their HIV-positive status, including those on treatment. Reasons include doubts about the accuracy of a previous test, feeling sick or healthy, or wanting to check on or come to terms with an HIV-positive diagnosis *(46).* Such retesting is not recommended and can provide incorrect results if the person with HIV is on ART.

For some people who know their HIV status but have not initiated or discontinued treatment, retesting is an important opportunity to initiate or re-engage in care and build trust and gain familiarity with health workers and the process of linking to care *(49)*.

A combination of interventions is needed to improve linkages to prevention, care and treatment for specific groups at risk, especially for key populations and men, and to reduce loss to follow-up along the testing and treatment pathway. With increasing ART coverage, appropriate and focused messages on retention in care are needed.

1.1.8 Challenges to quality HIV testing

Just as important as strategically expanding HTS is assuring that all clients who test for HIV receive correct diagnoses. Recent reports suggest that misdiagnosis of HIV status is occurring in resource-limited settings, largely due to the use of suboptimal testing algorithms and strategies *(42).* Recent analysis of policy in more than 90 low- and middle-income countries highlights this challenge. As of 2018, only 25% of countries have HIV testing algorithms and strategies in full compliance with WHO recommendations *(50)*. Less than one third of policies specified products in the testing algorithm, and less than one fifth mentioned the need to verify an HIV-positive diagnosis through retesting prior to initiating lifelong treatment, both necessary to provide and accurate HIV diagnosis *(50).*

> Only 25% of national policies have HIV testing algorithms and strategies in full compliance with WHO recommendations, which assure the most accurate diagnoses.

Beyond use of suboptimal testing strategies and algorithms, poor-quality HIV testing can result from a number of problems, including poor product performance, improper storage or management of supplies, clerical or transcription errors, user errors in performing or interpreting the test, and poor documentation and record-keeping. Lack of training for providers, supportive supervision or standard operating procedures (SOPs) can aggravate these problems. Thus, it is important that quality assurance (QA) systems function effectively and expand in parallel with the delivery of HTS.

Recent mathematical modelling has shown that the use of the correct WHO-recommended HIV testing strategy, along with QA measures such as retesting to verify a positive diagnosis, is cost–effective, as it prevents misdiagnosis and unnecessary initiation of costly lifelong treatment *(51-53).*

To address these gaps, more proactive, people-centred HIV testing initiatives are needed as well as stronger efforts to implement quality HTS using WHO-recommended HIV testing strategies with quality assurance. This includes more emphasis on quality improvement *(54)*, more focused promotion of testing in geographical areas with a high HIV burden and among key populations, strategic investment in efforts to increase the demand for testing services.

1.2 Rationale

These guidelines seek to address gaps that countries have identified in the 2015 WHO consolidated guidelines on HTS. The guidelines provide new and updated

recommendations on HIVST, social network-based approaches to testing and move away from western blotting in national testing algorithms and strategies.

These guidelines also highlight operational considerations for programmes and ways to optimize delivery of testing services. Operational considerations include messages, counselling and demand creation activities; strategic opportunities to integrate services such as the use of HIV/syphilis dual tests into antenatal care; delivering correct HIV diagnoses; and to strategically use available testing options and resources to reach people with HIV and those at risk of HIV acquisition.

Countries and other end-users of HTS guidelines have indicated that this new guidance will enable them to make decisions about how to introduce and scale up new HTS approaches, as well as to increase the effectiveness and efficiency of HTS programmes as part of national and global efforts to achieve and maintain low HIV incidence *(55).*

1.3 Scope of the guidelines

These guidelines outline a public health approach to strengthening and expanding HTS. They present and discuss key updates to existing WHO guidelines on HTS, with a focus on new evidence, new recommendations, good practices and operational considerations that respond to the changing needs of national programmes.

This consolidated guidance addresses the issues, elements and service delivery models for effective HTS delivery that are common in a variety of settings and contexts and that serve diverse populations with specific needs.

- Chapter 2 describes the methodology for developing these guidelines.
- Chapter 3 details guidance and good practices on pre-test services, which include mobilization, demand creation and pre-test information and messaging.
- Chapter 4 details guidance and good practices on linkage to prevention and treatment, including post-test counselling.
- Chapter 5 provides guidance and recommendations on HTS approaches, including facility-based HTS, community-based HTS, HIVST, provider-assisted referral and social network-based approaches.
- Chapter 6 examines operational considerations for HTS to focus on priority populations in greatest need of HTS.
- Chapter 7 offers strategic ways to rationalize limited resources and presents and discusses a framework for effectively focusing HIV testing approaches in different epidemic and population contexts.
- Chapters 8 and 9 provide guidance on correctly performing HIV testing, HIV testing strategies, verification of national algorithms, procurement and supply chain issues, and quality of HTS.

These guidelines are an update to both the 2015 *Consolidated guidelines on HIV testing services (2)* and the 2016 *Guidelines on HIV self-testing and assisted partner notification*

services (56). They are also available as abridged policy briefs: https://www.who.int/publications/i/item/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic.

The background documents developed to support these guidelines and Grading of Recommendations Assessment Development and Evaluation (GRADE) tables for new recommendations appear in the annexes listed in the Table of contents. These are included in the published guidelines and posted on the Internet at https://www.who.int/hiv/pub/guidelines/en/.

GRADE tables resulting in new recommendations and good practice statements appear in the following annexes:

- Annex A. Which demand creation approaches are effective for increasing the uptake of HIV testing and onward linkage to prevention, treatment and care?
- Annex B. Should HIV self-testing be offered as an additional HIV testing approach?
- Annex C. Should social network-based approaches be offered as an additional HIV testing approach for key populations and their contacts?
- Annex D. Should western blotting and line immunoassays be used in national testing strategies and algorithms?

Modelling to inform operational considerations:

- Annex E. Accuracy and performance of HIV testing strategies: considerations for accuracy across heterogeneous epidemic settings
- Annex F. Modelling the cost–effectiveness of maternal HIV retesting in high and low HIV burden settings
- Annex G. Modelling the cost-effectiveness of using HIV/syphilis dual tests in antenatal care in high and low HIV burden settings.

1.4 Using these guidelines

These guidelines will be used to help countries implement a strategic mix of HTS approaches in the context of a public health approach to HTS, which is guided by the human rights principles outlined in the WHO 5Cs: **C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect results and **C**onnection (linkage to prevention, treatment and care) (see section 1.7).

1.5 Goal and objectives

The primary goal of these guidelines is to update the existing *Consolidated guidelines on HIV testing services (2)* and, thus, better support countries and national programmes seeking to reach people who may not otherwise test and who are at highest risk for HIV.

The primary goal of these guidelines is to better support the addition of HTS approaches that can reach people who may not otherwise test and who are at highest risk.

These consolidated guidelines are an effort to further support countries, programme managers, health workers and other stakeholders seeking to achieve national and global goals to achieve and sustain low HIV incidence by 2030 *(55).* They provide important operational and implementation considerations on how to deliver the most effective and efficient HTS programmes using differentiated HTS approaches to serve the specific populations and settings in need of services.

Specific objectives in support of this goal include the following:

- provide comprehensive evidence-based recommendations for HTS;
- support the implementation and scale-up of a strategic mix of evidence-based HTS approaches, in both facility and community settings, for those in need of HIV testing, prevention and treatment services;
- support integration of services through HTS, such as the use of HIV/syphilis dual testing as the first test in ANC;
- support programmes to implement quality HTS using WHO-recommended testing strategies and algorithms and to stop using western blotting;
- provide guidance on how programmes can strategically plan and effectively rationalize resource use;
- reinforce greater national and global commitment to implement effective and efficient HTS as a key element of the national and global HIV response.

1.6 Intended audience

These guidelines address national HIV programme managers, particularly in ministries of health. Such managers are responsible for the national health sector's response to HIV, including HTS, as well as prevention, care and treatment services for the populations of Member States. These managers play a key role in ensuring the availability of the continuum of prevention, care and treatment services in their countries. These guidelines also will assist national and subnational programme managers responsible for the provision of HTS and a comprehensive range of integrated services as well as officers at the national level responsible for other communicable diseases, especially other STIs, TB and viral hepatitis.

Finally, these guidelines will be helpful to other implementers of HTS, including international and national nongovernmental organizations (NGOs), civil society and community-based organizations. They can also serve donors as the normative guidance to support effective funding, planning and implementation of HTS.

1.7 Guiding principles

It is important to deliver HTS with a public health and human rights-based approach. A human rights-based approach to public health highlights priority areas, including universal health coverage (UHC), gender equality and health-related human rights such as the accessibility, availability, acceptability and quality of services. For all HTS the

public health benefits must always outweigh the potential harm or risk. The primary reasons for testing must always be both to benefit the individuals tested and to improve health outcomes at the population level. HTS should be expanded not merely to achieve high testing uptake or to meet HIV testing targets, but to provide access for all people in need to appropriate, quality HTS with effective linkage to prevention, care, treatment and support services. HIV testing for diagnosis must always be voluntary and consent for testing must be informed by pre-test information. Coerced or mandatory testing is never appropriate, whether that coercion comes from a health-care provider or from a partner or family member.

The primary reasons for testing must always be both to benefit the individuals tested and to improve health outcomes at the population level.

All HTS approaches should adhere to the WHO 5 Cs: **C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results and **C**onnection (linkage to prevention, care and treatment services) (2) (see box).

WHO's 5 Cs

The 5 Cs are principles that apply to all HTS and in all circumstances.

- **Consent.** People receiving HTS must give informed consent to be tested and counselled. (Verbal consent is sufficient; written consent is not required.) They should be informed of the process for HIV testing and counselling and of their right to decline testing. It should not be assumed that people who request or report self-testing for HIV are providing or have implicitly provided consent. It is important that all people who self-test are informed that mandatory or coercive testing is never warranted. Provider-assisted referral and social network-based approaches, which offer HTS to their clients' sexual partners, drug injecting partners and social contacts, are voluntary and implemented only with the consent of clients and contacts.
- **Confidentiality.** HTS must be confidential, meaning that what the HTS provider and the client discuss will not be disclosed to anyone else without the expressed consent of the person being tested. Although confidentiality should be respected, it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should discuss, among other issues, whom the person may wish to inform and how they would like this to be done. Shared confidentiality with a partner or family members – trusted others – and health-care providers is often highly beneficial.

- **Counselling.** Concise pre-test information and post-test counselling can be provided in a group setting if appropriate, but all persons should have the opportunity to ask questions in a private setting if they request it. All HTS must be accompanied by appropriate post-test counselling, based on the HIV test result. QA mechanisms as well as supportive supervision and mentoring systems should be in place to ensure the provision of high-quality counselling. Various channels and tools can used to deliver messages, information and counselling, including peer providers and innovative digital approaches such as videos, social media and other mobile phone applications or services.
- **Correct.** Providers of HTS should strive to provide high-quality testing services, and QA mechanisms should ensure that people receive a correct diagnosis. QA may include both internal and external measures and should include support from the national reference laboratory. All people who receive a positive HIV diagnosis should be retested to verify their diagnosis before initiation of ART or engagement in HIV care.
- **Connection.** Linkage to prevention, care and treatment services should include the provision of effective and appropriate follow-up as indicated, including long-term prevention and treatment support. Providing HTS where there is no access or poor linkage to care, including ART, has limited benefit for those with HIV. Linkage is the responsibility of providers and testers delivering HTS.

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METHODOLOGY

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2 METHODOLOGY

2.1 Overview

These guidelines were developed in response to Member States' requests to update the World Health Organization (WHO) guidance on HIV testing services (HTS) *(1, 2)* and to provide guidance on how to implement effective and efficient services, given the changing HIV epidemic and the needs of diverse populations, settings and contexts.

The WHO HIV Department led the development of these guidelines in accordance with the procedures and reporting standards laid out in the WHO handbook for guideline development *(3)*. All current WHO recommendations that pertain to HTS are included.

2.2 Establishing the groups to develop the guidelines

The WHO HIV Department set up three groups to perform specific guideline development functions. Members of the groups were selected to ensure a range of expertise and experience, including appropriate geographical, gender and community representation. (See Acknowledgements for lists of participants.) The three groups were these:

1. WHO Guideline Steering Group (SG). The WHO HIV Department, Key Population and Innovative Prevention Unit, led this group and served as the WHO secretariat. Participants included WHO staff from other units in the HIV Department, the Department of Essential Medicines and Health Products, the Department of Reproductive Health and Research, the Global Hepatitis Programme and the Global Tuberculosis Programme. This group also included WHO technical staff from all WHO regional offices. WHO country offices and other United Nations (UN) agencies and partner organizations also made contributions.

2. Guideline Development Group (GDG). This group consisted of 26 members, with a balanced representation of geographic regions, gender and backgrounds, including academia and research and programme implementation and policy, and community organizations and networks. The group members were selected in coordination with the SG and WHO country and regional offices. The SG reviewed curricula vitae (CVs), declarations of interest and confidentiality agreements, the proposed membership list was posted for public review and comment and then was finalized. This group was responsible for the formulation of the new WHO recommendations and implementation and service delivery considerations and for review and approval of the final content of the guidelines document.

3. External Review Group. This group was selected in consultation with the WHO SG and GDG to assure geographic and gender balance. It comprised 95 peer reviewers from academia, policy and research, implementing programmes and community organizations, and networks, including key population networks.

2.2.1 Involvement of key stakeholders

An important element of this work was engaging with a diverse set of stakeholders to update and synthesize key messages throughout existing WHO guidance on HTS. These stakeholders comprised ministries of health and laboratory services in countries, researchers, international and national implementing agencies, WHO regional and country offices and other UN agencies, community networks and implementers. They also included key populations, people living with HIV and additional experts in the field.

2.2.2 Declarations of interest

All members of the GDG, non-WHO staff participating in meetings or guideline development, and external peer reviewers submitted declarations of interest and confidentiality statements to the WHO secretariat. The WHO secretariat and the GDG reviewed all declarations and found no conflicts of interest sufficient to preclude anyone from participating in the development of the guidelines. A full compilation and summary of the declarations are available in Appendix 1.

2.3 Defining the scope of the guidelines

To develop these guidelines, the WHO SG mapped all existing guidance concerned with HTS including updates since the 2015 *Consolidated guidelines on HIV testing services (2)* and 2016 *Guidelines on HIV self-testing and assisted partner notification (1)*. Following initial mapping, between November 2017 and July 2018, multiple scoping meetings were held with external experts representing the various constituencies to review the preliminary framework and to identify key gaps that had to be addressed in the guidelines update process.

This process led to a list of reviews to be conducted and recommendations to be considered. The WHO SG then reviewed and agreed on this outline, reaching consensus on key areas to be reviewed and included in addition to those addressed by the existing recommendations.

Four critical gaps requiring normative guidance were identified:

1. **demand creation** to enhance uptake of HTS and subsequent initiation of prevention or treatment.
2. **HIVST** (the 2016 recommendation required updating due to the large amount of new evidence from trials and implementation projects);
3. **social network-based approaches** for key populations; and
4. use of **western blotting** in national HIV testing algorithms and strategies.

The SG also identified additional operational issues relevant to implementation:

1. **messaging and counselling** practices during pre-test information and post-test counselling;
2. **optimal HIV testing strategies** in the context of declining national estimates of HIV positivity (defined as the number of tests conducted where an HIV-positive result was returned to a person);
3. **integrated service delivery** approaches, such as using dual HIV/syphilis rapid diagnostic tests (RDTs), and HIV testing in presumptive TB cases and in family planning and contraceptive services;
4. **retesting issues**, including testing pregnant and postpartum women of negative or unknown status, people with HIV who know their status and may be on treatment, and individuals at high ongoing risk, including those taking PrEP; and
5. **strategies and tools to further focus HTS**, including service delivery in communities.

2.4 Review of the evidence

These guidelines present existing recommendations, as well as one updated recommendation, two new recommendations, two new good practice statements and a range of implementation considerations.

The GDG and SG recommended commissioning four systematic reviews to inform normative guidance and recommendations on 1) demand creation to enhance uptake of HTS and onward linkage, 2) HIVST, 3) social network-based approaches, and 4) the use of western blotting in national testing strategies and algorithms.

Each systematic review adhered to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology[1] and reported on the effectiveness and the certainty of the evidence. In addition, reviews were conducted of values and preferences, feasibility, resource use and equity. Background literature, policy reviews and mathematical modelling complemented these reviews to address implementation issues and considerations.

2.5 Development of recommendations

As noted, the scoping exercise identified a need for evidence-based recommendations concerning demand creation, HIVST, social network-based approaches and use of western blotting in HIV testing strategies and algorithms. The WHO SG drafted a single PICO question – Population, Intervention, Comparator, Outcome (PICO) – for each of these four areas. The GDG reviewed and finalized the PICO questions and the outcomes and stratifications of interest for each systematic review. The GDG then ranked the importance of each outcome for each review on the GRADE rating scale of 1–9 (0–3: not important; 4–6: important; 7–9: critical) *(4).*

Once the PICO questions were completed and agreed, external researchers, supported by the WHO HTS team, conducted each review.

1 For more information see http://www.gradeworkinggroup.org/#pub.

1. Anjuli Wagner and Ruchi Tiwari of the University of Washington, led the systematic review on demand creation for HTS and linkage.
2. Muhammad Jamil, a WHO consultant, Charles Witzel of London School of Hygiene and Tropical Medicine and Ingrid Wilson and Elvin Geng of Washington University led the systematic review on HIVST.
3. David Katz, Sarah Masyuko and Julia Dettinger of the University of Washington led the systematic review on social network-based approaches among key populations.
4. Sandy Walker and Kim Wilson of the Australian National Serology Reference Laboratory and Myra McGuinness of the University of Melbourne led the systematic review on the use of western blotting in national HIV testing strategies and algorithms.

All review teams developed protocols and conducted systematic reviews of the available scientific evidence, as described below. Both protocols and reviews were assessed and reviewed by Nandi Siegfried, the appointed independent methodologist, as well as the GDG, SG and WHO secretariat.

2.5.1. GRADE systematic reviews

The WHO SG and GDG developed the four PICO questions to inform the development of guidance. Researchers used the same search strategies to identify studies presenting information on user values and preferences (for example, people seeking testing, health-care providers, communities, policy-makers) and resource use related to the PICO question. Table 2.1 provides details, as do Annex A-D.

Information related to resource use, including cost and cost-effectiveness, is summarized across studies, where available. Cost comparisons were made according to the Global Health Cost Consortium (GHCC) guidelines for estimating the costs of services and interventions *(5)*.

For comparisons across studies, costs were converted to 2018 US$ using World Bank currency exchange rates[2] and local GDP deflator[3] *(6)*.

The results of all values and preferences reviews, including resource use, are summarized in Annexes A-D and in Chapter 3 (demand creation), Chapter 5 (HIVST and social network-based approaches) and Chapter 8 (western blotting).

2 http://data.worldbank.org/indicator/PA.NUS.FCRF?page=1, accessed 15 July 2019

3 http://data.worldbank.org/indicator/NY.GDP.DEFL.ZS, accessed 15 July 2019

Table 2.1. GRADE systematic review and PICO question summary

	Demand creation[1]	HIV self-testing	Social network-based approaches	Western blotting
Search dates	Searched up to 8 September 2018	Searched up to 4 May 2019	Searched up to 8 September 2018	Searched up to 3 December 2018
Question	*Which demand-creation strategies are effective in enhancing the uptake of HIV testing services?*	*Should HIVST be offered as an additional approach to deliver HIV testing services?*	*Should social network-based approaches to HTS be used as an additional option for key populations and their contacts?*	*Should western blotting or immunoblotting be used in HIV testing algorithms?*
Population	Population requiring HIV testing services (HTS), excluding voluntary medical male circumcision (VMMC)[2]	People receiving HIV testing services	Key populations and their social, sexual and drug-using/sharing contacts	People receiving HTS who need further testing to confirm their HIV status
Intervention	Any demand-creation strategy	HTS that include self-testing or (for multi-arm or randomized controlled trials [RCTs] with no standard of care) include HIVST and other interventions	Use of partner services or social network-based approaches to HIV testing	Western blotting or immunoblotting used to confirm reactive results of HIV rapid diagnostic tests (RDTs) and/or enzyme immunoassays (EIAs) that detect antibodies to HIV only or to HIV antibodies and antigen which are used together within a testing algorithm/strategy
Comparator	Alternative demand-creation strategies or no demand-creation strategy	HTS that do not include self-testing or (for multi-arm RCTs or RCTs with no standard of care) that use HIVST alone	No HTS; HTS without social network-based approaches; or other social network-based approaches	HIV RDTs and/or EIAs that detect antibodies to HIV only or to HIV antibodies and antigen used in which are used together within a testing algorithm/strategy in a testing algorithm without using western blotting or immunoblotting

Table 2.1. GRADE systematic review and PICO question summary, continued

	Demand creation[1]	HIV self-testing	Social network-based approaches	Western blotting
Critical outcomes	• uptake of HTS • new HIV-positive diagnoses • yield of HTS (that is, the number and proportion of testers who test HIV-positive) • linkage to HIV care and initiation of ART after testing positive • viral suppression (that is, <1000 copies/mL) • linkage to HIV prevention services	• uptake of HTS • HIV positivity rate • linkage to additional HIV testing • linkage to clinical assessment or ART after testing positive • misuse of self-tests (social harm) and other adverse effects • condom use or condomless sex	• uptake of HTS among partners/ contacts • reaching first-time testers • uptake of HTS among index clients • uptake of HTS among partners/ contacts • reaching first-time testers • uptake of HTS among index clients • reaching non-recent testers (that is, >1 year previously) • partners or contacts tested for HIV and diagnosed HIV-positive (adjusted to exclude people aware of their HIV infection) • linkage to clinical assessment or ART after testing positive • identification and/or linkage of people with HIV not in HIV care, not on ART or not virally suppressed • linkage to prevention visit if HIV-negative'	• diagnostic accuracy of final determination of HIV status (sensitivity and specificity) • social harm or adverse events (for example, misdiagnosis of HIV) • diagnostic accuracy of final determination of HIV status (sensitivity and specificity) • social harm or adverse events (for example, misdiagnosis of HIV) • loss to follow-up (for example, measured as the proportion of clients who do not receive final HIV status) • time to providing HIV status (for example, measured as the median number of days until patient receives HIV diagnosis) • time to linkage to care, treatment or prevention programmes following determination of HIV status

1 Demand creation was defined as activities intended to improve an individual's knowledge and attitudes, motivation and intention and, eventually, decision and behaviour to seek HIV testing services. The following categories inductively summarize demand-creation approaches: incentives; mobilization; individualized and customized interventions; messaging types and approaches; and digital platforms. See Annex A for details.

2 WHO guidelines on enhancing uptake of VMMC were under development while these guidelines were being developed. Thus, male populations receiving demand creation activities to enhance VMMC uptake were excluded. Results will be reported in the forthcoming WHO guidelines: *Updated recommendations on safe male circumcision for HIV prevention and related service delivery for adolescent boys and men in generalized HIV epidemics.*

2.6 Evidence assessment

Under the WHO guideline development process, the GDG formulates the recommendations, guided by the certainty of available evidence. Other factors – values and preferences, costs and feasibility, acceptability and equity, and human rights – are also taken into consideration when determining the direction and strength of the recommendation.

2.6.1 Interpreting the quality of evidence

The greater the certainty of scientific evidence, the more likely that a strong recommendation can be made. The GRADE approach to recommendation development, which WHO has adopted, defines the quality of evidence as the extent to which one can be confident that the reported estimates of desirable or undesirable effects available from the evidence are close to the actual effects *(4)*.

The GRADE approach specifies four levels of quality of evidence, as described in Table 2.2.

Table 2.2. Interpretation of the four GRADE levels of evidence

Quality of evidence	Rationale
High	We are very confident that the true effect lies close to the estimate of effect.
Moderate	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.
Low	Our confidence in the estimate of effect is limited. The true effect may be substantially different from the estimate of effect.
Very low	We have very little confidence in the estimate of effect. Any estimate of effect is very uncertain.

2.6.2 Determining the strength of a recommendation

The strength of a recommendation reflects the degree of confidence of the GDG that the desirable effects of the recommendation outweigh the undesirable effects (Table 2.3). Desirable effects (potential benefits) may include beneficial health outcomes (for example, increased uptake of HTS or earlier linkage to HIV services), reduction of burden on the individual and/or health services and potential cost savings for the individual, community, programme and/or health system. Undesirable clinical outcomes, adverse effects and potential harm, such as self-harm, intimate partner violence or coercive HIV testing, include those affecting individuals, families, communities or health services. Additional burdens considered include resource use and the cost implications of implementing the recommendations for programmes, care providers and patients.

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

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

A **conditional recommendation** (for or against) is one for which the GDG concludes that the desirable effects of adherence to the recommendation *probably outweigh* the undesirable effects or are closely balanced, but the GDG is not confident about these trade-offs in all situations. The GDG may formulate conditional recommendations when the certainty of evidence is low or may apply only to specific groups or settings. If implemented, a conditional recommendation should be monitored closely and evaluated rigorously. Further research will be required to address the uncertainties and is likely to provide new evidence that may change the calculation of the balance of trade-offs.

The values and preferences of users, feasibility and costs, acceptability, human rights and equity, as well as consideration of potential benefits and harm contribute to determining the strength of a recommendation (Table 2.3).

Table 2.3. Domains considered when assessing the strength of recommendations

Domain	Rationale
Benefits and harm	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.
Certainty of evidence	High certainty of evidence is likely to lead to a strong recommendation.
Values and preferences (of users)	If the recommendation is likely to be widely accepted or valued highly, it is likely that a strong recommendation will be made. If there is a great deal of variability or strong reasons that the recommended course of action is unlikely to be accepted, it is more likely that a conditional recommendation will be made.
Acceptability (to providers and stakeholders)	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 that the recommended course of action is unlikely to be accepted, it is more likely that a conditional recommendation will be made.
Cost/financial implications	Lower costs (monetary, infrastructure, equipment or human resources) or greater cost–effectiveness contribute to a strong recommendation.
Feasibility	If an intervention is achievable in a setting where the greatest impact is expected, a strong recommendation is appropriate.
Equity & human rights	If the recommendation is likely to increase access to an intervention for those most in need, a strong recommendation is likely.

2.7 Developing the recommendations

From November 2018 through August 2019, WHO convened one in-person and four virtual guideline development meetings (two parallel morning and afternoon meetings on two separate occasions to make participation possible for different time zones) and 12 WHO SG meetings.

During these meetings participants considered the evidence for formulating a new recommendation and reviewed all relevant sections of the consolidated guidelines. Individuals representing a broad range of stakeholders participated in the guideline development meetings as either part of the GDG or as expert observers. Participants at these meetings assessed the evidence to answer all four PICO questions along with the other factors outlined above and, through a discussion facilitated by the methodologist, determined recommendations. Prior to the guideline meeting, the WHO SG and GDG determined that the goal for decision-making would be to reach consensus, defined as agreement of the group, but that if consensus could not be reached, a vote of at least 60% would be required to approve the recommendation.

After reviewing the evidence, the GDG resolved disagreements through continued discussion and revision of the recommendation and provided additional clarification or qualifications not included in the PICO question. In addition, during the GDG discussions, implementation considerations and research gaps were recorded when members raised these.

The Group reached consensus and unanimously agreed on the direction and strength for three recommendations pertaining to HIVST, social network-based approaches and western blotting.

The GDG unanimously agreed not to make a recommendation on demand-creation approaches but agreed on a good practice statement, which includes information and remarks on pre-test information and counselling messages.

The GDG also reviewed operational and implementation considerations for existing WHO guidelines, in particular WHO-recommended HIV testing strategies for an accurate diagnosis and the optimal times for retesting, and use of the HIV/syphilis dual test among pregnant and postpartum women. The GDG unanimously agreed that these were important issues to address in the guidelines in order to capacitate countries to implement high quality and high impact HTS programmes.

See the Executive summary and Chapters 3, 5 and 8 for the final recommendations and good practice statements agreed by the GDG.

2.8 Additional background work

In addition to systematic reviews on demand-creation, HIVST, social network-based approaches and western blotting, WHO conducted additional background work, including policy reviews, background literature reviews and mathematical modelling.

2.8.1. Policy reviews

WHO reviewed national HTS policies from 146 countries, primarily from low- and middle-income countries, to assess uptake of WHO recommendations and guidance. Reviewers adapted a standardized protocol developed during development of the 2015 *Consolidated guidelines on HIV testing services*, using two reviewers and translating policies as necessary.

Policy uptake was also assessed using results of the 2019 WHO, Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Children's Fund (UNICEF) Global AIDS Monitoring (GAM) survey *(7).* All indicators reporting on HTS policy uptake were validated between April and July 2019 based on country reporting. All validated responses are available at: http://lawsandpolicies.unaids.org/selectdataresult.

Across these two resources – the policy repository and the GAM – the following topics were assessed and reported on throughout the guidelines:

1. uptake and implementation of WHO *Consolidated guidelines and Guidelines on HIV self-testing and assisted partner notification (8, 9)*;
2. uptake of national policies and operational guidance on HIVST *(8, 10)*;
3. retesting policies, including maternal retesting among pregnant and postpartum women and key populations *(8, 11, 12)*;
4. age of consent for HIV testing *(8, 13)*;
5. uptake of WHO HIV testing strategies and algorithms *(14)*;
6. HTS integration in family planning clinics *(15)*.

2.8.2. Mathematical modelling

Mathematical modelling was conducted to provide more specificity to existing WHO recommendations and to address operational questions on how to implement them. Modelling included the following:

- **Mathematical modelling on the accuracy and performance of HIV testing strategies in response to changes in the global HIV epidemic.** This modelling provides implementation considerations for existing WHO guidance that recommends using three consecutive reactive tests to establish an HIV-positive diagnosis in settings where HIV positivity of the people being tested is less than 5% *(2, 16-18).* See Chapter 8, and Annex E.
- **Mathematical modelling on the optimal and most cost-effective time points for maternal retesting among women of negative or unknown status in high and low HIV burden settings.** This modelling provides implementation considerations for existing WHO guidance that recommends maternal retesting during late pregnancy and the postpartum period in high HIV burden settings *(2, 19-21)*. See Chapters 6 and 7, Annex F.
- **Mathematical modelling on the use of HIV/syphilis dual tests in antenatal care for pregnant and postpartum women in high and low burden settings**. This modelling provides implementation considerations for existing WHO recommendations and guidance on the use of dual HIV/syphilis testing among pregnant women *(19-23).* See Chapters 6 and 8 and Annex G.

2.9 Producing the guidelines

Following the GDG virtual consultations and the face-to-face meeting, WHO revised the full draft guidelines and circulated them electronically to the GDG, WHO SG and External Review Group for comments and feedback. All responses were considered and addressed as appropriate in the final draft.

2.10 Plans for dissemination

The guidelines will be disseminated through the WHO HTS Info app (https://www.who.int/hiv/mediacentre/news/hts-info-app/en/) and through print publication. The guidelines will also be made available in electronic format as modules on the WHO website in the six official United Nations languages (http://www.who.int/hiv/topics/vct/en/). The app and web version will include all the annexes. For easy reference, a series of policy briefs and slide sets will summarize the new and existing recommendations. The WHO website will offer a library of all supporting documentation and evidence.

WHO headquarters will work closely with WHO regional and country offices and implementing partners to ensure that the guidelines are disseminated through regional and sub-regional meetings. WHO will assist Member States to adapt the guidelines to their national contexts.

2.11 Updating

WHO will continue to monitor the uptake and implementation of WHO guidelines through the bi-annual GAM survey, policy reviews and country and partner dialogues on facilitators and barriers to policy change. In addition, through the WHO HTS Info app, WHO will routinely monitor use of the guideline and make complementary and interactive content available.

These guidelines will be a module within a broader set of consolidated guidelines produced by the WHO HIV Department. Implementation tools and materials will be developed with Member States and WHO regional offices to support further implementation in 2020.

The HIV Department will review this guidance and consider potential updates in 2024–2025. In the interim, if important new evidence becomes available, the Department may issue technical and programmatic updates.

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MOBILIZING DEMAND AND IMPLEMENTING EFFECTIVE PRE-TEST SERVICES, INFORMATION AND MESSAGING

3

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KEY POINTS

- **Concise communication** prior to HIV testing that is informative, encouraging and motivating is an effective way to create demand for HIV testing among people with HIV who do not know their status and to engage those at high ongoing risk without increasing stigma and discrimination.
- **An enabling environment** that removes barriers such as stigma, discrimination and criminalization, and age of consent issues is important for increasing access to and uptake of HIV testing services (HTS), particularly among those at high ongoing risk and key populations.
- Demand creation and mobilization will be most successful when **developed with communities and tailored** to the specific interests, concerns and needs of each priority community in its local setting. Efforts need to prioritize people at high risk who have never tested or have not tested recently, as well as HIV-positive individuals who are aware their HIV status but not currently in care.
- **Evidence-based approaches to demand creation** include peer-led and digital platforms; advertisement of specific HTS attributes such as testing in a workplace setting and weekend or late-night hours; messages encouraging testing during couples-oriented counselling; messages related to risk reduction; and motivational messages.
- As HTS and antiretroviral therapy (ART) coverage increase, retesting among people at low risk is becoming more common. Demand creation efforts, particularly those involving mobilization, need to address this issue to ensure that they are promoting **efficient and effective HTS** and not further increasing the cost per person diagnosed with HIV.
- WHO does not recommend pre-test counselling. Instead, programmes should **provide concise pre-test information** for individuals receiving HTS, their families and their partners in a process that provides general information, answers clients' questions and offers an opportunity to refuse testing.
- It is critical that demand creation efforts include informational and counselling messages that **explain the benefits of early ART** and that people with HIV who achieve and maintain an undetectable viral load cannot transmit HIV to their partners.
- **Integrating brief HIV-specific information and counselling messages** into health visits and broader prevention and support packages may be beneficial, particularly messages that address the needs of people in high HIV burden settings and people at high ongoing risk.
- It is important to **protect and maintain client confidentiality**, especially when offering testing as part of partner services and when the pre-test information session includes questionnaires screening for risks, symptoms or indicator conditions.

3 MOBILIZING DEMAND AND IMPLEMENTING EFFECTIVE PRE-TEST SERVICES, INFORMATION AND MESSAGING

Box 3.1. NEW WHO good practice statement on demand creation

Demand creation to increase HTS uptake and engage those in greatest need of services is a valuable tool for mitigating stigma, discrimination and criminalization. Demand creation approaches may need to be prioritized, depending on the setting, focus population and available resources, as part of a strategy to reach people with HIV who do not know their status and who have high HIV-related risk. A wide range of demand creation strategies have been rigorously tested to assess impact on HIV testing uptake and the proportion of people with HIV diagnosed, but often later outcomes related to linkage to care or prevention have not been measured.

Evidence-based platforms for delivering demand creation include:

- peer-led demand creation interventions, including mobilization
- digital platforms, such as short pre-recorded videos encouraging testing.

Approaches that have showed evidence of increasing demand include:

- advertisement of specific HTS attributes
- brief key messages and counselling by providers (less than 15 minutes)
- messages during couples counselling that encourage testing
- messages related to risk reduction and economic empowerment, particularly for people who inject drugs
- motivational messages.

Evidence suggests that the following approaches may be less effective for demand creation:

- personal invitation letters
- individualized content messaging
- counselling focused on building relationship between the client and counsellor[a]
- general text messages, including SMS.

Some studies report increases in HTS uptake when incentives are offered, however when considering the use of incentives for demand creation, benefits and risks should be carefully weighed, such as:

- resource use and sustainability, especially for providing financial incentives, which may undermine the principles of universal health coverage
- longer-term behavioural changes associating HTS and other services with incentive, weighed against short-term increases in uptake
- negative effect on equity, due to prioritization of some populations and diseases
- potential to deprioritize systematic implementation of strategies that improve service delivery and reduce barriers and disincentives, such as patient costs associated with accessing health services more broadly.

[a] Often called "therapeutic alliance counselling", this focuses on the relationship between client and provider and on mutually agreed upon goals, assignment of tasks mutually perceived to be effective and relevant, and developing a bond between client and counsellor based on relationship and trust. See Annex A for details.

3.1 Introduction

Attaining the United Nation's prevention and treatment targets for 2020 largely depends on HIV testing services and their ability to reach people with HIV who do not know their status and those at high ongoing risk of HIV, and then to facilitate linkage to HIV prevention and treatment services *(1, 2)*. While HIV testing, prevention and treatment services have been scaled up, gaps remain. It is currently estimated that one in every five people with HIV are still unaware of their status, and that there are 1.7 million new HIV infections each year *(3)*.

Many of those unreached by HTS are key populations, partners of people with HIV, people with sexually transmitted infections (STIs), tuberculosis (TB) or viral hepatitis B or C (HBV/HCV) and, in East and southern Africa, men and adolescents and young people *(2)*. In addition to efforts to provide an enabling environment for HIV testing, specific strategies and interventions to create demand and increase uptake are needed to address people at risk of acquiring HIV infection and people with HIV who do not know their status.

Historically, HIV testing was one of the first interventions in the global HIV response *(4)*. Early on in many programmes, in the absence of vaccines or treatment, messages that sometimes conveyed fear were developed to try to motivate people to test for HIV *(4)*. Mobilization efforts largely used mass media campaigns focused on raising awareness and promoting behaviour change *(5)*. While there were short-term effects increasing HTS uptake, the potential long-term benefits in changing behaviour were often unclear *(6)*. Testing services also often provided lengthy pre-test counselling aimed at encouraging less risky behaviour and motivating people to return for their test results *(4, 7, 8)*.

Following the scale-up of ART, additional HIV prevention options and routine rapid testing, demand creation and pre-test counselling messages and strategies changed. Demand creation efforts increasingly included mixed media strategies, social marketing, workshops and more targeted or peer-led strategies *(5, 9)* using messages emphasizing positive living and the need to learn one's status, to start ART (if HIV-positive) and to take up relevant HIV prevention options to improve one's health and prevent transmission. Furthermore, in 2015, on the basis of evidence suggesting no particular benefit to intensive or lengthy pre-test counselling *(8, 10-14)*, WHO advised programmes instead to provide brief pre-test information that offers general information, answers clients' questions and provides an opportunity to decline services *(15, 16)*.

With the introduction of additional HTS approaches, including HIV self-testing (HIVST) and partner services (particularly provider-assisted referral and social network-based approaches), tailored, client-centred messaging has become more frequently prioritized *(17)*. In some programmes questionnaires and other screening tools identifying risk factors, symptoms and indicator conditions are being introduced into pre-test information packages to improve targeting and increase programme efficiency *(18)*. The wide-scale use of digital technologies, such as videos, text messages, social media and websites, has introduced more ways to promote HTS and linkage to care, as well as to provide pre-test information and messages *(10, 19, 20)*. For example, a health-care worker may provide a group demonstration on how to self-test, encourage partner testing and refer to videos and social media for support, information and follow-up – all within one brief pre-test information session *(21)*.

Box 3.2 summarizes core pre-test communication activities, including developing an enabling environment, demand creation and pre-test information strategies and platforms.

Box 3.2. Pre-test service delivery package: core approaches and strategies for consideration

Enabling environment

- protecting confidentiality
- preventing social harm, stigma, discrimination and criminalization
- empowering communities
- ensuring appropriate age-of-consent policy.

Mobilization platforms for creating demand

- peer-delivered, participatory and community-led approaches, such as using peer educators, community groups and faith-based programmes
- digital tools based on HTS approach, setting and context, including social media, text messages, mhealth, ehealth mass media and other digital media including short videos.

Mobilization strategies for creating demand

- targeted promotions, advertisements and messaging related to a specific HTS attributes, such as unique setting or option, late-night or weekend hours
- educational programmes (for example, drama, sport-based and faith-centred);
- counselling strategies (for example, motivational messages)
- couples-oriented counselling and partner services (including provider-assisted referral and social network-based approaches).

Pre-test information and messages

- benefits of testing and of available prevention and treatment services
- explanation of issues and services for those on ART seeking further testing, as relevant
- opportunity to ask questions.

Screening (as relevant)

- risk-based screening (for example, providing for self-assessment of risk to prompt testing or, in low HIV burden settings, offering HTS to people who, when asked, report risk behaviour or concern about potential exposure)
- symptoms and co-infection screening (for example, for TB, STI, viral hepatitis)
- screening for indicator conditions (see Chapter 5).

3.2 Mobilizing demand for HIV testing services

Poor HTS uptake often results from a range of individual, structural and systemic barriers, including lack of awareness, fear of a positive test result, lack of confidentiality, fear of stigma, cost, laws and policies (such as age of consent for testing, criminalization of HIV and/or key populations), inconvenient services, long distances and difficult travel, and negative attitudes and practices of health workers *(22-26)*.

General knowledge and awareness of HTS varies across settings and populations. In many countries, even if the majority of people know where to get an HIV test, the proportion of adolescents, men and key populations who know is often much lower *(27)*. Few people may know where or how to obtain HIV testing outside of facilities, such as HIVST or community-based services *(28-30)*.

Efforts to increase HIV testing are needed among those at risk of acquiring an HIV infection and people with HIV who do not know their status. In addition to improving the accessibility, friendliness and quality of services, demand creation tools and interventions may be the only way to reach people who are uninformed about testing and the latest advances in treatment and prevention, those who are unable to access testing easily and those who may be hesitant to test because of fear of a positive HIV diagnosis.

3.2.1 Creating an enabling environment

Enabling people to make an informed and healthy choice to access HIV testing and engage in HIV treatment or prevention is a core public health function. Outside of the health sector, the implementation of laws and policies that support human rights and foster access to and uptake of services is crucial to public health impact. Examples of policies that may encourage the uptake of HTS are policies that protect patient consent and confidentiality, protections against mandatory or coercive testing, laws and policies that address stigma and discrimination against people with HIV and against key populations and that decriminalize drug use, sex work and same-sex relationships. For adolescents, age-of-consent policies are needed that enable them to test without parental consent *(31)*. Policies and laws are also needed to implement effective HTS approaches, including lay provider-delivered testing (such as, policies enabling task sharing), voluntary provider-assisted referral (such as, policies addressing medical secrecy) and access to self-testing (such as, policies addressing use of medical devices).

WHO advises that all HTS be implemented in accordance with the "5 Cs" – including patient consent and confidentiality, pre-test information and post-test counselling, correct results, and connection (linkage to care) *(15)*. WHO recommends that countries protect privacy in law and policy and put in place policy, laws and norms preventing discrimination and stigma toward people with HIV and key populations *(32)*.

Although these factors are not always the direct responsibility of the health sector, health-care providers and organizations delivering HTS should work with community organizations, key populations and other affected communities, government institutions, legal authorities and advocacy organizations to ensure that the environment supports and enables people to learn their HIV status (Fig. 3.1).

Fig. 3.1. Addressing critical enablers for HTS programmes

* Includes decriminalization and age of consent.

Source: WHO, 2016 *(4)*.

Key considerations include:

- **Ensuring consent.** Consent is giving verbal permission or agreement to test for HIV. Mandatory or coercive testing is never warranted. All individuals should have an opportunity to refuse testing, and policies should protect those who opt out of HIV testing. Testing should not be a condition for obtaining other benefits, and refusing testing should not be a reason for withholding other benefits *(15, 33, 34)*.
  - WHO recommends voluntary partner services to sexual and drug injecting partners, and voluntary disclosure where beneficial. Partner services, including provider-assisted referral, and disclosure, must be done only with consent of the person tested *(32, 34-36)*.
  - It is recommended that adolescents be provided sexual and reproductive health services, including HIV testing, family planning/contraceptive information and other services, without mandatory parental and guardian authorization or notification *(37)*. Countries also are encouraged to examine their age-of-consent laws and policies and consider revising and aligning them across sectors and policies to reduce age-related barriers to HIV services and to empower providers to act in the best interest of the adolescent *(36)*.
- **Protecting confidentiality.** Lack of confidentiality discourages people from testing for HIV *(22-26)*. Respect for confidentiality applies not only to a client's receipt of an HIV test and the test result, but also to any personal information, such as information concerning personal risk, sexual behaviour or the use of drugs, and the identity of sexual or drug-injecting partners. Health workers and others who provide HIV testing may need special training and sensitization regarding the confidentiality of medical records and how to keep registers, records and documents with identifying information safe, particularly where key populations are concerned. Programmes and facilities where HTS are delivered need site-level policies and standard operating procedures that protect clients' privacy and confidentiality.

- Providers should be sensitive to how and where they offer HTS, avoiding practices and situations that may lead to inadvertently revealing clients' personal information to others or that discourage individuals from asking for testing. Such harmful practices may include publicly asking personal questions about risk behaviour or symptoms and offering testing and pre-test information in facility waiting rooms, outpatient departments or other settings that are not private.

- **Preventing social harm, violence, stigma, discrimination and criminalization.** Fear of and acts of violence, stigma and discrimination against people with HIV and key populations deter people from HIV testing *(31)*. So, also, does criminalization of risk behaviours that might be implied by a request to be tested. Within a facility, all staff members have a role in providing a *safe, friendly and welcoming* environment. Health-care worker training can be effective for reducing stigma and discrimination at facilities. To prevent violence, training and educating law enforcement agents can be effective *(38, 39)*. It can be important to screen for IPV before HIV testing and as part of partner services and to refer for available services as needed in line with WHO guidance in this area *(15, 34, 35)*.

  - Efforts at a national level to reduce stigma and discrimination, such as promoting anti-discrimination and protective policies for all populations, can foster a supportive environment for HIV testing, particularly within the health-care and justice systems *(31)*. Policies are most effective when they simultaneously address individual, organizational and public policy factors that enable or allow stigma and discrimination *(40)*. Both within and outside the health sector, programmes need to institute anti-stigma and anti-discrimination policies and codes of conduct for personnel.

  - Laws and policies are important to protect the rights and safety of vulnerable groups, including key populations, adolescents, women, migrants and refugees. Specific strategies may include: (1) establishing or increasing awareness of mechanisms for reporting rights violations and pursuing disciplinary action; (2) conducting sensitization workshops for people with pivotal roles in the community (for example, government officials, police, media, health-care workers and religious leaders); (3) creating safe spaces such as drop-in centres and outreach programmes; (4) considerations relating to IPV; (5) creating early warning and rapid response mechanisms with the involvement of affected communities; and (6) provision of essential services, official documentation and recourse for those who experience social harm, violence, stigma, discrimination and abuse by authorities.

- **Empowering communities.** Empowerment is a critical enabler for improving access to HTS among vulnerable communities, including key populations. Many different actions can support community empowerment, such as meaningful participation of people from key populations in designing and delivering services, peer education activities, legal literacy and services programmes and fostering key population-led groups, programmes and service delivery.

Box 3.3. WHO recommendations and good practice statements for creating an enabling environment for HIV testing services

Consent and confidentiality

- Initiatives should be put in place to enforce privacy protection and to institute policy, laws and norms that prevent discrimination and promote tolerance and acceptance of people living with HIV. This can help create environments where disclosure of HIV status is easier *(strong recommendation, low quality of evidence)*.
- HIV testing must be voluntary. All people being tested should be made aware of their right to refuse testing, and they must give informed verbal consent to be tested. Mandatory or coercive HIV testing is never appropriate.
- Countries are encouraged to examine their age-of-consent policies and consider revising them to reduce age-related barriers to HIV services and to empower providers to act in the best interest of the adolescent.

Friendly services and enforcing anti-stigma, anti-discrimination and protective policies

- Services should be delivered in safe and acceptable spaces that offer protection from the effects of stigma and discrimination, where individuals and partners can freely express their concerns and where providers demonstrate patience, understanding, acceptance and knowledge about the choices and services available.
- Adolescent-friendly health services should be implemented in HIV services to ensure engagement and improved outcomes *(strong recommendation, low-quality evidence)*.

Violence prevention

- Women who disclose any form of violence by an intimate partner (or other family member) or sexual assault by any perpetrator should be offered immediate support. Health-care providers should, as a minimum, offer first-line support when women disclose violence. If health-care providers are unable to provide first-line support, they should ensure that someone else (within their health-care setting or another that is easily accessible) is immediately available to do so *(strong recommendation, in direct evidence)*.
- Health-care providers should ask about exposure to intimate partner violence when assessing conditions that may be caused or complicated by intimate partner violence, in order to improve diagnosis/identification and subsequent care *(strong recommendation, indirect evidence)*.
- Health and other support services should be provided to all people with HIV and to key and vulnerable populations. People experiencing sexual violence should have timely access to comprehensive services, including post-rape care, in accordance with WHO guidelines. Incidents of violence should be monitored and reported and should be addressed in partnership with affected communities, as well as in prisons and other closed settings.

Box 3.3. continued...

- Law enforcement officials and health- and social-care providers, including lay providers, need to be trained to recognize and uphold the human rights of people with HIV, key populations and other affected communities, and they need to be held accountable if they violate these rights.

Community empowerment

- Services should include a package of interventions to enhance community empowerment among people with HIV, key populations and other affected communities.
- Programmes should include legal literacy, training and services so that individuals know their rights and can seek support from the justice system when aggrieved.
- Training on human sexuality may facilitate greater understanding of sexually diverse communities, particularly those identifying as lesbian, gay, bi-sexual, transgender, questioning or intersex (LGBTQI), as well as adolescents and young people seeking accurate information on HIV prevention and contraceptives, including how to use them and where to get them.

Sources: WHO, 2013 *(38)*; WHO 2014 *(31)*; WHO, 2015 *(15)*; WHO, 2016 *(37)*; WHO, 2016 *(34)*; WHO, 2019 *(41)*; WHO, 2019 *(42)*.

3.2.2 Demand creation strategies and approaches

Demand creation and mobilization strategies include activities intended to directly improve an individual's knowledge, attitudes, motivations and intentions to test and to inform the decision to obtain HIV testing services. Such interventions may include: (1) targeted promotions, advertisements and messaging; (2) educational programmes; (3) brief motivational messages and counselling strategies; and (4 couples-oriented counselling and partner services. These strategies can be implemented using peer-based or community-led approaches as well as digital tools (such as videos or text messages (SMS), and other mhealth and ehealth mass media).

Demand creation and mobilization efforts should consider adopting the most effective approaches for reaching those most affected by HIV and with lowest testing uptake and knowledge of status, such as key populations, adolescents and young people, men, pregnant and postpartum women, clients with presumptive or diagnosed TB, partners of people with HIV, first-time testers and other affected and vulnerable groups. Strategies need to be tailored to suit the intended audience, considering such issues as who delivers demand creation messages (for example, health workers, peer mentors, partners, popular or respected celebrities or other public figures), media (for example, face-to-face, social media, theatre, radio, posters, SMS), format (for example, drama, celebrity role-modelling and endorsement, appeals to logic, practical information on location and hours of testing services), location and setting (for example, a friendly setting in a health facility, local bar or hangout), the best times to reach people, the length and frequency of efforts (for example, once a month for one hour, twice a day for one minute) and whether messages are integrated into broader health promotion or more narrowly promote specific testing services to specific populations.

Depending on the goals of the programme and the settings, general promotion and awareness efforts for HIV testing services may not be as necessary or as effective as those that focus on specific populations or settings. Promoting HIV testing in general through mass media, including radio, television, billboards and posters, the internet and electronic social media, can increase knowledge and awareness *(5)*. However, in the current era this more generalized approach may not have the impact on uptake of testing that focused efforts can have. Given the changing epidemiology of HIV, due to increased HTS and ART coverage, more focused mobilization strategies need to be prioritized – strategies designed to reach people with HIV who do not know their status and those at high ongoing risk.

Clear signage, posters, videos, websites, brochures and other materials in local language(s) are important to inform prospective clients about testing services and direct them to services. Such information is crucial wherever testing services are delivered, whether in health facilities, in the community, through mobile services or through outlets for self-testing kits. In settings where HIV testing is routinely offered, such as antenatal care (ANC), family planning/contraceptive services, sexually transmitted infection (STI) clinics and TB services, signs, posters and fliers, and group health education sessions can inform clients and their family members about why HIV testing is important and where and when testing is offered.

WHO conducted a systematic review to update existing operational guidance on effective demand creation approaches and counselling messages. In this guideline update, WHO issues a new good practice statement on demand creation and counselling messages to help countries and implementers prioritize evidence-based strategies. The following section summarizes the results of the systematic review and the WHO good practice statement (see also Annex A).

Review of the evidence on demand creation platforms and approaches

The systematic review included 86 randomly controlled trials (RCTs) on demand creation interventions for HTS. These studies were conducted in the Americas (n=39) (primarily in the United States of America (n=33)), Africa (n=33), Europe (n=7), Southeast Asia (n=2), Western Pacific (n=3); two were multi-country and regional. These RCTs were primarily among the general population and key populations. Six RCTs were among pregnant women and their partners, six were among adolescents and young people (ages 10–19 or 15–24), one was among children, and five were among other populations at high ongoing risk, such as those adults seeking STI services and those taking PrEP.

Table 3.1 describes and defines the demand creation intervention categories employed in these RCTs. Several RCTs reported outcomes related to multiple demand creation categories. Main outcomes are summarized in Box 3.4.

Section 3.3 discusses evidence and considerations on counselling messages and pre-test information. Chapter 4 presents information on linkage to care and post-test counselling messages.

Table 3.1. Definitions and descriptions of each demand creation intervention category

Demand creation category (number of studies reporting)	Intervention type	Definitions
1. Incentives (n=12)	Incentives to clients and incentives to providers	Interventions categorized as incentives included the provision of resources (financial or non-financial) based on HIV testing uptake. This could include transfers of resources to testers, health-care providers, parents or partners and couples either unconditionally or conditionally, including payments conditioned on HIV testing or performance-based incentives. The resource included financial incentives (range: US$ 1 to US$ 10) and non-financial incentives such as household goods/supplies.
2. Mobilization (n=7)	Activities aimed at increasing HIV uptake in specific communities	Interventions categorized as mobilization included a range of vehicles (theatre, sport, games, educational material, sermons, printed material) seeking to mobilize community members to take up HIV testing. Mobilization took place in a range of settings, including places of worship or other faith-based centres, other community settings and locations where people seek sexual partners.
3. Targeted and tailored (n=20)	Advertisement of a special attribute, personalized content, peer-led, and personal invitation	Tailored and targeted interventions are interventions that aim to overcome a specific barrier to HIV testing. This may include testing at an alternative venue, youth-friendly services, peer-led programmes and education addressing a specific concerns or barriers.
4. Counselling (information and messaging) (n=27)	Message framing, motivational, general counselling, couple-oriented counselling and reduced duration or intensity of counselling	Counselling interventions sought to understand how improvements in client counselling by HIV testing providers can improve uptake. Counselling interventions can include changes to message framing, implementation of motivational counselling, couples counselling and approaches to shorten counselling.
5. Digital platforms (n=28)	Video, audio, social media, websites and SMS	Interventions in this category used digital platforms (videos, Internet websites or social media, SMS, etc.) to improve HIV testing uptake. This could include interventions to use social media for peer support or targeted advertising, personalized web directories of HIV testing services and SMS reminders for HIV testing.

Platforms for delivering demand creation

Digital platforms and peer-led approaches for delivering an array of demand creation interventions, including information, messages and counselling, increased uptake of HIV testing. There was moderate quality evidence from a meta-analysis of two RCTs that peer-based interventions resulted in better HTS uptake compared with interventions without peers. However, because the quality of evidence was very low, it is uncertain whether the involvement of peers increased the proportion of people with HIV diagnosed.

A meta-analysis of three RCTs found that using digital platforms to deliver information and messages, either video-based or audio-based, probably increased HTS uptake compared with in-person or other text-based content. The quality of evidence was moderate.

Video counselling messages had the greatest effect on HTS uptake when compared with in-person counselling. A meta-analysis of three RCTs showed video counselling using pre-recorded messages resulted in a 10-fold increase in uptake. The quality of evidence

Box 3.4. Key findings from the systematic review – demand creation platforms and approaches

Platforms for delivering demand creation

- Peer-led interventions improve HTS uptake. The effect on the proportion of people diagnosed with HIV is uncertain.
- Digital platforms that use video-based information and counselling messages improve HTS uptake. Audio recorded messages have little or no effect on HTS uptake.

Demand creation approaches

- Advertising a unique HTS attribute (for example, availability in the workplace) can improve HTS uptake but may reduce the proportion of people diagnosed with HIV. The effects of promoting youth-friendly services are uncertain.
- Brief messaging and information (under 15 minutes) results in HTS uptake similar to longer or more intensive pre-test information but can be more feasible and efficient.
- Messages during couples counselling that encourage testing improve HTS uptake. The effect on the proportion of people diagnosed with HIV is uncertain.
- Messages related to risk reduction and economic empowerment improve HTS uptake, particularly for people who inject drugs.
- Motivational messages increase HTS uptake.
- Fixed financial and lottery-based incentives of varying value improve HTS uptake, particularly those conditional on linkage. The effect on the proportion of people diagnosed with HIV and linkage to prevention and care is uncertain. The issues of sustainability, equity and resource use need to be addressed and its benefits and risks carefully weighed when considering financial incentives for demand creation.

was moderate. However, effects were largely driven by one study. This study took place in a high-income setting and combined video-based messages with routine offer of HTS using rapid tests in a facility setting *(43)*.

Use of SMS or audio messages made little to no difference in HTS uptake when compared with alternatives, including content provided in in-person or other text-based content. The quality of evidence was moderate. However, audio messages may be relevant for specific populations such as those with lower literacy or key populations. For example, one RCT showed greater HTS uptake among previously incarcerated people on parole who received computer-based brief negotiation interviews (motivation-oriented messages) compared with in-person counselling or text-based content.

Outcomes related to linkage to prevention and care were not reported for peer-led approaches or digital platforms.

Demand creation interventions

A range of evidence-based demand creation interventions to increase HTS uptake were identified. The following summary highlights key evidence and approaches that may increase HTS uptake.

Mobilization in community settings. There was low-quality evidence from a meta-analysis of five RCTs that mobilization led by peers and communities may increase HTS uptake when compared with standard HTS without mobilization. There was also moderate-quality evidence from a meta-analysis of two RCTs that mobilization may increase the proportion of people with HIV diagnosed compared with standard HTS without mobilization. One RCT (44) suggested that mobilization could increase retesting. However, we are uncertain of this effect because of the quality of evidence was very low.

Advertising a unique HTS attribute.[1] There was low-quality evidence from a meta-analysis of two RCTs *(45, 46)* that advertising a unique attribute of a testing site or service that addresses specific barriers may increase HTS uptake. Promoting workplace HTS on site, compared with standard referral for offsite testing, was particularly effective *(45)*. However, the effect on uptake of advertising adolescent and youth-friendly HTS was uncertain because the quality of evidence was very low. Low-quality evidence from one RCT suggests that advertising a unique attribute of testing site *(46)*, such as testing in churches or bars, increased HTS uptake but resulted in a lower proportion of people diagnosed with HIV compared with standard testing.

Couples-oriented counselling. There was moderate-quality evidence from a meta-analysis of three RCTs *(47-49)* that couples-oriented counselling increased HTS uptake compared with standard HTS. However, the effect on the proportion of people with HIV diagnosed was uncertain because the quality of evidence was very low.

Personal invitation letters and referral cards. There is low-quality evidence, from a meta-analysis of two RCTs that sent invitation letters to participants *(50, 51)*, suggesting that personalized invitation letters as part of a broader intervention result in greater HTS uptake than generic invitations alone. It is uncertain whether invitation letters and referral cards alone increase uptake compared with standard HTS, as the quality of evidence is very low. One RCT *(52)* reported that personalized invitation letters led to a higher proportion of people with HIV diagnosed than generic invitation letters. However, because there were very few positive diagnoses overall, the quality of evidence is very low and this effect is uncertain.

Incentives of varying types and values. There is moderate-quality evidence from a meta-analysis of five RCTs that fixed financial incentives for clients increases HTS uptake compared with no incentives. Because the quality of evidence was very low, it is unclear whether fixed-value incentives may slightly increase the proportion of people with HIV diagnosed. Results varied among studies. There is low-quality evidence that lottery-based incentives may only slightly increase HTS uptake and that neither fixed-value or lottery-based incentives, with and without messages either framed as benefits of HTS or risks of HTS, may make no more difference to HTS uptake compared with standard HTS.

The effects of other types of incentives on HTS uptake or proportion of people with HIV diagnosed, including non-financial incentives, fixed-value incentives with and without messaging packages, as well as incentives to providers, is unclear because of very low-quality evidence *(53-57)*.

[1] Includes unique attributes of HTS such as special location, flexible hours and times, and design friendly to a specific population. See abbreviated definitions in Table 3.1 and full details in Annex A.

Overall, evidence on demand approaches that would increase linkage to onward care was very limited, and effects were uncertain because of very low-quality evidence. This continues to be a key area for further research related to demand creation. Forthcoming WHO guidelines on enhancing uptake of male circumcision may offer further insight.

Values and preferences

Fifteen RCTs reported additional values and preferences among potential beneficiaries of demand creation interventions, messaging and counselling *(51, 54, 57-69)*. Five RCTs reported that various demand creation interventions, including incentives, targeted advertisements and services, and digital platforms, alleviated fears related to accessing HTS and were perceived to be fun and accessible *(54, 58, 64, 66, 67)*. Many of the values and preferences addressed not only the demand creation portion but also other components of the tested interventions, such as HIV self-testing acceptability.

While not specifically related to demand creation interventions, there were some concerns about the potential for a negative reaction from a partner when interventions focused on couples and, in settings where there were concerns about lack of privacy, stigma and discrimination. Two RCTs reported quantitatively about social harm; neither found elevated risk of social harm *(50, 57)*. One RCT reported that, despite some initial participant concerns, personalized letters for partners were considered acceptable *(51)*.

Cost and resource use

Eight studies reported on costs related to demand creation interventions *(20, 43, 59, 64, 66, 68, 70-72)*. Costs varied greatly and spanned a wide range of time periods. Across three RCTs, from varying years, the cost per person tested (including cost of demand creation) ranged from US$ 20.73 to US$ 238.00, with a median cost per person tested US$ 40.00. In South Africa one RCT reported modest incremental costs per person reached by using SMS (US$ 2.41) *(64)*.

Two RCTs compared costs of different demand creation interventions. In an RCT in Malawi, the cost per person tested using standard HTS was US$ 9.95. Adding fixed-value incentives and phone call reminders increased cost per person tested by at least US$ 14.00 and as much as US$ 31.29 *(71, 72)*. In another RCT testing videos for demand creation among men who have sex with men in China, costs per person tested was high (US$ 238) when a professional company produced the video but was much less (US$ 31) with a video developed through crowd-sourcing (that is, when community members with implementers worked to develop the video) *(20)*. The cost per person tested reported was not too different from that reported by Kurth et al. (US$ 40) for video-based counselling in the USA *(43)*.

Cost per positive test varied greatly, with one RCT reporting US$ 799 per new HIV case identified among men who have sex with men in China *(20)* and another study, focused on emergency department patients in the USA, reporting US$ 10 000 *(43)*. This cost difference highlights that, while various demand creation interventions can be affordable and effective in many settings, they need to be appropriately focused on populations with the greatest risk and burden of undiagnosed HIV infection.

Feasibility

Many demand creation interventions identified are highly feasible and part of existing national guidelines, such as community mobilization and peer-led approaches, which have been used to scale up HTS programmes and achieve high coverage in many settings. While currently implemented in some settings, tailored and targeted approaches can be further scaled up and focused on those in greatest need of testing, prevention and treatment services, such as key populations and partners of people living with HIV. Such tailored approaches include couples-oriented counselling, personalized letters as part of partner services and promoting a unique HTS attribute.

Digital platforms, particularly videos, may be feasible in some settings. The utility of these tools will vary by context, population of interest and availability and coverage of digital interventions in various settings. Some innovative methods such as crowd-sourcing with community may increase feasibility by reducing costs. It is important to consider ways to adapt these tools for low- and middle-income settings, such as using social media or web-based platforms.

Mobilization is a feasible strategy to achieve high coverage, but it likely requires modification to suit the context and specific populations trying to be reached. Community and peer involvement may play a strong role in implementation and should be considered as a cross-cutting strategy for implementing demand creation interventions. Mobilization tends to be most useful when uptake of an intervention in a population is generally low and widespread awareness is needed. It may be less useful to current programmatic efforts to focus on high risk populations. Targeted and tailored information has potentially greater feasibility and acceptability for key populations. It, too, requires heavy contextual modification.

Incentives, particularly for clients, are potentially difficult to implement in low- and middle-income countries, and they are costly. While incentives may appear to have some benefit and to be popular with clients, feasibility may be limited in the long-term. Incentives, particularly financial incentives, also could undermine broader goals of universal health coverage and may influence short-term health behaviour, but not necessarily long-term outcomes. Political will to implement incentives for HIV testing particularly may be low, considering the need to support demand for a broad range of health services. There are currently no national guidelines in low- or middle-income countries that recommend incentives for HTS, although incentives are used in other programmatic settings and disease areas.

Equity and human rights

In light of the evidence reviewed, the GDG noted that demand creation interventions could increase equity when focused appropriately but could also exacerbate gaps. If incentives are used, it is important to consider and weigh the potential trade-offs between short-term gains and longer-term effects if they become associated with HTS, as well as the potential negative effect on equity when incentives focus on certain populations or diseases.

When planning, designing and implementing demand creation approaches, careful consideration and engagement with communities and populations in greatest need of HIV testing, prevention and treatment are needed.

Good practice statement

Considering the evidence reviewed and information on acceptability, feasibility, resource use and equity, the Guideline Development Group (GDG) came to a consensus and decided not to make a recommendation about demand creation interventions. This was largely because of evidence related to linkage to prevention and care was limited, as well as because the studies varied so much. Further, the number of people with HIV who do not know their status is declining, which makes focusing demand creation approaches highly contextual. The GDG instead crafted a good practice statement to highlight evidence-based demand creation approaches that could help countries and programmes prioritize limited resources and focus on high-impact methods (see Box 3.1).

Box 3.5. NEW WHO good practice statement

Demand creation to increase HTS uptake and engage those in greatest need of services is a valuable tool for mitigating stigma, discrimination and criminalization. Demand creation approaches may need to be prioritized, depending on the setting, focus population and available resources, as part of a strategy to reach people with HIV who do not know their status and who have high HIV-related risk. A wide range of demand creation strategies have been rigorously tested to assess impact on HIV testing uptake and the proportion of people with HIV diagnosed, but often later outcomes related to linkage to care or prevention have not been measured.

Evidence-based platforms for delivering demand creation include:

- peer-led demand creation interventions, including mobilization
- digital platforms, such as short pre-recorded videos encouraging testing.

Approaches that have showed evidence of increasing demand include:

- advertisement of specific HTS attributes
- brief key messages and counselling by providers (less than 15 minutes)
- messages during couples counselling that encourage testing
- messages related to risk reduction and economic empowerment, particularly for people who inject drugs
- motivational messages.

Evidence suggests that the following approaches may be less effective for demand creation:

- personal invitation letters
- individualized content messaging
- counselling focused on building relationship between the client and counsellor[a]
- general text messages, including SMS.

Some studies report increases in HTS uptake when incentives are offered, however when considering the use of incentives for demand creation, benefits and risks should be carefully weighed, such as:

- resource use and sustainability, especially for providing financial incentives, which may undermine the principles of universal health coverage
- longer-term behavioural changes associating HTS and other services with incentive, weighed against short-term increases in uptake
- negative effect on equity, due to prioritization of some populations and diseases
- potential to deprioritize systematic implementation of strategies that improve service delivery and reduce barriers and disincentives, such as patient costs associated with accessing health services more broadly.

[a] Often called "therapeutic alliance counselling", this focuses on the relationship between client and provider and on mutually agreed upon goals, assignment of tasks mutually perceived to be effective and relevant, and developing a bond between client and counsellor based on relationship and trust. See Annex A for details.

3.2.3 Implementation considerations for demand creation interventions

- Demand creation efforts need to focus on those in greatest need of HTS, including people with HIV who do not know their status and key populations and their partners at high ongoing risk. Consider the local context and culture and be sure to engage communities in designing and implementing demand creation approaches.
- Within a facility, all staff members have a role in providing a *safe, friendly and welcoming* environment. Without this, clients – especially those from key populations and at high ongoing risk – may remain reluctant to respond to demand creation interventions.
- As HTS and ART coverage increase, retesting among people at low risk is becoming more common. Demand creation efforts, particularly those involving mobilization, need to be sure to address this issue to ensure that they are promoting efficient and effective HTS and not substantially increasing the cost per person diagnosed with HIV.
- Couples-oriented counselling and simple invitation letters within broader interventions are beneficial, but they should be considered and implemented to support scale-up of partner services including provider-assisted referral and social network-based approaches, which WHO recommends as a high-impact approach.
- It is critical that demand creation efforts include informational and counselling messages explaining the benefits of early ART and the fact that people with HIV who achieve and maintain an undetectable viral load cannot transmit HIV sexually to their partners.
- Demand creation approaches for HIV testing are highly relevant for other disease areas, particularly TB, STIs, HBV and HCV and sexual and reproductive health more broadly. Opportunities to leverage evidence-based approaches for other disease areas, as well as to promote further integration, should be considered.
- Digital platforms and interventions are promising and should be considered where feasible and helpful, such as video-based messages and counselling in high-volume clinics where HTS coverage is sub-optimal, and among populations who may be more likely to find them appealing, such as adolescents, young people and key populations. In low- and middle-income countries, social media and web-based approaches may be important for introducing, scaling up and focusing demand creation efforts. This is an important area for operational research.
- Close attention and monitoring are needed to ensure that demand creation is increasing programme efficiency and effectiveness by reaching people at high ongoing risk and those with HIV who do not know their status. Adjustments should be made routinely to optimize implementation and achieve programme goals.

3.3 Pre-test information and messaging

Before the introduction of rapid testing and same-day delivery of test results, pre-test counselling was routine *(7)*. Pre-test messages focused on encouraging clients to return for their test results, providing risk-reduction counselling and preparing clients to cope with a potential HIV-positive diagnosis in the absence of treatment. With the current wide availability of highly effective prevention and treatment options, however, pre-test counselling is no longer needed and may create barriers to service delivery *(7, 8, 15, 73)*. Individualized pre-test counselling is no longer recommended *(15)*.

WHO recommends providing concise pre-test information to people testing for HIV. This communication should provide general information, answer clients' questions and offer an opportunity to refuse testing. Lengthy and intensive pre-test information or counselling generally does not change risk behaviours or increase HIV knowledge, and it may deter testing among some populations, particularly those that need frequent retesting *(10, 11)*. See chapters 5 and 7 for more information on service delivery approaches.

Depending on local conditions and resources, programmes may provide pre-test information through individual or group information sessions and through media such as posters, brochures, websites and short video clips shown in waiting rooms. When children and adolescents are receiving HTS, information should be presented in an age-appropriate way to ensure comprehension. Care should be taken to protect client confidentiality during pre-test information sessions, particularly when using screening tools to evaluate risk and when discussing IPV, disclosure of test results, risk behaviours and other personal information.

In some situations, individuals who receive HIV testing may not need pre-test information as they have received this information, sometimes several times, when previous tested. For example, individuals who have tested before or who retest frequently (for example, key populations and people taking PrEP who receive quarterly testing). In these situations, priority should be given to ensuring informed consent and giving the client the opportunity to ask question or raise concerns.

When pre-test information is needed by clients (individually or in a group), concise informational messages may include the following:

- the benefits of HIV testing and implications of undiagnosed HIV;
- the meaning of an HIV-positive diagnosis and of an HIV-negative diagnosis;
- benefits of early ART and the fact that people with HIV who achieve and maintain an undetectable viral load cannot transmit HIV sexually to their partners;
- the importance of telling the provider if one was previously diagnosed with HIV;
- the potential for incorrect results if a person already on ART is tested and the services available if those taking ART want further testing;
- the services available to those who test HIV-positive, including where ART is provided;
- the importance of disclosure and encouragement for partner testing;
- prevention options, including risk and harm-reduction information, that are relevant and available, focused on those at high ongoing risk;
- the confidentiality of the test result and any information shared by the client;
- the client's right to refuse testing and that declining testing will not affect the client's access to HIV-related services or general medical care;
- potential risks of testing to the client in settings where there are legal implications for those who test positive and/or for those whose sexual or other behaviour is stigmatized;
- the opportunity to ask the provider questions.

Review of the evidence for pre-test information and messaging

Of the 86 RCTs included in this review, 27 focused on information and counselling messages: 12 on general counselling messages prior to HTS *(65, 66, 74-82)*, six on message and content framing prior to HTS *(62, 64, 83-85)*, three on motivational counselling messages prior to HTS *(86-88)* and four on reduced duration or less intensive counselling prior to HTS *(63, 89-91)*. An additional seven RCTs focusing on personalized content and messages were also identified *(59, 61, 63, 70, 92-94)*. The majority took place in the Americas (n=22), primarily in the USA, with much fewer in Africa (n=3), Europe (n=5) and Asia (n=2). Most RCTs were conducted among the general population (n=12) or key populations (n=10), with fewer among other high-risk populations (n=4), pregnant women (n=2) and adolescents (n=4).

Main outcomes related to counselling messages and information are summarized in Box 3.6. Section 3.2.2 summarizes evidence on platforms for delivering demand creation and specific demand creation approaches such as couples-oriented counselling. Details appear in Annex A.

Box 3.6. Key findings from the systematic review – demand creation, including counselling, information and messages

Overall, 27 RCTs included in the systematic review showed the following about pre-test information and counselling messages:

- **With concise information and counselling (less than 15 minutes), HTS uptake is similar to that with longer and more intensive information and counselling sessions.**
- **General counselling with HIV-specific information may increase HTS uptake, while counselling which primarily emphasizes the relationship between client and provider may reduce HTS uptake**, particularly among key populations and those at high ongoing risk.
- **Motivational messages and counselling increase HTS uptake**, particularly among people with high ongoing risk. However, effects on the proportion diagnosed with HIV are unclear.
- **Sexual risk-reduction interventions that include the offer of HTS may increase HTS uptake.**
- **Personalized messages and content do not affect HTS uptake.**
- Effects of other counselling messages including content on benefits of ART, benefit-oriented messages, risk-related messages, behaviour insights or priming messages that orient or prepare clients for HTS are uncertain.

The systematic review identified evidence-based approaches for delivering information and counselling messages. The following summary highlights key evidence and approaches.

Concise pre-test information and counselling. There is moderate-quality evidence from a meta-analysis of three RCTs *(63, 89, 90)* that shorter counselling has as much effect on HTS uptake as longer counselling. There were no differences between shorter

intervals (such as 2–5 minute versus 30-second counselling *(63)*); multiple sessions and lengths (such as four sessions at of 23 minutes each versus two sessions of 15 minutes each *(89)*); and longer intervals (such as 60-minute versus 34-minute counselling *(91)*).

Overall, evidence on pre-test information and counselling messages that would increase the proportion of people with HIV diagnosed and of those linked to onward care was very limited, and effects were uncertain because of very low-quality evidence.

General counselling with HIV-specific information. There is low-quality evidence from a meta-analysis of five RCTs *(65, 74, 77, 79, 81)* that HIV-specific information and counselling messages prior to testing may slightly increase HTS uptake compared with HTS without specific information and counselling messages. Key populations may particularly benefit from these messages. All three RCTs favouring specific counselling messages over standard HTS were conducted among key populations. Two were among people who inject drugs and one, among men who have sex with men *(74, 79, 81)*; two of these studies used digital platforms, either text messaging (SMS) or videos *(79, 81)*. In contrast, one RCT among adolescents *(76)* found that HIV-specific messages did not influence HTS uptake, but the quality of evidence was very low, and so effects were uncertain.

One RCT comparing group and individual counselling messages found that group counselling increased HTS uptake *(78)*. However, the quality of evidence was very low, and so effects were uncertain.

There is low-quality evidence from one RCT that text messages (SMS), with either motivational or informational messages, generally do not increase HTS uptake when compared with HTS without SMS *(64)*. Ten informational messages via SMS, however, may slightly increase HTS *(64)*.

Motivational and counselling messages. There is moderate-quality evidence from a meta-analysis of three RCTs *(86-88)* that motivational messages and counselling increase HTS uptake over standard HTS without these messages. The difference was seen in three RCTs among people with HIV-related risk, including two RCTs among STI patients and one among people taking post-exposure prophylaxis (PEP). However, the effect on the proportion diagnosed with HIV is unclear, as the quality of evidence was very low.

Risk-reduction information and counselling. There is low-quality evidence from one RCT *(75)* that risk reduction information and counselling prior to HTS may increase uptake of testing among people who inject drugs over uptake achieved with standard HTS without these messages. However, because of the very low quality of the evidence, it is unclear whether risk reduction information and counselling increases the proportion of people diagnosed with HIV.

Sexual risk-reduction interventions. There is low-quality evidence from one RCT that implementing multi-session sexual risk-reduction interventions that offer HTS may increase uptake of testing compared with existing HTS *(95)*. However, there did not appear to be an effect on the proportion of people diagnosed with HIV, as none of those receiving HTS following the intervention had an HIV-positive test result. This effect is uncertain because the quality of evidence is very low.

Other types of messaging and counselling

Therapeutic alliance counselling.[2] There was low quality evidence from one RCT *(74)* that this approach to counselling may slightly reduce HTS uptake compared with standard HTS. When compared with providing HIV-specific information, therapeutic alliance counselling was reported to result in lower HTS uptake.

Benefits of HIV treatment and reduced transmission when on ART and virally suppressed. There is weak evidence from one RCT *(83)* that messages about the benefits of HIV treatment and reduced transmission when virally suppressed increased HTS uptake by 60% compared with standard messages that do not discuss benefits of ART or viral suppression. This effect is uncertain because the quality of evidence is very low.

Additional content framing. The effect of framing counselling messages, wither with benefits of HTS, risk-related messages, behaviour insights or priming messages on HTS uptake is uncertain because the quality of evidence is very low.

Values and preferences for pre-test information and counselling messages

Fifteen RCTs reported values and preferences of messaging and counselling individuals among providers *(51, 54, 57-69)*. In one RCT *(66)* counselling with HIV information and economic empowerment increased people's confidence and self-efficacy and their comfort discussing HIV prevention. An RCT that delivered brief information prior to self-testing or self-sampling reported a high level of satisfaction with testing *(63)*. Digital platforms providing counselling, information and messaging were also acceptable for preparing to self-test and to decrease risk behaviours *(68)*. Videos, in particular, were acceptable to men who have sex with men *(68)*.

There were no reports of social harm related to several types of information and counselling messages identified and included in this review. Counselling is considered to be acceptable and safe.

Cost and resource use

One RCT *(66)* demonstrated low costs of training per beneficiary reached in a low-resource setting through an HIV educational information and economic empowerment trial. As noted above, digital platforms, particularly video-based information and messages, can be affordable. According to one RCT, the cost per person tested using video-based counselling in the USA was US$ 40 *(43)*. However, the total programme costs were high. Strategies would need to be adapted for implementation in low- and middle-income countries.

Feasibility of implementing pre-test information

While costs for delivering information and counselling messages have been acceptable historically, adapting and updating content to incorporate the latest information and practices, as well as conducting refresher training, may be costly. Retraining large groups of health-care workers to either modify messages or shorten counselling may be challenging.

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[2] Therapeutic alliance counselling focuses on the relationship between client and provider and on mutually agreed upon goals, assignment of tasks mutually perceived to be effective and relevant, and developing a bond between client and counsellor based on relationship and trust. See Annex A for details.

While WHO previously advised countries to implement brief pre-test information, in many settings lengthy or more intensive pre-test counselling is still the standard.

Reducing length and intensity may make HTS implementation more feasible in many settings, including where managers have been hesitant to introduce HTS because of the increased burden on the health system and health workers.

Equity and human rights

Considering the evidence reviewed, the GDG noted that pre-test information and counselling messages could be used to provide the latest information about the benefits of HIV treatment, prevention and care services. HTS presents an important opportunity to address important health and personal concerns, as well as other disease areas such as TB, STIs, HCV and HBV. If concise messages were to leave out information on consent and confidentiality, however, there could be harm, such as mandatory or coercive testing.

Good practice statement

Considering the evidence reviewed, as well as values and preferences, feasibility, resources and equity, the GDG came to a consensus and decided not to make a recommendation on counselling. This was largely because evidence on linkage to prevention and care was limited, there was great variation among the studies, and the quality of the evidence was low. The GDG instead crafted a good practice statement that highlight evidence-based information and counselling messages that could help countries and programmes update their messages and deliver information and counselling in an evidence-based manner. These are grouped with broader demand creation efforts in the good practice statement presented in Box 3.1.

3.3.1 Implementation considerations for pre-test information and counselling messages

- Programmes may need to review their national and site-level HIV-specific information and counselling messages to incorporate latest evidence and good practices. Engaging communities, including key populations and those at high ongoing risk, is important for updating and revising messages.
- It is critical that informational and counselling messages explain the benefits of early ART and the fact that people with HIV who achieve and maintain an undetectable viral load cannot transmit HIV sexually to their partners. Adapting this information for different cultures and contexts is critical, to ensure people understand messaging and can also correctly communicate and explain to others in their community.
- Retraining health-care workers and testing providers is essential. This may take time and needs to be conducted in a phased approach. Programmes will need to plan and consider how they can retrain testing providers, as well as trainers; options might include integrating training with other updates and activities such as introduction of new testing algorithms and strategies or new service delivery approaches. Supportive supervision should also include questions and routine monitoring on pre-test information and counselling to ensure that practices align with the latest evidence and good practices.

- All training materials should address applicable laws and regulations regarding age of consent for HIV testing and situations in which minors may consent for themselves. All staff members involved in delivering HTS should be aware of their country's laws and regulations and be able to discuss them with young clients and parents. Programmes delivering services, including pre-test information and counselling, to adolescents should consider the global standards for adolescent care; see https://www.who.int/maternal_child_adolescent/documents/global-standards-adolescent-care/en/.
- Options are important. There may be various approaches for delivering information and counselling messages. While videos and digital tools may be effective in some settings, people should be able to obtain in-person counselling when desired.
- HIV-specific information, education and messages are particularly relevant for people at high risk and key populations, including people presenting for STI testing and treatment, and as part of a broader package of services for prevention and care, such as harm reduction services and substance use programmes.
- Integrated messages can be effective and increase uptake of testing and onward care for HIV, HBV, HCV, TB and syphilis. Integrated messages should be prioritized for key populations and their partners and for pregnant women.
- Concise information and counselling messages are advised, but this recommendation does not mean that programmes can stop adhering to the "5Cs", screening for risk of intimate partner violence, addressing clients' needs and answering clients' questions.

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ESSENTIAL POST-TEST SERVICE PACKAGE: COUNSELLING MESSAGES AND LINKAGE TO PREVENTION, TREATMENT AND OTHER SERVICES

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KEY POINTS

- Diagnosing individuals with HIV and facilitating their engagement in care and early ART initiation is the **professional and ethical responsibility of testers and a primary goal of all testing services.**
- The **core package of post-test services** needs to include concise messages and effective supportive interventions, approaches and tools to facilitate rapid ART initiation and additional linkages to HIV prevention, care, support and other relevant services.
- Post-test counselling messages need to be **tailored to specific populations** and their situations and whether their test results are HIV-positive, negative or inconclusive or they already know their status and need to engage or re-engage in care.
- Concise post-test counselling needs to be implemented as **part of a deliberate strategy to support linkage**. Post-test counselling alone does not improve linkage or lead to sustained behaviour change.
- All people with an HIV-positive diagnosis should be offered a **package of support interventions** that ensure timely linkage to care. **WHO recommends co-located and well-coordinated ART services and peer support to facilitate linkage**. Several other approaches could be considered in settings where co-locating services is not possible and, depending on the setting, for specific populations whose linkage rates are low (for example, men, young people, people who inject drugs).
- Many people who are **HIV-negative do not need post-test counselling**. Lengthy and intensive post-test counselling for people testing negative may even deter future testing among those with ongoing risk, and it is likely to be an inefficient use of time and resources. To optimize impact and cost-effectiveness, **among those who test HIV–negative, testing services should focus on reaching those at continuing risk.**

4. ESSENTIAL POST-TEST SERVICE PACKAGE: COUNSELLING MESSAGES AND LINKAGE TO PREVENTION, TREATMENT AND OTHER SERVICES

4.1 Introduction

HIV testing services (HTS) are not complete without effective linkage to appropriate HIV prevention, treatment and care services. Diagnosing individuals with HIV and facilitating their engagement in care and antiretroviral therapy (ART) initiation as early as possible is the professional and ethical responsibility of providers and testers and a primary goal of all testing services *(1, 2)*. For those testing HIV-negative, there are increasing opportunities to link to new, effective prevention interventions. These include male and female condoms and lubricants, testing and treatment for sexually transmitted infections (STIs), voluntary male medical circumcision (VMMC) for men in sub-Saharan Africa, harm reduction for people who inject drugs and pre-exposure prophylaxis (PrEP) for those at substantial risk of HIV acquisition *(1)*.

Thus, post-test counselling and other services that lead people to appropriate care are an essential component of HTS and should be implemented as an essential part of an explicit linkage strategy. The core package of post-test services needs to include:

- clear and concise **counselling messages**
- **referral and offer of rapid ART initiation**
- **additional linkages** to HIV prevention, care, support and other relevant services

This chapter briefly describes the evolution of HIV testing, prevention and treatment services, the need for post-test counselling messages that align with the latest developments in services, and the primary role of HTS providers in facilitating linkage to HIV prevention, treatment and care. There follows a summary of the latest WHO guidance on post-test counselling messages and evidence-based approaches to support timely linkage to treatment, prevention, care, support and other relevant services.

4.2 Overview and evolution of HIV services

Following the development of the first HIV antibody tests in 1985, ways of offering and providing HTS have continuously evolved *(3, 4)*. Early in the HIV epidemic, due to the lack of treatment options and limited knowledge and information about HIV, post-test services focused on psychosocial support and education, emphasizing prevention and encouraging behaviour change that would reduce risk of HIV transmission *(3)*.

Following the introduction and scale-up of ART, HTS implementation changed. The first rapid HIV tests, which generally provide same-day diagnosis, were developed in the early 1990s. After the introduction of rapid testing, HTS became widely available and was integrated into facility-based health services such as antenatal care (ANC) *(6, 7)*. As of 2014 WHO no longer recommended routinely offering pre-test counselling and instead promoted brief pre-test information *(1, 5)*.

Early global and national ART guidelines did not advise all people with HIV to start treatment immediately. Instead, they recommended that people with HIV receive clinical assessment, including CD4 testing, to determine who should start ART and who should be referred to pre-ART services, which included care, counselling and monitoring every six months to monitor when people became eligible for ART *(8)*.

During the course of the epidemic, new, effective HIV prevention interventions became available. These included male circumcision *(9)*, harm reduction for people who inject drugs *(10, 11)*, early ART for pregnant and breastfeeding women to prevent mother-to-child transmission of HIV *(12)* and early ART initiation and pre-exposure prophylaxis (PrEP) for serodiscordant couples and others at substantial risk *(12-17)*. This expansion of prevention options encouraged integration of HIV treatment and prevention services and improved access through decentralization and ART delivered in the community *(18, 19)*. Post-test counselling messages now emphasized referral and linkage to HIV treatment and care and prevention options *(1, 8, 19)*.

In late 2015 WHO recommended that all people with HIV should be offered ART immediately after diagnosis, a strategy dubbed "treat all" (2, 20). Treating all has dual benefits – clinical benefits for those taking ART and a prevention benefit for their partners due to the suppression of the ART user's viral load. In the same period, WHO recommended the use of anti-retroviral drugs for prevention (PrEP) as an additional option for people at substantial risk of HIV infection (2).

These developments led to major shifts in how HTS were delivered. With new HIV treatment and prevention options that offer direct benefits to those who test and their partners, there was more motivation for the provider to offer HIV testing and for the client to choose to be tested. WHO recommended new approaches to delivering HTS to better reach all people with HIV. These included community-based testing, HIV self-testing (HIVST) and provider-assisted referral (often called assisted partner notification), or index testing, which can include testing of partners and biological children of mothers with HIV *(1, 2, 8, 21)*.

Post-test messages need to evolve, too, in light of these developments in testing, treatment and prevention and to be **tailored to people's test result and situations**. Post-test messages for people with HIV now need to include information on the health and prevention benefits of immediate treatment, fewer ART side-effects, ART adherence plans and follow-up visits, as well as provider-assisted referral, family planning/contraceptive services and comprehensive prevention and support *(1, 2, 20-23)*. A literature review on post-test counselling messages showed that condom use, sexual behaviour and linkage to care are often discussed, but these messages are rarely tailored to clients' results and needs. The information that people with HIV who are taking ART and are virally suppressed cannot transmit HIV to their partners is not sufficiently addressed *(24)* (see section 4.3.1).

There are people with HIV who were diagnosed prior to the "treat all" era and who, according to guidance at the time, were not considered eligible for ART. There are also people with HIV who know their status but are not currently engaged in care because they felt "not ready" to start treatment immediately or they discontinued ART. These groups need specific and appropriate post-test messages; they need to be made aware of the benefits of HIV prevention and treatment to encourage them to retest to initiate or reinitiate ART.

Many people who are HIV-negative will not need to be linked to specific additional prevention services. Only those at ongoing risk need education, information and encouragement to take up comprehensive HIV prevention services (see section 4.3.2).

Pathways to care also have evolved, requiring new post-test counselling messages and optimized support tools and mechanisms. Many people are now being tested and diagnosed in the community, through partner services or by self-testing, and then linked to further testing and ART in facility settings *(21, 25-28)*. Also, growing number of people with HIV are initiating or being retained in care outside of clinical settings, which requires peer- and community-delivered support and other tools to help keep them engaged *(18, 28, 29)*.

People with a reactive self-test or test-for-triage result, in particular, will need information and post-test counselling messages that facilitate linkage to further testing to confirm reactive (positive) test results. Informational materials and support tools, such as instructions for use, hotlines, videos, social media, short text messages and peer support and peer navigation can be considered, based on the context and population *(30)*. Chapters 3 and 5 discuss demand creation and service delivery considerations, including for HIVST and test-for-triage.

Because of this evolution in HIV service delivery, linkage to HIV treatment, prevention, care, support and other relevant services is now the primary responsibility of the testers and counsellors delivering HTS. Greater efforts are needed to support HTS sites and their providers to deliver an effective package of post-test services that lead to rapid ART initiation as well as linkage to and engagement in HIV prevention, care, support and other relevant services.

Linkage to HIV treatment, prevention, care, support and other relevant services is now the primary responsibility of HTS and the testers and counsellors delivering HTS services.

4.3 Post-test key messages and information

The messages and information included in post-test counselling and their intensity need to be tailored according to the test result. For those with negative results, this will further depend on whether they face ongoing HIV risk. Messages should always be **clear and concise** and **client-centred** to address clients' needs and situations. However, in many settings this does not happen in practice.

The information and messages provided in post-test counselling should be **acceptable** to the client and delivered in a **safe, confidential** and **non-judgemental** manner.

Post-test counselling **can be provided in many ways**, such as one-on-one or with couples and partners and in both facilities and community settings. **New digital platforms**, including computer-based, online and mobile phone-based applications, videos and social media can provide virtual support, especially for self-testing. Health workers, professional counsellors, social workers and trained lay providers can provide counselling.

In any post-test counselling, messages in these key areas need to be clearly communicated **to all people tested for HIV**:

- that their HIV status and any other personal information that clients may share is **confidential** and will not be disclosed without their permission or consent;
- the **meaning of the test result**;
- that the **results can be trusted**, provided the diagnosis is based on the full national testing algorithm;
- **available HIV prevention, treatment, care, support and other relevant services and their benefits,** depending on HIV status and ongoing HIV risk;
- whether **retesting** is needed or not, based on context, population and individual behavioural risks;
- the benefits of **disclosure, partner testing and**, for key populations, **social network-based testing approaches** and any potential **risks**, including social harms and legal implications;
- **opportunities to ask** the provider additional questions.

Sections 4.3.1 through 4.3.6 highlight key considerations for counselling messages according to test result and population group.

Post-test counselling provides a pathway to a range of essential services for people who undertake HIV testing. It should not be expected to lead to sustained behaviour change on its own, however *(31, 32)*. General post-test counselling should be concise. At the same time, more intensive post-test counselling can be beneficial for certain populations and individuals – for example, in the context of couples counselling *(33, 34)*, harm reduction and interventions addressing alcohol and substance use *(24, 31, 35)* and for individuals who need more support in accepting their diagnosis.

4.3.1 Special considerations for people with an HIV-positive status

An HIV-positive diagnosis can be a life-changing event. When giving HIV-positive test results, the health worker, trained lay provider or counsellor should keep in mind the WHO **5 Cs**, particularly **Correct** test results and **Connection** to further services *(1)* (see Chapter 1). An important responsibility of the provider is to ensure that an HIV-positive diagnosis is based on the national testing algorithm and that people with HIV are given correct information and support for linkage to care.

Important functions of post-test counselling and messages are to effectively provide information, implement provider-assisted referral (in which providers contact the client's sexual and drug-injecting partners to offer them HTS) and facilitate linkage to care and ART initiation as soon as possible *(1, 20, 21)*.

When dealing with an HIV-positive diagnosis, counsellors need to give clients time to consider the results and help them cope with their diagnosis. People with HIV who are trained in counselling may be particularly understanding of the needs and concerns of people newly diagnosed with HIV *(1)*.

In addition to communicating general post-test counselling messages, post-test counselling for people with an HIV-positive diagnosis should include the following, as relevant:

- Communicate clearly:
  - **the meaning of the HIV-positive diagnosis** – that HIV is a chronic, manageable condition requiring lifelong treatment, but with treatment most people will live healthy lives and will usually live as long as people who do not have HIV;
  - the **benefits of immediate ART initiation**, and that, if they remain **adherent** to treatment and become virally suppressed, they will not transmit HIV to their partner(s); also, that ART is **safe and side-effects are minimal**;
  - for **women with HIV**, as relevant, information on safe conception, ART use during pregnancy to prevent mother-to-child transmission, and breastfeeding.
- Recognize that **some people will need time to adjust to their positive status** and may need further support for starting ART and choosing when and how to link to services.
- When clients are ready, **plan for starting ART**, including making an **adherence plan** and considering options for future differentiated care, as desired, including **where and how to access services**, particularly those that are free, and offering additional support appropriate to the client.
- As needed, **discuss any barriers to linkage to ART**, **address concerns about ART side-effects** and **arrange for follow-up** of clients who are unable to enrol in HIV care on the day of diagnosis.
- Arrange for **active ART referral**. (An active referral is one in which the tester makes an appointment for the client or accompanies the client to an appointment, including an appointment for co-located services, and enrolment into HIV clinical care.)
- Assess **mental health issues**, discuss **immediate concerns** and help the client think who might provide emotional support, and refer to services as needed.
- **Encourage the client to seek follow-up** counselling and mental health and other support services as needed.
- Provide education on **ways to prevent HIV transmission** and offer male and female condoms, lubricant and guidance on their use, but emphasize that, once a person is on ART and virally suppressed, HIV cannot be transmitted to sexual partners.
- **Provide additional referrals for prevention, counselling, support and other services** as appropriate (for example, tuberculosis (TB) screening and treatment, prophylaxis for opportunistic infections, STI screening and treatment, contraception, ANC, opioid substitution therapy and access to sterile needles and syringes).
- **Invite questions** throughout and provide time for the client to ask them.

Disclosure. Counselling should discuss the **benefits and risks of disclosing HIV-positive status to partner(s)** and support individuals and couples with disclosure. For couples, mutual disclosure has many benefits. People with HIV who can share their results with a trusted partner will often find it easier to cope with their diagnosis and to adhere to ART. It is important that providers discuss, as part of post-test counselling, options for **partner services** and encourage them to use **provider-assisted referral** to inform their sexual and drug-injecting partner(s) about their potential exposure to HIV and offer them voluntary HTS. Where it is supported, **social network-based HIV testing approaches** among key population clients may be suitable. (Section 4.3.6 discusses special considerations for disclosure.)

Disclosure and the potential for violence. Planning for disclosure should include steps to maximize clients' physical safety. Counselling for women who are considering voluntary or mutual disclosure of HIV-positive status should include discussion about the challenges of their situation, the potential risk of violence and ways to disclose more safely. Options when women fear violence or are experiencing violence include mediated or delayed disclosure or, where there is risk of severe violence, advice not to disclose *(36)*.

WHO recommends that all women with signs or symptoms of violence should be screened for intimate partner violence. These women and women who volunteer that they have experienced violence should be referred to violence response services, where available. At a minimum, they should be offered first-line support (an adaptation of psychological first aid), treatment for any presenting health conditions and referral to additional services as needed *(36)*.

Because post-test messages amount to a lot of information at the time of diagnosis, some issues and information can be addressed and re-emphasized at subsequent visits. For example, provider-assisted referral and advice on safe conception may be offered at a later visit or periodically after ART is initiated.

Section 4.3.6 addresses communication about retesting for people with HIV. Section 4.4 covers effective ways to facilitate linkage.

4.3.2 Special considerations for people with HIV-negative status

In many settings people with an HIV-negative diagnosis – for example, in ANC testing in low HIV burden settings – receive only their test result, with no post-test counselling. For those who test negative but face ongoing risk, lengthy post-test counselling may deter subsequent testing. For those who are HIV-negative, counsellors can optimize their time and efficiency by focusing concisely on supporting linkage to prevention services. However, some additional information about the test results is important for people with an HIV-negative diagnosis who had a false reactive or discrepant result at any point during the testing process (see section 4.3.4).

In addition to general post-test counselling messages, brief counselling for those testing negative can include the following information:

- the **explanation that the HIV-negative test result** means that they do not have HIV;
- a reminder of the importance of telling the provider if one was previously diagnosed HIV-positive and is **now taking ART**, as this may affect test results, messaging and follow-up services needed;
- the importance of knowing the **HIV status of sexual partner(s)** and the availability of partner testing and other relevant services. Where they are supported, **social network-based HIV testing approaches** may be appropriate among clients from key populations;
- information, followed by referral when appropriate, on available and effective **HIV prevention options**, including condoms and lubricants; STI testing and treatment; VMMC; PrEP; harm reduction for people who inject drugs; other sexual and reproductive health services, including contraception/family planning and prevention of mother-to-child transmission (PMTCT); advice on **retesting**, if needed, based on the client's level of recent exposure and/or ongoing risk of exposure; and correction of the common misconception that retesting is necessary every three months due to the window period (see Chapters 6 and 7 for details);
- opportunities for the client to **ask questions** and request counselling as needed.

Based on the information shared by the client, including whether the person has had a recent potential high-risk exposure, providers delivering services will need to determine the appropriate messages on retesting. Section 4.3.5 provides more information on retesting for people who are HIV-negative.

4.3.3 Special considerations for people with a reactive test for triage or self-test result

No single HIV test can provide an HIV-positive diagnosis. In many settings people are tested for HIV by a lay provider using a single rapid test (that is, test for triage) or are testing themselves using an HIVST kit. When such a test result is negative, the person testing is considered to be HIV-negative. When such a test result is reactive (positive), the person needs further testing, beginning with the first test (A1) in the national testing algorithm (see Chapter 8 for further discussion).

Providers distributing HIVST kits or following up with self-testers need to refer clients who disclose that they had a reactive self-test result to a facility where they can receive further testing, as well as ART or prevention services as needed (an HIV testing site, ART clinic, laboratory or site serving a key population). These providers should encourage clients with a reactive test to go as soon as possible to such a facility for additional testing and diagnosis. Community outreach using a test for triage or supporting self-testing must make every effort to prevent loss to follow-up along the care cascade, from further testing through to diagnosis and linkage to ART, HIV prevention and other health services. They must also make sure that clients understand that a single reactive test always needs confirmation, and it is not always mean an HIV positive diagnosis.

4.3.4 Special considerations for people with inconclusive HIV status

An HIV-inconclusive test status means that individuals had discrepant results on the test (for example, first test reactive, second test nonreactive, third test reactive) and so could not be given an HIV-positive or HIV-negative diagnosis. Inconclusive results are rare, but they may occur when (1) cross-reactivity exists between kits or patient-related factors, (2) the tester or test kit makes an error; and/or (3) individuals are seroconverting and in the window period, when infection cannot be determined. The window period is the time from exposure to HIV infection to when the body produces enough HIV antibodies to be detected by an HIV antibody test. This time can vary across different types of tests, where some tests may be able to detect antibodies earlier than another test, which can lead to discrepant test results. All people with an inconclusive HIV status should be encouraged to **return in 14 days for retestin**g.

Receiving inconclusive results could be confusing and stressful for clients and may be difficult for the provider to explain. Post-test counselling needs to take time to explain carefully what an HIV-inconclusive status means, stating that it is neither HIV-positive nor HIV-negative, and that retesting in 14 days is needed to establish the correct diagnosis. Because definitive diagnosis cannot be made on the day of testing, and immediate referral to HIV care or ART initiation is not appropriate, providers need to help clients make a clear plan for follow-up and schedule an appointment for retesting. Also, clients should be informed about prevention options and how to stay HIV-negative, as well as about the availability and benefits of ART.

Those suspected of having an acute HIV infection[1] – for example, if they report or present with symptoms associated with acute HIV infection – should be followed up closely. This is a period of high infectiousness due to high viral load, and clients need to be informed how to protect their partners. Individuals at high ongoing risk of HIV can be informed about PrEP and encouraged to discuss options depending on their final HIV status when they come back for retesting.

4.3.5 Special messages on retesting

Retesting among people who are HIV-negative

Retesting among people who are HIV-negative or of unknown status has two key purposes: (1) **monitoring the effectiveness of HIV prevention** interventions and (2) **identifying and treating new HIV infections as early as possible** when prevention efforts fail *(1)*.

Most people who have an HIV-negative test will not need retesting *(1)*. One lifetime HIV test is sufficient for most people in low HIV burden settings and who do not have ongoing HIV risk *(1, 37)*.

Retesting of people who are HIV-negative (or of unknown status) is for people with ongoing HIV-related risk. This is important and should not be deprioritized. The following describes situations where retesting is needed or may be beneficial. People from these groups may benefit from additional health education and counselling as well.

1 Acute HIV infection is also known as primary HIV infection or acute retroviral syndrome. It is the initial stage of HIV infection, and it lasts until the body has created antibodies against HIV that HIV tests detect.

Window period retesting. Post-test counselling messages earlier in the epidemic encouraged all people testing negative to retest every three months because they might be in the window period. This is an inefficient use of resources and no longer needed because many tests today can detect HIV infection within 6–12 weeks of acquiring infection *(1)*. In many settings very few people present for testing in this period.

Retesting of HIV-negative individuals is needed only when they report recent or ongoing risk of HIV exposure.

Annual retesting. Only specific groups of people in high HIV burden settings or individuals with HIV-related risks need post-test counselling encouraging retesting at appropriate intervals. WHO guidance recommends annual retesting for:

- **all sexually active individuals in high HIV burden settings** and;
- people who have **ongoing HIV-related risks in all settings**. These include:
  - **key populations**, defined as men who have sex with men, people in prison or other closed settings, people who inject drugs, sex workers and transgender people;
  - **people with a known HIV-positive partner** who is not virally suppressed on ART.

Retesting in specific groups. In certain conditions and situations, individuals who have been tested for HIV in the past can be advised to retest. These include:

- individuals presenting with a diagnosis or receiving treatment for **STIs or viral hepatitis**
- individuals with a confirmed or presumptive **TB diagnosis**
- outpatients presenting with **clinical conditions or symptoms indicative of HIV**
- individuals with **recent HIV risk exposure**.

Frequent retesting in specific groups. Annual retesting for people with ongoing HIV risk is sufficient in most cases, including among members of key populations. However, more frequent retesting – that is, every 3–6 months – may be advisable based on individual risk factors or as part of HIV prevention interventions. This would include, for example, individuals taking PrEP, who require quarterly HIV testing, or members of key populations who present with an STI.

All pregnant women should be tested for HIV, as well as syphilis and hepatitis B virus[2], at least once and as early as possible during pregnancy. In high HIV burden settings, post-test counselling should encourage retesting for women of negative or unknown status during late pregnancy (for example, during a third trimester visit). However, in low HIV burden settings, retesting messages in late pregnancy are advised only for women of negative or unknown status, women from key populations and those who have a partner with HIV that is not virally suppressed.

In specific districts or regions with high HIV burden or incidence and for HIV-negative women (or women of unknown status) from key populations and those whose partners have HIV that is not virally suppressed, an additional message could encourage retesting at 14 weeks, six months or nine months postpartum. Selecting the right time point for

2 Particularly in settings with a ≥2% HBsAg seroprevalence in the general population.

one additional retest will based on local context, as well as HTS coverage and time and frequency of ANC visits, and the immunizations schedule.

More information on retesting messages for people who are HIV-negative are available in Chapter 3 and in WHO's *Delivering HIV test results and messages for re-testing and counselling in adults (38)* (http://www.who.int/hiv/pub/vct/hiv_re_testing/en/).

Chapter 7 discusses considerations for optimizing retesting, particularly among pregnant and postpartum women.

Retesting among people with HIV who already know their status

Even though pre-test messages alert people that test results may not be accurate for those taking ART, people who know that they are HIV-positive seek retesting for various reasons, and some may not share that they know their positive status and/or are on treatment *(39)*. For some, retesting is a way to check or come to terms with an HIV-positive diagnosis, and they may seek retesting as an opportunity to talk with a knowledgeable health-care provider about their personal or health concerns *(40).* For others it is a way to initiate or re-engage in care and part of building trust with health workers *(41).*

All clients should be asked if they have been previously diagnosed with HIV and, if so, if they are taking ART. For clients who are taking ART, it is important to emphasize that ART may have affected their test results and that they should not stop ART. More in-depth counselling and engagement with their clinical provider may be needed. In any case, however, the following messages may be beneficial *(42)*:

- Once you are on ART, HIV testing using rapid tests, including self-testing, may not be accurate. A negative test result while on ART would usually be false.
- ART is for life and does not cure HIV. Do not stop taking it – or you could start to get sick.
- To check your health, your HIV status or treatment success, keep taking your ART and talk with a clinical provider.
- An "undetectable" viral load test result is not the same as a negative test result on an HIV rapid test. An "undetectable" viral load test result means that ART is controlling the virus. It does not mean that the virus is gone and you are cured. It does not mean you can stop taking ART.
- It is important to tell a person providing HIV testing or distributing HIV self-tests that you are taking ART.
- Talk to a counsellor or health worker if you have doubts or concerns about the accuracy of an HIV-positive diagnosis.

For clients who were previously diagnosed and either never started ART or else stopped taking ART, a request for HIV testing provides an **opportunity to engage or re-engage in care**. Additional information or encouragement from providers may help. It is important that post-test counselling includes all general messages and those for people diagnosed with HIV (see section 4.2.1). However, greater emphasis on the following may be particularly beneficial:

- **Early ART initiation has many health benefits** and is recommended for all people with HIV regardless of their disease stage. Individuals diagnosed with HIV before the "treat all" era (which began in 2016 in many countries) may need to be informed that treatment is now available for all people with HIV, while those who declined or discontinued ART may need information on the latest treatments, which are safe and have minimal side-effects. They also need information about the preventative benefits of treatment.
- **Explain the next steps and the pathway to care, including where and how to access ART,** care, support and other health services, particularly those that are free and offer additional support.
- **Discuss barriers to linkage to care** and the client's questions and concerns about ART side-effects and other aspects of treatment and care.
- Explain that, **once a person is taking ART, HIV testing, including self-testing, may not be accurate**, and future negative results while on ART would usually be false.
- **Encourage these clients to talk to a counsellor or other knowledgeable health worker when needed** and describe how and where to access counselling, mental health and other support services.
- **Encourage and provide time for the client to ask additional questions.**

Retesting among people with HIV to verify diagnosis before treatment

Delivering the correct test results is essential to HTS. Following an HIV-positive diagnosis, all people are recommended to link to care and start lifelong ART as soon as possible. But, once a person starts ART and becomes virally suppressed, it is difficult, using available tests, to distinguish that person from a person who is HIV-negative *(1, 21, 42).*

Thus, WHO recommends **retesting all people newly diagnosed with HIV before they start ART**. This is an important quality assurance measure to prevent unnecessary lifelong treatment due to errors in the testing process, such as suboptimal testing services, poor counselling, misunderstanding of test results, mislabelling, specimen mix-up or other human errors. Post-test information and counselling messages should explain that this retesting is part of routine quality assurance for the national HIV programme. Once a person starts ART, people with HIV will not be retested again to verify their status.

Chapter 8 provides more information on retesting procedures to verify a diagnosis before initiating ART.

4.3.6 Special considerations concerning disclosure

People who test HIV-negative rarely need assistance or support with disclosing their test results to others. In contrast, maintaining privacy about a reactive self-test or an HIV-positive diagnosis is a serious concern for many. Disclosing one's HIV status to partner(s), family members or other contacts has many benefits both for infected person and for his or her contacts.

Disclosure should always be voluntary. WHO does not support mandatory or coercive disclosure to sexual and/or drug-injecting partners. However, in some settings laws or regulations require this. Providers need to be aware of laws and regulations that make clients susceptible to adverse outcomes of disclosure, such as discrimination, violence, abandonment or incarceration. Where such laws exist, clients may need additional information and counselling as part of the informed consent process before testing as well as to support appropriate disclosure afterwards. Law enforcement authorities should never be involved in disclosure or partner services, including provider-assisted referral.

Individuals, especially women who have experienced intimate partner violence or who are sex workers, may be at risk of violence from their partner(s) after disclosing their HIV status or test results. WHO recommends voluntary provider-assisted referral to contact sexual and drug injecting partners to offer HTS *(21)*. Provider-assisted referral should not be carried out without the consent of the client with HIV.

Chapter 6, Box 6.6, provides a consolidated list of WHO recommendations for couples and partners in the context of HIV. Where disclosure is not feasible or safe, partner testing can be offered through anonymous testing approaches that do not disclose the HIV-positive status of a client. These methods can include social network-based approaches for people from key populations, in which social contacts, sexual and drug-injecting partners of HIV-negative or HIV-positive clients are offered HTS (see Chapter 5).

Three forms of disclosure are relevant and appropriate to HTS:

1. **Disclosure by a health worker to a sexual partner of the individual.** WHO recommends that all people with HIV be offered voluntary provider-assisted referral to offer HTS to their sexual and drug-injecting partners *(43)*. While some people with HIV may want the provider to disclose their HIV status to partners, others may not want to disclose their status. Providers need to discuss options with clients to determine what is the most appropriate and preferred option for the given situation or relationship with the partner(s). See Chapter 5 for discussion of options for service delivery.
2. **Disclosure by the individual to sexual partner(s), family members or other contacts.** Individuals who do not accept the offer of provider-assisted referral and who prefer to disclose their HIV status directly to partners should be encouraged and supported to do so. Individuals may choose a different method of disclosure for different partner(s). For example, they may want to disclose their HIV status to the primary partner themselves but may prefer provider-assisted referral for other partners. It is the provider's responsibility to determine, in consultation with the client, which disclosure method is appropriate for each different partner.

   Distributing a self-test kit to a partner, or encouraging someone to access HTS, does not necessarily require disclosure of one's HIV status or self-test result. Individuals with a reactive self-test result should be advised that a reactive result is not the same as an HIV-positive diagnosis. Partners who self-test together, and both or one has a reactive result, need further testing to determine their HIV status.

3. **Disclosure by a health worker to other health workers** involved in the client's care. Providers need to inform people who are diagnosed HIV positive that the diagnosis will be shared as needed with other providers involved in the client's care. Some clients diagnosed HIV-positive may need time to absorb their diagnosis before they are ready to disclose and inform their partners, which may happen at subsequent visits. Thus, other providers will need to be informed to ensure appropriate follow-up. These disclosures should respect the basic client right to privacy and confidentiality of all medical information.

   Trained providers distributing HIVST kits can ask about the test result as part of follow-up. However, it is important that self-testers are informed that sharing their self-test results is voluntary and not required.

   Disclosure by a health worker to law enforcement or other legal authorities is not considered ethical in the context of HTS unless the client has consented to this disclosure. In that case HTS providers should obtain written consent for disclosure of HIV test results to legal authorities.

4.4 Linkage to HIV treatment, prevention, care, support and other relevant services

4.4.1 Defining linkage

Regardless of HIV status, linkage is the first step toward onward services (Box 4.1). Linkage is essential to achieve programmatic impact and one of the core responsibilities of providers delivering HTS. Without linkage to care and treatment, being tested and learning one's HIV-positive status have limited value. Similarly, those who test HIV-negative and are at continuing risk need linkage to prevention services. Also, those with a reactive test for triage or self-test result also need to be linked to further HIV testing to establish HIV status and connect to additional services, as needed.

HTS sites, testers and counsellors are responsible for ensuring linkage. They need to provide post-test service packages that include up-to-date post-test counselling messages and evidence-based strategies and support tools to facilitate linkage depending on the context, setting and population.

Table 4.1 summarizes WHO-recommended services and interventions that people with HIV and those who test HIV-negative may be linked to.

Box 4.1. What is linkage?

Linkage to further testing. In some cases, such as after a reactive self-test, a test for triage or the rare case in which an individual could not be diagnosed on the same day and is given an inconclusive status, linkage to further testing is needed *(1, 21).*

Linkage to ART. For all people diagnosed with HIV, WHO recommends that treatment be offered and ART be initiated as early as possible.

(Re)linking to ART. People with HIV who know their status and are not currently taking ART need to be supported to engage in care and initiate treatment. People in this group might include: (1) people diagnosed with HIV before the "treat all" era who never started treatment; (2) people who were offered ART but who were not yet ready to start; and (3) people who started ART but later discontinued. Sometimes, these individuals need to retest to "re-link" to care and initiate or (reinitiate) ART. When people present for testing, providers cannot always identify who already knows their status or who was previously engaged in care. For these people linkage from HTS sites can be critical to initiating or re-initiating treatment *(1, 2, 20).*

Linkage to prevention. While prevention, such as relevant information and condoms, is beneficial for all people testing for HIV, most people testing HIV-negative do not need to be linked to additional prevention services. For those who are HIV-negative, at ongoing risk and not accessing prevention services, linkage to a specific HIV prevention intervention may be beneficial.

Measuring linkage. Most programmes monitor linkage to care within 30 to 90 days of an HIV-positive diagnosis, monitor time to ART initiation within seven or 14 days of diagnosis, and report on the number of people with HIV newly initiated on treatment in the preceding 12 months. Programmes do not routinely monitor linkage to HIV prevention following HTS, but it may be reported as part of prevention programme data and in special projects and surveys. Annex H presents considerations for measuring and monitoring linkage to care and ART initiation following HIV testing.

A combination of interventions is needed to improve linkages to prevention, care and treatment, particularly to minimize loss to follow-up between HIV testing, on one hand, and care and treatment, on the other. This needs attention especially for people with HIV who are reached outside of health facilities, in settings where ART is not available onsite and for populations that may face barriers to services. Such groups include key populations, men, young people, migrants and displaced populations, and people who are very ill or have advanced HIV disease *(1, 2, 20, 25).*

Depending on need, approaches to improve linkages include integrating and co-locating services (providing HTS, ART and other related services in a single facility) whenever possible *(44)*, implementing quality improvement approaches *(45)*, streamlining service delivery by moving away from the use of western blotting *(46)*, conducting CD4 testing at the point-of-care to prioritize ART for those with advanced disease *(44)*, peer outreach and support models and/or peer navigators, and case management *(47)* (Box 4.2).

Table 4.1. HIV prevention, treatment and care services

	People with HIV	People testing HIV-negative
Treatment	Antiretroviral therapy (ART)	NA
Prevention	Male and female condoms and condom-compatible lubricants	
		PrEP for people at substantial ongoing risk of HIV infection
		Post-exposure prophylaxis (PEP) following suspected exposure
		Voluntary medical male circumcision (VMMC) (in 14 priority countries)
	Harm reduction for people who inject drugs (needle and syringe programmes, opioid substitution therapy, other drug-dependence treatment and opioid overdose prevention and management)	
	Behavioural interventions to support risk reduction, particularly for people with HIV and members of key populations	
Sexual and reproductive health	Contraception and family planning	
	Prevention of mother-to-child transmission	NA
	Cervical cancer screening and treatment	
	Anal cancer screening (for men who have sex with men)	
	STI testing and treatment	STI testing and treatment for those with ongoing risk, including people from key populations
HIV testing for partners and biological children	Testing for all partners and biological children (includes partner services and index case testing)	For partners and social contacts of people from key populations, where appropriate
Retesting and confirmatory testing	Retest before ART initiation Confirmatory testing following a reactive (positive)community-based test-for-triage or HIVST result	Retest at least every 12 months if at high ongoing risk, particularly people from key populations
Other clinical services	Assessment and provision of vaccinations, such as for hepatitis B virus (HBV) for people from key populations, pregnant women and infants; and, where appropriate, tetanus vaccination for adolescent boys and men receiving VMMC	
	HBV testing and vaccination and hepatitis C virus (HCV) testing and treatment	HBV and HCV testing particularly for members of key populations, according to epidemiology, and treatment or vaccination
	Co-trimoxazole chemoprophylaxis to prevent Pneumocystis carinii pneumonia	
	Intensified TB case finding and linkage to TB treatment	
	Provision of isoniazid preventive therapy if person does not have TB	
	Malaria prevention (such as bed nets and prophylaxis), depending on epidemiology	
Other support services	Mental health services	
	Psychosocial counselling, support and treatment adherence counselling	
	Support for disclosure and partner services	
	Legal and social services	
	Services for responding to violence against women, including first-line support and psychosocial support, post-rape care and other support services including shelters, legal services and women and child protection services.	

NA = not applicable

Box 4.2. WHO recommendations and best practice statements on linkage to care and rapid ART initiation

WHO recommendations

Rapid ART initiation should be offered to all people with HIV following a confirmed HIV diagnosis and clinical assessment *(strong recommendation, high-quality evidence for adults and adolescents, low-quality evidence for children)*.

Following an HIV diagnosis, a package of support interventions should be offered to ensure timely linkage to care for all people with HIV *(strong recommendation, moderate-quality evidence)*.

The following interventions have demonstrated benefit in improving linkage to care following an HIV diagnosis:

- streamlined interventions to reduce time between diagnosis and engagement in care, including (i) enhanced linkage with case management, (ii) support for HIV disclosure, (iii) patient tracing (referred to as partner services), (iv) training staff to provide multiple services and (v) streamlined and co-located services (moderate-quality evidence);
- peer support (including peer counselling) and navigation approaches for linkage *(moderate-quality evidence)*; and
- quality improvement approaches using data to improve linkages *(low-quality evidence)*.

NEW Western blotting and non-rapid line immunoassays should not be used within HIV testing strategies/algorithms *(strong recommendation, low-quality evidence)*.

WHO best practice statements on linkage to treatment and care

ART initiation should follow the overarching principles of providing people-centred care. People-centred care should be focused and organized around the health needs, preferences and expectations of people and communities, upholding individual dignity and respect, especially for vulnerable populations. It should promote the engagement and support of people and families to play an active role in their own care through informed decision-making.

All people newly diagnosed with HIV should be retested, to verify their HIV status prior to starting ART, using the same testing strategy and algorithm as the initial test. To minimize the risk of misdiagnosis, this approach should be maintained in settings in which rapid ART initiation is being implemented.

The introduction of the "treat all" recommendation (ART for all people living with HIV regardless of CD4 cell count) supports the rapid initiation of ART, including the offer of same-day initiation where there is no clinical contraindication.

People with no contraindication to rapid ART initiation should be fully informed of the benefits of ART and offered rapid ART initiation, including the option of same-day initiation.

Rapid start of ART is especially important for people with very low CD4 cell counts, in whom the risk of death is high. People should not be coerced to start immediately and should be supported in making an informed choice regarding when to start ART.

Sources: WHO, 2016 *(2)*; WHO, 2017 *(20)*.

The following sections provide further information on effective linkage approaches and implementation considerations that can be adapted to suit the context, population and setting.

4.4.2 Linkage to care and rapid ART initiation for people with HIV

People may delay linking to services for several reasons, including individual and structural barriers such as distance to services, transportation costs, fear of stigma, lack of confidentiality, concerns about disclosure and long waiting times in the facility. For those with a reactive result or an HIV-positive diagnosis in a community setting where ART is not available, there may be additional challenges for linkage if not supported by strategic approaches. The following are some promising approaches that can be considered.

Facility-based services and co-located HTS and ART. Evidence suggests that well-coordinated, integrated and co-located services, where HTS and ART are both readily available, facilitate linkage to care *(44, 48-50)*. Co-locating services may not be feasible in all settings, however. Where it is not possible, peer support, peer navigation and case management may be particularly helpful to ensure good linkages to prevention, treatment and care following HIV diagnosis.

Accelerating ART by offering same-day diagnosis and immediate ART initiation also facilitate linkage, particularly for people who are ill and present with advanced HIV disease and who need to start treatment as soon as possible *(51)*. A recent review of linkage since implementation of "treat all" policies showed that the immediate supply of ART with the option of "same-day start" improved linkage rates *(52)*.

In health facilities, people who are newly identified as HIV-positive should be initiated on ART at the same place that they are tested. Clients should not need to move through multiple rooms and providers before ART initiation.

In settings where western blotting is routinely used and required for a final diagnosis, or when rapid testing is not available, there is an increased risk of loss to follow-up (never receiving results), delayed linkage to care and later ART initiation *(46)*. **WHO recommends that countries stop using western blotting** in HIV testing strategies and algorithms. Switching to simpler rapid diagnostic tests and enzyme immunoassays that can provide a diagnosis on the same day needs to be prioritized.

Additional strategies, such as differentiated ART delivery models, as well as peer support and adherence counselling, are needed to make it easier to stay in care and prevent treatment drop-out, particularly for members of key populations, men, young people and pregnant women *(2, 20, 28, 29).*

While evidence on demand creation for linkage was very limited, Chapter 3 details relevant approaches for enhancing HTS uptake.

HIVST and community-based HTS. HIVST and community-based HTS can achieve good linkage rates, comparable to those for conventional facility-based services *(1,21,30,53-56),* for people with HIV earlier in the disease *(53, 56)* and for those who would not test or receive care otherwise *(1, 21, 30, 54-56)* (see Chapter 5). However, strategies are needed to address linkage from HIVST and community-based HTS when it is suboptimal *(57-61).*

Some service delivery models that support linkage may achieve better linkage rates than others. For example, there is low-quality evidence that HIVST plus home-based ART initiation and linkage escorts, compared with facility-based ART initiation and self-referral, may improve linkage *(30)*. For community-based HTS, high linkage rates were achieved by HIV testing in the context of partner services (79% pooled linkage); a combination of models – mobile, outreach, home-based (78% pooled linkage for the general population, 85% pooled linkage for key populations); and stand-alone voluntary counselling and testing for key populations (83% pooled linkage). Linkage rates were lower with some models and for some populations – for example, home-based testing (51% pooled linkage), transgender people (41% pooled linkage) and people who inject drugs (44% pooled linkage). Additional linkage support may be needed in these models and for these populations.

Chapter 5 further discusses delivering HIVST and community-based HTS.

Provider-assisted referral (also called assisted partner notification or index testing). WHO recommends provider-assisted referral for all people with HIV as a way to offer voluntary HIV testing to their sexual and/or drug injecting partners. Partner services, which include provider-assisted referral, are recommended, as they can achieve good linkage to care (see Box 4.2).

Other evidence-based implementation strategies. Counselling, while important, needs to be implemented as part of an evidence-based linkage strategy, because post-test counselling messages alone have little effect on linkage *(44, 52).* While there is evidence that people newly diagnosed with HIV are likely to change behaviours, counselling alone does not lead to behaviour change *(31).*

In contexts, settings and populations where linkage is suboptimal, the following additional evidence-based implementation strategies can be considered. These may be particularly useful for supporting scale-up of self-testing and community-based HTS, most notably, home-based and outreach models, which could have low linkage rates.

- **Peer and community support and follow-up, including patient navigators and linkage escorts.** WHO recommends peer support and navigation for facilitating linkage. Evidence suggests that patient navigators can improve linkage to care *(44, 62, 63).* Peer and community-led support, including support from people with HIV, also can facilitate linkage *(64).* In one randomized controlled trial (RCT) in Zambia among young people (ages 15–24) who self-tested, patient escorts nearly tripled linkage to ART compared with self-referral cards *(65)*. In Eswatini peer-based case management using patient navigators, weekly phone calls, reminders and follow-up counselling for people diagnosed with HIV in community settings resulted in 96% initiating ART during the study period *(66).*
- **Home-based ART initiation and care.** Home-based ART initiation, following home-based HTS or other outreach, can achieve high levels of linkage. In Lesotho an RCT reported 13% greater linkage and a 16% increase in viral suppression with home-based HTS and same-day home-based ART initiation compared with home-based HTS and

referral for facility-based ART initiation *(67)*. In an RCT in Malawi, home-based HIVST distribution and ART initiation led to a three-fold higher linkage rate than home-based HIVST distribution and standard, facility-based ART initiation *(68)*.

- **Incentives, including financial incentives.** Evidence on the effect of incentives on linkage is mixed. A recent review found that offering economic incentives in settings where "treat all" policies were implemented did not increase linkage or ART initiation *(52)*. According to a WHO systematic review, there is limited and highly varied evidence on how incentives may affect linkage to prevention, treatment and care. Overall, while incentives may slightly improve uptake of HTS (low- to moderate-quality evidence), they did not appear to affect rates of ART initiation or viral suppression (very low- to low-quality evidence) *(69)*. (See Chapter 3 for details.)
- **Friendly and flexible services.** Services that are flexible, inclusive, non-judgmental and free of cost support linkage and rapid ART initiation. Structural, legal and policy barriers, as well as fear of criminalization and prosecution, can adversely affect linkage due to loss to follow-up and delay, particularly among key populations and adolescents and young people. Programmes need to continue to work to provide a supportive environment that enables and encourages people with HIV to access care and treatment (see Chapter 3).
- **New digital platforms.** Use of digital health tools, including social media, videos, text messaging and other applications appears promising. Review of evidence on demand creation for HTS and onward linkage to prevention, treatment and care showed that videos increased uptake of HTS, but it may or may not affect linkage (low-quality evidence), and it was expensive *(69)*. Costs varied, and in some cases video-based approaches may be less costly than intensive in-person approaches. Further research is needed on whether and how digital media platforms, particularly social media and web-based tools, can be adapted to facilitate linkage and rapid ART initiation at an affordable price (see Chapter 3).
- **(Re)linking people to treatment and care.** Evidence is limited on strategies to support people with HIV who already know their status and link them back into care after declining ART or being lost to follow-up. Further research is needed.

Linkage policy. Although supporting linkage to ART and prevention is critical after testing, approaches which can improve linkage vary in specific settings and populations. Therefore, countries should review their national guidelines and consider including a clear linkage strategy and policy, including specific approaches, interventions and designation of cadres supporting linkage and rapid ART initiation, and monitoring effectiveness. Policies need to support HTS sites and testing providers to support linkage to care.

4.4.3 Special considerations for linkage to HIV prevention and other services

Due to the declining number of people with HIV who do not know their status in many countries, the great majority of people testing for HIV are likely to be HIV-negative. To maximize programme impact and improve cost-effectiveness, it is important to optimize service delivery to reach people who are HIV-negative but at ongoing risk and to link them to effective prevention (see Chapter 7). HTS presents an opportunity to reach people at high ongoing risk (Fig 4.1). When these people attend HTS, it is important to prioritize and facilitate linkage to prevention.

Once a person is engaged in prevention interventions, HTS will continue to serve as part of "prevention monitoring" – such as quarterly testing among people taking PrEP – to identify new infections so these people can be started on ART as soon as possible.

Box 4.3 details available guidance on rapid ART initiation, linkage to prevention and monitoring and reporting.

Fig. 4.1. The HIV prevention continuum

Source: McNairy M and El-Sadr W, 2014 *(70).*

Box 4.3. Additional WHO guidance on ART initiation, HIV prevention services and monitoring and reporting

Guidance on ART initiation

- Update of recommendations on first- and second-line antiretroviral regimens; 2019. https://www.who.int/hiv/pub/arv/arv-update-2019-policy/en/
- Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy; 2017. https://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/
- Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach; 2016. https://www.who.int/hiv/pub/arv/arv-2016/en/
- WHO, CDC, PEPFAR, USAID, IAS. Key considerations for differentiated antiretroviral therapy delivery for specific populations: children, adolescents, pregnant and breastfeeding women and key populations; 2017. https://www.who.int/hiv/pub/arv/hiv-differentiated-care-models-key-populations/en/

Guidance on HIV prevention services

- Updated recommendations on safe male circumcision for HIV prevention and related service delivery for adolescent boys and men in generalized HIV epidemics; 2019.
- What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: Update to WHO's recommendation on oral PrEP; 2019. https://www.who.int/hiv/pub/prep/211/en/
- Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations; 2016. https://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/
- WHO implementation tool for pre-exposure prophylaxis of HIV infection; 2017. https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/

Guidance on monitoring and reporting

- Cascade data use manual to identify gaps in HIV and health services for programme improvement; 2018. https://www.who.int/hiv/pub/toolkits/hiv-cascade-data-use-manual/en/
- HIV self-testing strategic framework: a guide for planning, introducing and scaling up; 2018. https://www.who.int/hiv/pub/self-testing/strategic-framework/en/
- Module 5, Monitoring and evaluation: WHO implementation tool for pre-exposure prophylaxis of HIV infection; 2018. https://apps.who.int/iris/bitstream/handle/10665/279834/WHO-CDS-HIV-18.10-eng.pdf
- Consolidated guidelines on person-centred HIV patient monitoring and case surveillance; 2017. https://www.who.int/hiv/pub/guidelines/person-centred-hiv-monitoring-guidelines/en/

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KEY POINTS

- HIV testing services (HTS) need to **focus on people with HIV who remain undiagnosed** and on diagnosing and linking them to treatment and care services as early as possible. People who are HIV-negative and at ongoing risk also need to be tested and linked to appropriate prevention services.
- There are many approaches to deliver HTS, including facility-based, community-based, HIV self-testing (HIVST), and a package of voluntary HIV partner services, including provider-assisted referral and social network-based approaches. A **strategic mix of differentiated HIV testing approaches** is needed for an effective and efficient national HTS plan depending on the epidemiology, focus populations, and resources available.
- **Integrating HTS** with screening or testing for other infections and with other relevant services needs to be prioritized to minimize missed opportunities for testing at facilities. Services where HTS can be integrated include tuberculosis (TB); viral hepatitis; sexually transmitted infections (STIs); reproductive, maternal, newborn, child and adolescent health services including antenatal care (ANC), postnatal care (PNC) and contraception/family planning; services for key populations; voluntary medical male circumcision (VMMC) programmes in priority countries; and screening and care for other conditions including noncommunicable diseases.
- **Task sharing** and use of **trained lay providers** need to be adopted more widely to expand HTS, especially community-based HTS. **Focused community-based HTS** effectively reaches certain populations, such as men and key populations.
- WHO recommends that **HIVST** should be offered as an approach to HTS (update to 2016 recommendation). Provision of appropriate HIVST service delivery and support options is desirable and communities need to be engaged in developing and adapting HIVST models.
- Voluntary HIV partner services remain effective in identifying undiagnosed HIV infections. **Provider-assisted referral should be prioritized** where feasible within a comprehensive package of services for all people with HIV.
- WHO has issued a new recommendation that **social network-based HIV testing can be offered as an HIV testing approach for key populations** as part of a comprehensive package of care and prevention.

5. SERVICE DELIVERY APPROACHES FOR HIV TESTING

Box 5.1. New WHO recommendations on HIVST and social network-based approaches

Updated HIV self-testing should be offered as an approach to HIV testing services *(strong recommendation, moderate quality evidence).*

Remarks

- Providing HIVST service delivery and support options is desirable.
- Communities need to be engaged in developing and adapting HIVST models.
- HIVST does not provide a definitive HIV-positive diagnosis. Individuals with a reactive test result must receive further testing from a trained tester using a verified national testing algorithm.

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

5.1 WHO HTS standards

All HTS must adhere to WHO's essential 5 Cs (**C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results, **C**onnection/linkage to prevention, care and treatment) *(1)*. HTS must be voluntary. All people offered testing should be made aware of their right to refuse testing, and they must give **verbal informed consent** to be tested. Mandatory or coercive HIV testing is never appropriate *(2)*.

Providers delivering HTS should be appropriately trained and supervised. Health-care workers as well as trained lay providers, sometimes called community health workers, can perform HTS *(3)*. All HTS sites should have standard operating procedures (SOPs) and ethical codes of conduct protecting client information and ensuring confidentiality, which they must adhere to. Clients undergoing HTS can be provided with clear and concise **pre-test information** as needed. Those diagnosed HIV-positive and those who are HIV-negative and at ongoing risk should receive **post-test counselling**.

An HIV-positive diagnosis should be based on a **verified national HIV testing algorithm based on the WHO-recommended testing strategy** (see Chapters 8).

HTS without linkage to appropriate services is not beneficial. It is critical to **support timely linkage** to prevention, treatment and care following HTS as needed (see Chapter 4).

It is the responsibility of the health sector, health-care providers and other implementers delivering HTS to work with community organizations, key populations, affected communities, government institutions, legal authorities and advocacy organizations to ensure a **supportive and safe environment** for people to learn their HIV status (see Chapter 3).

5.2 Strategies to make HTS accessible

WHO-recommended programming practices and strategies can be adapted to expand HTS and make it more accessible, efficient and cost-effective. These practices include:

- integration of HTS with other testing and services
- decentralization, task sharing and test for triage.

5.2.1 Integration of HIV testing with testing and services for other health areas

Integration is the co-location and sharing of services and resources across different health areas. In the context of HIV, this may include provision of HIV testing, prevention, treatment and care services alongside other relevant health services. **WHO recommends integration of HIV services, including HTS, with a range of other relevant clinical services**, such as those for TB; viral hepatitis, STIs; reproductive, maternal, newborn, child and adolescent health services, including ANC, PNC and contraception/family planning; services for key populations; VMMC programmes in priority countries; and screening and care for other conditions including noncommunicable diseases *(1, 4)*.

Integration involves not only providing related health services in a common facility or setting, but also connecting patient recording and reporting systems to share information, with the consent of the client, and to provide appropriate referrals between services and providers.

> Integration seeks to make HTS more convenient and to reduce missed opportunities for HIV testing.

The primary purpose of such integration is to make HTS more convenient for people coming to health facilities for other reasons and so to reduce missed opportunities for HIV testing. Also, integrated services can improve client satisfaction and reduce stigma for some clients *(5-7)*. In some settings, certain services, such those for TB, viral hepatitis, STIs, harm reduction, ANC and contraception/family planning, attract people who are also at risk for HIV. Service integration in such settings creates opportunities to diagnose additional HIV infections as well as co-infections and to start treatment and care at the same time and place, saving clients' time and costs. For the health system, integration may reduce duplication of services, reduce visits and improve coordination and efficiency *(8, 9)*.

Integration is appropriate in all epidemic settings and particularly in high burden settings. Chapter 7 discusses strategic planning and considerations for service integration.

5.2.2 Decentralization, task sharing and test for triage

Decentralization of HTS refers to providing HTS at peripheral health facilities such as primary health-care facilities as well as outside of health facilities in the community. Providing HTS in places closer to people's homes may reduce transportation and other costs and waiting times experienced in central hospitals, thus improving accessibility and uptake. HTS in community settings may be more attractive for men, young people and key populations, who are otherwise less likely to test in facilities (see section 5.3.2).

Decentralization of services may be appropriate in both high and low HIV burden settings. However, careful consideration is needed when embarking on decentralization of HTS as sometimes it may not be acceptable or a good use of resources. For example, key populations or other vulnerable populations may fear being seen attending HTS due to stigma and discrimination, particularly in settings where key population behaviours are criminalized. In some low HIV burden settings, decentralizing HTS may be inefficient and costly. The context, needs, service gaps, costs, community preferences, and the overall balance of benefits and harms, should be weighed when deciding where HTS should be decentralized. Decentralization should be accompanied by efforts to strengthen linkage and referral systems.

Task sharing is the rational redistribution of tasks between cadres of health-care providers with longer training and cadres with shorter training, such as trained lay providers. Task sharing for HTS is expected to support and expand the role of trained lay providers and so improve accessibility and acceptability of HTS and address gaps in service delivery. WHO recommends that **trained lay providers, sometimes called community health workers, should be used to deliver HTS using rapid diagnostic tests** (RDTs) *(1, 10).*

Task sharing for HTS is expected to support and expand the role of trained lay providers.

Trained peers can also function as lay providers. HTS in the community delivered by peers can offer non-judgemental and respectful services that are more acceptable and less stigmatizing and, thus, improve uptake and linkage to post-test services. Using trained lay providers for HTS also opens opportunities for delivering a range of health services within and beyond HIV prevention, treatment and care, including TB, viral hepatitis and STI screening and testing, contraception, sexual and reproductive health services, vaccination and bed net distribution for malaria prevention. Some countries may need to update polices and regulations or review how they are interpreted to enable nurses, other non-physician health professionals and trained lay providers to offer HTS (see Box 5.2). See further WHO guidance on harnessing the full potential of community health workers, including lay providers, and their proper integration in health systems and communities to optimize design and performance of programmes *(11).*

Box 5.2. WHO recommendations on lay providers

Lay providers who are trained and supervised can independently conduct safe and effective HIV testing services using rapid diagnostic tests *(strong recommendation, moderate-quality evidence).*

A lay provider is defined as any person who performs functions related to health-care delivery and has been trained to deliver specific services but has received no formal professional or paraprofessional certificate or tertiary education degree.

Lay providers can be trained to deliver all testing services, including pre-test information, collecting specimens, performing HIV RDTs, interpreting test results and reporting HIV status, offering post-test counselling and supporting linkage to prevention, treatment and care services. Peers can be trained to function as lay providers.

Source: WHO, 2015 *(1).*

Test for triage is when a trained provider performs a single HIV RDT and then facilitates linkage to appropriate further testing and services depending on test results. Anyone who has a reactive test for triage is promptly linked to further testing at a facility for confirmation of HIV status. This strategy supports the role of trained lay providers and expansion of community-based HTS.

The test for triage approach also applies to HIVST, where a person performs a self-test, and those with reactive results are supported to seek further testing at a facility for confirmation of their HIV status and linkage to appropriate services (see Chapter 8).

The "test for triage" approach can expand the roles of lay providers, community-based testing and HIVST.

5.3 HIV testing service delivery approaches

HTS need to focus on people with HIV who remain undiagnosed and on diagnosing and linking them to treatment and care services as early as possible. People who are HIV-negative and at ongoing risk also need to be tested and linked to appropriate prevention services.

To maximize the impact of HTS, programmes need to consider their specific epidemic context and resources available to determine a strategic mix of differentiated HTS approaches for an effective and efficient HTS plan *(12).* WHO recommends that the following HTS approaches be considered in the national HTS plan. Descriptions of these approaches follow. For guidance on strategic HTS planning, see Chapter 7.

- facility-based HTS
- community-based HTS

- HIVST
- voluntary HIV partner services package, including provider-assisted referral and social network-based HIV testing approaches.

5.3.1 Facility-based HIV testing services

Facility-based HTS encompasses testing in a health facility or laboratory setting. Facility-based HTS can be provided at stand-alone HTS sites (often referred to as voluntary counselling and testing (VCT) sites) or routinely offered at clinical sites (often referred to as provider-initiated testing and counselling (PITC)).

Stand-alone testing sites

Stand-alone, or VCT sites were an early HTS model, where typically the client initiated HIV testing process by requesting an HIV test. HTS was often delivered at dedicated stand-alone facilities, usually run by community or nongovernmental organizations. It also was sometimes offered as a service in health facilities or hospitals.

Population-based surveys in high HIV burden African countries estimated that, with the stand-alone HTS approach, only 10% of people with HIV in Africa were aware of their HIV status in 2005 *(13)*. Globally, only 12% of people who wanted to test for HIV were able to do so *(13)*. Given these gaps, the focus has since shifted to integrating HTS into routine health services, where it can either be offered to all clients attending services or focused on those in facilities that see a high number of people at risk of HIV. Despite the limitations of the stand-alone approach, it may still be useful as a complementary option to reach people in selected high burden settings as well as key populations in some settings *(14, 15).*

Routinely offered HTS at clinical sites

WHO recommends that voluntary HTS be routinely offered to all clients of unknown or HIV-negative status in all clinical facilities in high HIV burden settings (see Box 5.3). (See Chapter 7 for guidance on offering retesting to people with a previous negative HIV test result). In low HIV burden settings, facility-based HTS should be focused and offered routinely to members of key populations, people with HIV indicator conditions, clients with presumptive or confirmed TB, and in specific clinical settings such as malnutrition clinics, ANC and STI, viral hepatitis and TB services *(1, 16).* The decision where and in which facilities to routinely offer HTS should be guided by the local epidemiology and HTS coverage gaps (see Chapter 7).

The aims of routinely offering HTS are to increase HTS coverage, provide diagnosis earlier for those attending health facilities, normalize HIV testing and remove the need for personal motivation to seek HTS. It saves clients the possible embarrassment of asking for an HIV test and reduces missed opportunities for HTS *(16).* Routine offer of facility-based HIV testing has proved to be highly acceptable and has led to considerable increases in the uptake of HTS in many high HIV burden settings. However, routine offer of HTS must not lead to mandatory testing.

Box 5.3. WHO recommendations on routinely offered facility-based HTS

In high HIV burden settings, routine HIV testing should be offered to **all clients** (adults, adolescents and children) in all clinical settings.

In low HIV burden settings, HIV testing should be offered in clinical settings to **clients who present with symptoms or medical conditions** that could indicate HIV infection, including presumed and confirmed TB cases.

In all settings routine HIV testing should be considered for **STI, viral hepatitis, TB, ANC, malnutrition clinics and other health services for key populations.**

Source: WHO, 2007 *(16);* WHO, 2015 *(1).*

Routine facility-based HTS can be offered at public and private health facilities, outpatient clinics, specialized services such as those for TB, viral hepatitis and STIs; reproductive, maternal, newborn, child and adolescent health services, including ANC, PNC and contraception/family planning; health services for prisoners and detainees; district, provincial or regional hospitals; emergency departments; and inpatient hospital wards *(1).* HTS has been successfully and effectively integrated in some clinical settings such as ANC and TB services but less so in others. Significant opportunities exist for integrating HTS into many clinical services; this should be prioritized. Some considerations include:

- **ANC, PNC, contraception/family planning and paediatric services.** WHO recommends that all pregnant women should be routinely offered HTS, as well as testing for syphilis and hepatitis B[1], at least once and as early as possible during pregnancy in all settings. Syphilis testing and treatment coverage among pregnant women are typically lower than antenatal HIV testing and treatment coverage in many countries. To close this gap, new guidance from WHO suggests that dual HIV/syphilis RDTs can be used as the first test for pregnant women in ANC in all settings. This use of dual HIV/syphilis RDT among pregnant women is cost-saving and can immediately close the gap between HIV and syphilis testing, with the goal of eliminating adverse birth outcomes due to syphilis. Integration of HTS into ANC in many high HIV burden settings has been largely responsible for high testing coverage among women. However, this has not been effectively done in low HIV burden settings. See Chapter 6 for special considerations for testing pregnant women.

  Contraception/family planning services provide an opportunity for HTS as part of sexual and reproductive health and HIV prevention packages for adolescent girls and young women of reproductive age and their partners *(1).* This is particularly important in high HIV burden settings, where HIV incidence may be high among women seeking contraception services *(17)*. Integration of HTS and HIV prevention with sexual and reproductive health services may help address the diverse needs of sexually active adolescents *(18).*

1 Particularly settings with a ≥2% HBsAg seroprevalence in the general population.

WHO recommends routinely offering HTS for **infants and children** with unknown HIV status who are admitted for inpatient care or attending outpatient, malnutrition or immunization clinics in high HIV burden settings (1, 4). In all settings testing of HIV-exposed, sick or hospitalized children and children who have a biological parent with HIV remains an important WHO-recommended strategy for identifying additional HIV infections. See Chapter 6 for special considerations for HTS among infants and children.

- **TB services.** Global monitoring estimated that among all reported TB cases in 2018, 8.6% also had HIV *(19).* A 2018 systematic review found very high HIV prevalence among adults with TB symptoms in primary care (55.7%; IQR: 20.9–71.2%) and among hospital inpatients (80.7%; IQR: 73.8–84.6%) (20). WHO recommends that HTS be routinely offered to all clients with presumptive or confirmed TB, as well as intensified TB case finding among people with HIV to facilitate early TB detection and treatment *(21).* Indeed, a systematic review found high coverage of HIV testing in adults with TB symptoms (97.2%, IQR: 84.5–100%) *(22).* However, global monitoring suggests only 64% of all notified TB patients in 2018 had a documented HIV test result *(19).*

  TB is a leading cause of death among people with HIV. Early detection and prompt linkage to TB treatment along with ART can prevent deaths among people with HIV. HTS provides an important opportunity to screen for TB symptoms in settings with high HIV and TB burden and thus contribute to TB case finding *(23-25).* All people diagnosed with TB in HTS should be offered TB treatment promptly within HTS or, if that is not available, referred to appropriate TB services.

- **Clinical and prevention services for key populations.** These include drop-in centres, harm reduction services for people who inject drugs and clinical services in prisons and other closed settings. It is important to remember that key populations in many settings do access facilities for health services, and, when they do so, it is important to minimize missed opportunities for HTS. See Chapter 6 for special considerations for HTS among key populations.

- **Clinical services providing STI testing and treatment.** HIV and STI co-infection is common *(26)*. STI clinics provide an important entry point for HTS that should be prioritized. WHO recommends routinely offering HTS to all people with STIs *(1)*. HTS in STI clinics is feasible, and uptake of HTS is high in these settings *(27-29).*

- **Viral hepatitis services.** Major opportunities also exist to integrate HTS into viral hepatitis services. Integration should be prioritized for populations most affected by both HIV and hepatitis, such as people who inject drugs and prison populations *(30-32)*.

- **VMMC clinics.** Voluntary HTS is part of VMMC service delivery in the 14 high HIV burden countries of eastern and southern Africa[2] *(33).* When offered, HTS uptake is high among men in VMMC services *(34, 35).* In some settings, however, structural and policy barriers, such as intermittent stockouts of HIV test kits and the need for separate parental consent to test young adolescents, contribute to low testing uptake *(35).* These structural and policy barriers, including age of consent laws, need to be addressed to facilitate effective HTS integration with VMMC services.

2 Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

- **Outpatient, inpatient and emergency services in hospital settings.** In all settings, HTS should be offered in inpatient and outpatient hospital settings to clients with symptoms and clinical conditions indicative of or related to HIV infection *(36).* This approach has proved effective in Europe *(37-40),* but it has not been systematically implemented in other regions. Routine offer of HTS in hospital emergency departments can also be considered in high burden settings *(41).*

  In low HIV burden settings or where HTS among key and other vulnerable populations are not readily available, risk-based screening tools or questionnaires which identify people who can be offered testing may help to increase coverage among those who may not test otherwise *(42).* Such tools should be carefully considered and implemented only after validation, including review and consultation with populations with whom they would be used (see Chapter 7).

5.3.2 Community-based HIV testing services

Community-based testing refers to HTS offered in the community, outside of a health facility. WHO recommended community-based HTS in 2013 to expand testing, particularly among key populations and their partners, young people, men and others who may be less likely to test in facilities.

Community-based HTS can be delivered in many ways and in different settings and venues. These include HTS at fixed locations in the community, including community-based VCT sites, mobile outreach in hotspots and community sites such as parks, bars, clubs, cruising sites, saunas, and at event, places of worship, workplaces and educational establishments, sometimes with the use of mobile vans. Community-based HTS can also be delivered at peoples' homes, usually referred to as home-based HTS *(1)*. Home-based HTS can either be offered to eligible members in all households in a certain area – that is, door-to-door – or it can be more focused – for example, in the context of HIV partner services.

Community-based HTS can be conducted by trained lay providers and peers using RDTs and the test for triage strategy. Community-based HTS can be delivered either alone or in combination with testing and screening for other infections such as TB, viral hepatitis and STIs or as part of other community services such as maternal and child health, contraception and family planning. Appropriate training and supervision of providers is needed when combining HTS with other infections and services.

Box 5.4. WHO recommendations on community-based HTS

In high burden settings, community-based HIV testing services are recommended, with linkage to prevention, treatment and care services, in addition to routine facility-based testing, for **all populations**, particularly key populations *(strong recommendation, low quality of evidence).*

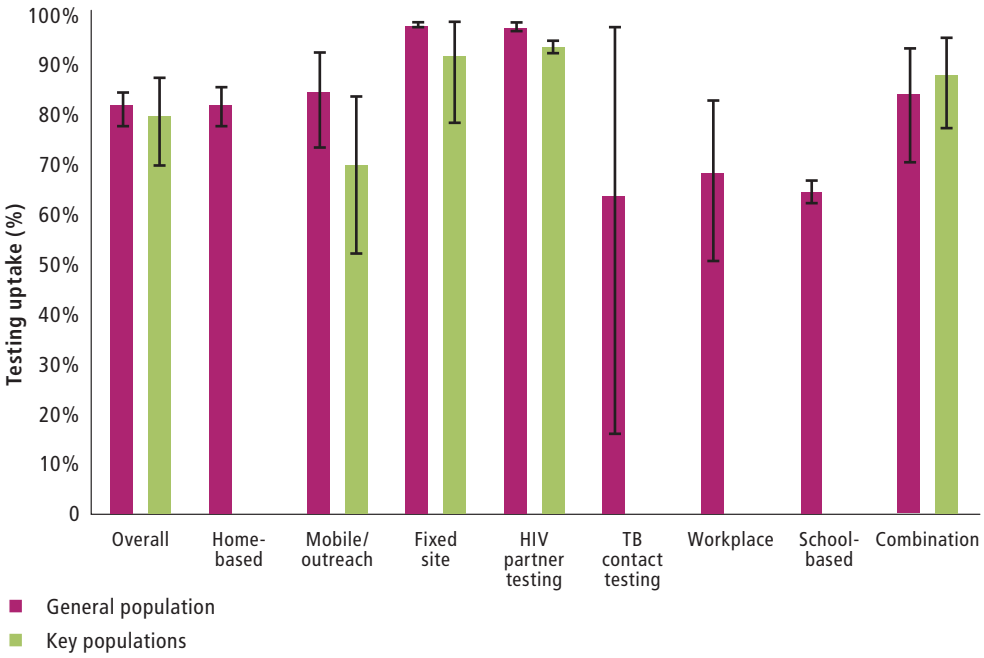
In low burden settings, community-based HIV testing services are recommended for **key populations**, with linkage to prevention, treatment and care services, in addition to routine facility-based testing *(strong recommendation, low-quality evidence).*

Source: WHO, 2013 *(43);* WHO, 2015 *(1).*

As of July 2019, 82% (107/130) of reporting countries globally were using community-based HTS approaches *(44).* A systematic review conducted to support this guideline update showed that the use of community-based HTS has expanded considerably and is an effective approach for reaching people who may not otherwise test. The review identified nearly 500 studies that reported on community-based HTS outcomes, with two thirds (n=336) of these studies published between 2015 and 2018 *(45).* The studies were conducted across all WHO regions; 390 reported HTS outcomes for the general population, and 190, for key populations.

This review showed high **uptake** of community-based HTS among those eligible or offered HTS in both the general population and key populations, with pooled HTS uptake of 82% and 80%, respectively. There were differences in uptake by community-based HTS model and target population (Fig. 5.1). In the general population studies, more than half (56%) of people tested were **men**, with workplace HTS reaching the greatest proportion of men (91%). Nearly half of all people tested (46%) in the general population were **first-time testers**, while over two thirds (70%) were first-time testers among key populations.

Fig. 5.1. Uptake of HIV testing in community-based HTS, by population type and community-based service delivery model, pooled results



Note: Error bars represent 95% confidence intervals; combination = combination of different community-based HTS models.

HTS needs to be efficient in reaching and diagnosing people with HIV and linking them to treatment. Pooled HIV **positivity** from the review showed 8% positivity for the general population and 9% for key populations. The proportion of people diagnosed HIV-positive through community-based HTS varied by approach, setting and population type. However, it is not always appropriate to directly compare positivity rates between service delivery models if they serve different populations with varying epidemiology and background HIV burden. The majority of those diagnosed through community-based HTS were **newly diagnosed**: 76% in the general population and 89% in key populations.

The proportion of people diagnosed HIV-positive through community-based HTS and **linked** to treatment or care varied by local epidemiology, setting, approach and population, but generally appeared comparable to the proportion in facility-based HTS. The pooled linkage estimates for the general population and key populations were 62% and 81%, respectively. It is possible that linkage in community-based HTS is underestimated due to loss to follow-up and because some people may already know their status and taking ART.

Combining community-based HTS with testing for other infections and conditions is feasible and achieves high HIV testing uptake.

The review also showed that **combining** community-based HTS with testing for other infections and conditions is feasible and achieves high HIV testing uptake. The uptake of HIV testing was generally high when HTS was delivered in combination with other STIs (pooled HTS uptake: 95%) or both STIs and TB (pooled HTS uptake: 91–93%), but relatively lower when HTS was combined with testing only for TB (pooled HTS uptake: 71%) or other chronic conditions (pooled HTS uptake: 67–77%).

Implementation considerations for community-based HTS

Community-based HTS has become an integral component of national HTS plans in many countries around the world. There are several issues to consider when implementing community-based HTS or selecting community-based HTS models for differentiated HTS:

- **Timing and frequency.** Community-based HTS can be offered continuously, on a regular schedule or as a one-time service at special events and campaigns. Continuous services may be appropriate for men and young people in high HIV burden settings or key populations, who typically have low uptake of HTS. Providing community-based outreach at convenient times for priority populations is important – for example, "moonlight" or evening testing for members of key populations or on weekends or after working hours for men. While dedicated events or campaign-style HTS may reach large numbers of people in a short period, it is likely to be not a useful strategy for identifying people with undiagnosed HIV infections or those at ongoing risk of HIV unless the events particularly attract a priority population.
- **Focused services.** Evidence shows that community-based HTS is highly acceptable and, when focused appropriately, can reach first-time testers and people with undiagnosed HIV infection. It can also achieve good linkage to

For greatest impact, community-based HTS needs to be focused on populations and settings with the greatest unmet testing need.

treatment or care among those diagnosed. Not all community-based HTS approaches may be appropriate or needed for all settings, however. For greatest impact, community-based HTS needs to focus on populations and settings with the greatest unmet testing need. It is also essential to engage communities when designing community-based HTS. Services are likely to succeed when they have the community's buy-in or are community-led *(46, 47).*

- **Resource use.** Because the cost of delivering community-based HTS varies widely in different settings, resource needs and sustainability needs to be carefully considered. The cost and cost-effectiveness of community-based HTS will depend on many factors, such as local epidemiology, the populations reached, the HIV positivity and the general costs of delivering HTS in the specific setting. Community-based HTS approaches that are focused and identify more people with HIV are likely to be cost-effective.
- **Linkage.** As for any HTS, linkage to appropriate services after community-based testing is critical. Evidence suggests that community-based HTS can achieve good linkage for those diagnosed HIV-positive. However, in some settings and for some populations – for example, transgender people, people who inject drugs and people diagnosed through home-based HTS – additional support may be needed to facilitate linkage. For those testing HIV-negative but at ongoing HIV risk, effective referral pathways to prevention services need to be established (see Chapter 4).
- **Workplace HTS.** HTS in the workplace is an effective strategy for reaching men in high burden settings, such as mining operations, the transport and logistics sector, the military and other uniformed services, as well as workers in the informal sector, such as in taxi ranks and markets. The number of people with HIV in the workforce is estimated to reach 30 million globally by 2020 *(48).* Thus, the workplace is an important venue for reaching people with undiagnosed HIV, especially men who often cannot readily access health services elsewhere. Any HTS in the workplace should be implemented within a framework of workplace policies that ensure confidentiality and protect workers who are diagnosed HIV-positive from losing their jobs and from other discrimination (*49).*
- **Mobile outreach.** When focused on key populations and men, mobile outreach can complement facility-based HTS in areas of low coverage and poor accessibility.
- **Faith-based HTS.** Faith-based settings also provide a promising avenue for HTS *(50).* The use of HIVST kits in this setting can improve acceptability of offering HTS.
- **Home-based HTS.** HTS offered in the home has the potential to reach undiagnosed people in high burden settings. It can reach men effectively only if offered at timings outside of work hours. Recent studies demonstrate that delivery of home-based combination prevention interventions including HTS can reduce HIV incidence if high coverage is achieved and sustained *(51, 52).* This strategy is likely to be resource-intensive. Therefore, potential benefits and resource needs should be carefully considered. Home-based HTS in the context of partner services, such as provider-assisted referral and TB contact testing, should always be available for partners and contacts of people with HIV (see section 5.3.4).
- **Community campaigns.** These may be designed to serve rural and remote populations with limited access to facility-based HTS, as well as men in high burden settings. Community campaigns will likely not be an effective approach for low burden settings

as the great majority of people tested will likely be HIV-negative, unless focussed on a priority population. Large-scale regional or national campaigns can promote and normalize HIV testing, although they may not be effective in identifying people with undiagnosed HIV and linking them to appropriate prevention, treatment and care.

- **School-based HTS.** This may not be an optimal approach for reaching people with undiagnosed HIV infection. However, in high burden settings school-based programmes offer opportunities for HIV testing in the context of broader HIV prevention and sexual and reproductive health education and interventions. Adolescents often have limited access to health facilities. Therefore, school-based HTS may provide an entry point for a range of health services for sexually active adolescents. It may be particularly relevant for reaching adolescent girls in settings with high HIV incidence.
- **Combination services.** Community-based HTS in combination with testing and screening for other infections and conditions is feasible and effective, particularly when offering HTS with STI testing for key populations. Depending on epidemiology, this strategy can be considered for optimizing the use of community-based testing resources and improving efficiency, where feasible.

5.3.3 HIV self-testing: evidence and recommendation

Background and rationale

HIVST is a process in which a person collects their own specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and interprets their results, when and where they want. In 2016 WHO recommended HIVST as an additional HIV testing approach *(53)*. HIVST has emerged as an effective tool in expanding HTS among people at risk of HIV who may not otherwise test and those at ongoing risk who need to test frequently *(53, 54).* Globally, many countries have developed HIVST policies, and implementation is growing *(44).* However, further operational guidance is needed to support implementation.

HIVST is a process in which a person collects their own specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and interprets their results, when and where they want.

WHO conducted a systematic review to update existing guidelines on HIVST and to provide new guidance to optimize HIVST implementation, including effective service delivery models, linkage to care and support tools. In this guideline WHO issues an update to the 2016 guidance and strongly recommends HIVST as an approach to HTS. The following sections summarize the findings of the systematic review and the updated guidance on HIVST (see also Web Annex B).

Review of the evidence: systematic review on HIVST

The systematic review included 32 randomized controlled trials (RCTs): 17 individual randomized RCTs *(55-71)* and 15 cluster RCTs *(72-86)*. Twenty-one RCTs were conducted in

the general population *(55-58, 61, 63, 65, 67, 68, 73-81, 83, 84, 86)* and 11 in key populations – eight among men who have sex with men *(59-61, 64, 66, 69-71, 87)* and three among female sex workers *(62, 72, 82).* No RCTs were conducted exclusively among other key populations, that is, transgender people, people who inject drugs and people in prisons or other close settings. Most RCTs used oral fluid HIVST kits, while one used blood *(88),* and one used both oral fluid and blood-based HIVST kits *(64).*

The RCTs used a range of HIVST service delivery models and support tools, which are classified as summarized in Box 5.5. Box 5.6 summarizes key findings from the systematic review.

Box 5.5. HIVST service delivery models and support tools* used in RCTs

HIVST service delivery and distribution models

- Kit requested online or over the phone and delivered through mail
- HIVST distribution from a facility or fixed site for later use
- HIVST at the facilities where HIVST kits were distributed
- Home- or community-based HIVST distribution
- Secondary HIVST distribution by facility clients to their peers
- Secondary HIVST distribution by ANC clients to their male partners
- Secondary HIVST distribution by HIV-positive facility clients to their partners

HIVST support tools**

- No support or basic support only with use of the standard, manufacturer-provided instructions for use (IFUs) and manufacturer-provided telephone hotline or other customer support
- Tailored, translated or pictorial IFUs designed for the populations being served with or without additional support such as local telephone hotline;
- One-on-one in-person HIVST demonstration
- One-on-one in-person HIVST demonstration with observation or supervision of self-testers
- HIVST demonstration in a group setting
- Virtual real-time support or supervision through online platforms

* This is not an exhaustive list. Only service delivery models and support tools used in the eligible RCTs are listed. Other models and tools are available that may be effective and can be considered.

** Some studies used support tools from more than one category but they were classified according to the most intensive support mechanism.

Box 5.6. Key findings from the systematic review

Overall, the 32 RCTs included in the systematic review showed, that compared with standard facility-based HIV testing:

- HIVST increases the uptake of HIV testing.
- Proportions of people diagnosed and linked to care with HIVST are comparable to those with facility-based testing.
- Misuse of HIVST and social harms associated with HIVST are rare. No suicides were reported.
- HIVST does not increase sexual risk behaviour among men who have sex with men.
- A range of HIVST service delivery models and support tools are found to be effective.
- Many people are willing and able to perform HIVST with minimal support.
- HIVST is acceptable and feasible in a range of populations and settings.

The evidence reviewed showed that HIVST using a range of service delivery and distribution models, either with or without support, consistently increased **uptake** of HIV testing compared to standard facility-based HTS among key populations and the general population including men, women and young people ages 15–24 years. A meta-analysis showed an overall 60% higher uptake of HIV testing with HIVST than with standard facility-based HTS.

Both HIV **positivity and linkage** following HIVST were comparable to standard facility-based HTS. A meta-analysis showed HIV positivity (number diagnosed positive among those who had an HIV test) with HIVST was similar to standard facility-based HTS. Among those diagnosed with HIV, meta-analysis showed the proportion that were linked to HIV care or ART initiation with HIVST was similar to that with standard facility-based HTS. The linkage rates did not differ between arms when HIVST arm participants diagnosed HIV-positive were offered support for linkage including financial incentive, home visit or in-person referral, phone reminder or follow-up and virtual real-time linkage support.

When HIVST only, without linkage support, was compared with HIVST with linkage support, meta-analysis showed that providing support with HIVST increased linkage. The effect seemed to be driven by studies that involved HIVST with home-based ART initiation *(79)*, HIVST with in-person referral (peer navigation) *(89)* and provider financial incentives conditional on linkage *(90).*

Misuse, adverse events and social harms associated with HIVST (including coercion and partner violence) were rare and were similar between HIVST and standard facility-based HTS arms. Adverse events, especially relationship breakdown, was often temporary and resolved within days and was sometimes exacerbated by pre-existing conditions within a couple, such as alcohol abuse and history of gender-based violence *(80)*. No suicides were reported in any of the RCTs.

Condomless sex did not increase among men who have sex with men who used HIVST. Meta-analysis showed the proportion of men who have sex with men reporting condomless anal intercourse with male partners was similar between the HIVST and facility-based HTS arms.

Review of **values and preferences** for HIVST included 74 studies from 23 countries *(66, 91-163).* Nearly half (49%) of studies included key populations. An additional 11 studies examining health-care worker and provider values and preferences were also included *(92, 103, 112, 118, 123, 125, 130, 137, 139, 154, 156).*

Willingness to self-test was high across studies in both the general population (72–98%) and key populations (61–100%). A study in Viet Nam that offered HIVST at drop-in houses or coffee shops reported a 50% willingness to use HIVST *(164).* Self-testers viewed many different HIVST service delivery models feasible, including HIVST distribution from pharmacies, vending machines, pick-up from a local store, peer-based distribution, community-based distribution, online ordering and mail delivery and facility-based distribution. Barriers to HIVST were few and related to a small proportion of users reporting concerns about HIVST accuracy, user errors, lack of counselling or support, and cost of HIVST kits.

Little information was provided on preferred support tools and whether counselling referred to pre-test information or post-test counselling. Self-testers generally expressed a desire for some support when self-testing, especially when coping with a reactive HIVST result. In two studies *(91, 159)* self-testers wanted support for linkage to care without the need to visit facilities, such as via phone or text messaging, to avoid stigma and discrimination. Men who have sex with men and transgender women typically did not want counselling with HIVST, but instead preferred support through systems that did not require them to see a provider, such as telephone or automated systems *(99, 139, 156, 157).*

Many participants expressed a preference for low-cost HIVST kits, and some would use HIVST only if kits were available free of cost. Health-care workers also felt that HIVST should be provided at the minimum possible cost and that governments should procure kits and regulate the prices *(112, 123, 137-139, 154).*

In general, participants expressed a preference for kits with discreet design and packaging and clear, simple instructions *(94, 122, 139, 145, 154, 157)*. There was no clear preference for one or the other type of specimen, that is oral fluid or blood. Some participants preferred oral fluid because it is painless and perceived to be simple *(93, 116, 134, 140, 144, 150).* Others considered a blood-based test to be more accurate *(98, 121, 124, 145, 163, 165).*

Providers and health-care workers were generally supportive of HIVST introduction, albeit with some concerns. They felt HIVST could increase access to HIV testing, particularly for high risk or vulnerable populations *(92, 114, 125, 137, 139, 156)*. Some expressed concerns about the potential for misuse and harm for users and that the availability of HIVST would affect their jobs *(123, 125, 137-139, 154, 156).*

Feasibility

The supply line of HIVST products is strong and diverse and has continued to grow. As of 2019, 77 countries have national policies that support HIVST, and 38 of them are implementing HIVST programmes. Policies are under development in another 47 countries, and 33 countries are piloting HIVST *(44)*. As of December 2019 WHO had prequalified four HIVST products[3] and stringent regulatory authorities have approved others *(166).* This provides a choice of suppliers and specimen type for national programmes and donors planning to procure HIVST kits.

Several HIVST studies and evaluations have been conducted in diverse geographies, representing nearly all regions and a range of populations including key and vulnerable populations. Lay users can perform HIVST reliably and accurately and achieve performance comparable to that of trained health-care workers *(167).* Evidence of high uptake, acceptability, accuracy and safety of HIVST; global progress in policy and implementation; and a strong product supply line indicate that HIVST is feasible to implement in many settings and that a strong foundation for implementation and scale-up exists.

Lay users can perform HIVST reliably and accurately and achieve performance comparable to that of trained health-care workers.

Cost and resource use

According to the 2018 HIVST market and technology landscape report *(166)*, the prices of quality-assured HIVST kits range from US$ 2–40 per kit. Prices are typically lower for the public sector procurement than the retail price in the private sector. Prices also tend to be lower in low- and middle-income countries (US$ 2–12) than in high-income countries (US$ 7.50–15).

HIVST cost data were available from 12 studies in five low- and middle-income countries (Kenya, Malawi, South Africa, Zambia and Zimbabwe) *(57, 61, 62, 73-75, 79-81, 168-170).* The reported HIVST cost estimates varied widely for cost per HIVST kit distributed (range: US$ 8.90–36.40); cost per person tested (range: US$ 4.70–86.30); cost per person testing HIV-positive (range: US$ 18.90–2651.70); and cost per person initiating ART (range: US$ 84.90–1698). Only one study reported costs from a high-income setting (USA), with a cost per person tested of US$ 41 and a cost per person tested HIV-positive of US$ 4620 *(171).*

The costs of HIVST generally appeared to be higher than costs of facility-based testing, and the cost of community- or home-based HIVST distribution tended to be higher than that of facility-based HIVST distribution. However, there are important limitations to such comparisons, given that cost data come from different sources and settings, therefore, are not directly comparable. Moreover, these costs are general programme costs and do not consider opportunity costs to testers or accessibility and equity issues.

3 The latest information can be accessed from the WHO public reports for all prequalified self-test kits at https://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/.

Four studies were identified, all in sub-Saharan Africa, that reported on the cost-effectiveness of HIVST *(172-175).* While all these studies report that HIVST can be cost-effective, the most recent study suggested HIVST is cost-effective in high prevalence settings when focused on priority populations, such as men and sex workers, and implemented in a time-limited manner (for example, five years or until undiagnosed HIV prevalence falls below 3%) *(176).*

Equity and human rights

In light of the evidence reviewed, the Guideline Development Group (GDG) noted that HIVST appears to reach people in need of HIV testing and who remain unreached by other HTS approaches. These include members of key populations and other vulnerable populations, including men and young people. The GDG felt that HIVST can improve equity and reach those who may not otherwise test.

Recommendation

Considering the evidence on effectiveness of HIVST, its acceptability and feasibility to implement and potential for cost-effectiveness and improving equity, the GDG deemed that the overall benefits of HIVST outweigh the potential harms and risks. By consensus, the GDG decided to update the 2016 recommendation on HIVST with additional remarks (see Box 5.7). The strength of the recommendation and quality of evidence was determined through the GRADE approach.[4]

Box 5.7. WHO recommendation on HIVST

Updated HIV self-testing should be offered as an approach to HIV testing *(strong recommendation, moderate quality evidence).*

Remarks

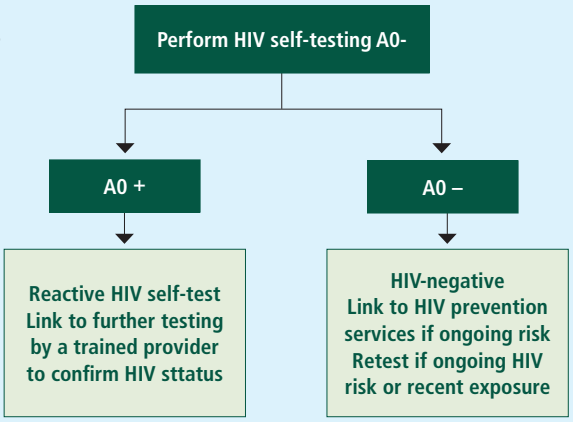
- Providing HIVST service delivery and support options is desirable.
- Communities need to be engaged in developing and adapting HIVST models.
- HIVST does not provide a definitive HIV-positive diagnosis. Individuals with a reactive test result must receive further testing from a trained tester using the national testing algorithm.

Considerations for successful HIVST implementation

National programmes should define a minimum communication package for HIVST including key information and messages for providers, self-testers and the community (see Box 5.8).

4 The Grading of Recommendations Assessment, Development and Evaluation (GRADE) for systematic reviews. See WHO handbook for guideline development, 2nd edition. https://apps.who.int/iris/handle/10665/145714.

Box 5.8. Key messages for providers, self-testers and communities



HIVST is a test for triage and does not provide a definitive HIV-positive diagnosis. **A reactive (positive) HIVST result is not equivalent to an HIV-positive diagnosis.** All reactive HIVST results need to be followed by further testing by a trained provider to confirm HIV status, starting with the first test in the national testing algorithm.

Nonreactive HIVST results should be considered negative, with no need for immediate further testing except for those starting pre-exposure prophylaxis (PrEP). **For people starting or already taking PrEP, HIVST cannot replace initial or subsequent quarterly facility visits and testing.**

Those with **invalid HIVST results** need to repeat the test using another HIVST kit or to seek testing from a trained provider. Any person uncertain about their HIVST result should be encouraged to seek testing from a trained provider.

HIVST is not recommended for people with HIV who are on ART, as false-negative HIVST results can occur. Those who are HIV-positive but not on ART should be encouraged and supported to initiate ART.

Retesting following a negative self-test result is necessary only for those at ongoing risk, such as people from key populations and those reporting potential HIV exposure in the preceding 12 weeks.

HIVST means testing yourself. HIVST is for individuals who want to test and learn their HIV status on their own. Offering a HIVST kit to a sexual partner, friend or adult family member and encouraging them to use the self-test can often be a good way to help them learn their HIV status. However, a person should never be coerced or forced to self-test. **Coercive or mandatory use of an HIVST kit should never be supported or encouraged and is not considered self-testing.**

WHO does not recommend parents or guardians use HIVST kits to test their babies or children. HIVST will not provide a correct result in children less than 18 months old because the mother's antibodies may still be present in the infant.

Other considerations for successful programming include:

- **Clear and supportive policies, regulations and standard operating procedures** need to be developed and disseminated to distribution sites and providers to support proper implementation. These should ensure access to **quality-assured HIVST products**[5] and adequate **post-market surveillance** including systems for reporting

5 WHO prequalification: https://www.who.int/diagnostics_laboratory/evaluations/pq-list/self-testing_public-report/en/.
Global Fund Quality Assurance Policy for Diagnostic Products: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/.
Additional information on these products and others in the pipeline is available in the 2018 Unitaid–WHO HIVST market and technology landscape report: https://unitaid.org/assets/HIVST-landscape-report.pdf.

and addressing complaints, adverse events and social harm (see Chapter 9). There are several quality-assured HIVST products to choose from, including three that have WHO prequalification – one oral fluid and two blood-based tests.

- **HIVST should be implemented within a differentiated national HTS plan in a focused way** that prioritizes areas and populations with the greatest gaps in testing coverage. Available resource will need to be considered when selecting service delivery models and support tools.
- **A range of HIVST service delivery and distribution models are effective** in increasing uptake of HIV testing and reaching those who are undiagnosed or at ongoing risk. HIVST kits can be provided through publicly funded or donor-supported programmes (for example, facility or community-based distribution), in the private sector (for example, through pharmacies or retail outlets), as well as through public–private partnerships (for example, workplace programmes). Where feasible, **offering choice in HIVST service delivery options and type of test kits** (such as between kits using oral fluid or blood) can help to reach more people.
- **Consider support needs of populations.** Many people will be able to perform HIVST with minimal or no support, although some people may need and want support such as those with lower literacy and older ages. When considering resource-intensive support options, such as home-based distribution, HIVST training, and in-person demonstration or supervision, the added benefit needs to be weighed against use of resources. Such resource-intensive support mechanisms can limit scalability and should only be considered for a limited time. The support needs of self-testers are expected to decline as programmes evolve, public awareness increases and people gain experience with HIVST. **New digital, social media and video or messaging platforms** can also be considered to support self-testers. These may be readily acceptable, especially to young people, and less costly than in-person support.
- It is important to **empower and effectively engage communities** in developing and adapting HIVST delivery and support models. The meaningful participation of community members and people from key populations in designing and delivering services should be ensured. Community organizations, local nongovernmental organizations, networks of people with HIV and people from key populations should be involved in programming, and they can also be engaged in HIVST delivery. Programmes and models that have buy-in from the community and are community-led are likely to succeed and achieve their goals *(177, 178).* Community engagement should include educating the community and providers to raise awareness and minimize misuse and harms in relation to HIVST (see Chapter 3).
- As for any HTS, **linkage to appropriate services after HIVST is critical** to achieve its full benefits. Those diagnosed HIV-negative but at ongoing risk should be linked to prevention services. Those with reactive HIVST results should be supported in linking to services for further testing by a trained provider using the national testing algorithm and, if diagnosed HIV-positive, to immediate ART initiation (see Chapter 4). Where resources are available, programmes can consider strategies such as home-based ART initiation, in-person referral/peer navigation and provider incentives to promote linkage.
- When comparing the cost of HIVST with other HTS approaches, it is important to **consider the full cost of service delivery**, not just the cost of the HIVST kits *(54).* Some delivery models in the private sector, such as pharmacy sales, will incur costs to

users, and this should be considered in the context of accessible and affordable HTS. Low-cost, high-impact HIVST models, with a focus on priority populations in strategic geographical areas, are more likely to be cost-effective.

- Careful **ongoing monitoring and evaluation (M&E) are necessary** to optimize HIVST implementation. This will require developing an M&E plan, selecting key programme indicators, collecting relevant data, reviewing progress regularly and adjusting service delivery accordingly. Pragmatic approaches and triangulation of available data – for example, use of programme data, ART coverage data and results of special surveys – are needed to effectively monitor HIVST outcomes and impact (see Web Annex H).
- Programmes should explore the potential for **integrating** HIVST with other currently available self-sampling technologies for STIs (chlamydia, gonorrhoea, human papillomavirus) as well as with broader self-care interventions including contraception to support the delivery of comprehensive sexual and reproductive health services *(179)*.

5.3.4 HIV partner services

Partner services, that is, offering voluntary HTS to sexual and/or drug injecting partners of people with HIV, is an effective way of identifying additional people with HIV. Partners who are diagnosed with HIV can be linked to treatment services, and those who are HIV-negative and at ongoing risk of HIV acquisition can be linked to effective HIV prevention. When conducting partner services, it is also important to offer HIV testing services to the biological children of the HIV-positive client, when their HIV status is unknown.

Partner services are highly effective in identifying additional people with HIV.

Box 5.9. WHO recommendations and best practice statement on partner services

Voluntary provider-assisted referral (often called assisted partner notification) should be offered to people with HIV as part of a comprehensive package of testing and care *(strong recommendation, moderate-quality evidence).*

HIV testing services for **couples and partners**, with support for mutual disclosure, should be offered to individuals with known HIV status and their partners *(strong recommendation for all people with HIV in all epidemic settings; conditional recommendation for HIV-negative people depending on the country HIV burden; low-quality evidence).*

Good practice statement

In all settings **biological children** of a parent with HIV should be routinely offered HTS and, if found to have HIV or to be at high risk for infection through breastfeeding, should be linked to services for treatment or prevention within a broader package of voluntary provider-assisted referral.

Sources: WHO, 2012 *(180);* WHO, 2016 *(53);* WHO, 2016 *(4).*

Partner services include partner notification, contact tracing, index testing and family-based index case testing for reaching partners of people with HIV. In this guideline we use the term "partner services" as an inclusive term encompassing a range of partner services packages and approaches including social network-based approaches.

HIV partner services can be delivered in many ways, including patient referral and provider-assisted referral, as summarized in Box 5.10. Provider-assisted referral is safe and acceptable and, compared with patient referral, has been shown to increase the uptake of HTS, identify additional undiagnosed HIV infections and improve linkage to care among partners *(53)*. In 2016 WHO recommended that voluntary provider-assisted referral (often called assisted partner notification) should be offered to people with HIV as part of a comprehensive package of testing and care *(53)*. Where feasible and acceptable to the client, provider-assisted referral should be prioritized, as it is more effective and provides the opportunity to offer comprehensive prevention interventions to partners who are HIV-negative but remain vulnerable to HIV acquisition.

HIV partner services have yet to be widely implemented in many settings globally, particularly among key populations. This is often due to policy and structural barriers and confidentiality concerns. **Social network-based HIV testing** offers a complementary approach for reaching the sexual or drug injecting partners and social contacts of key population members. These approaches also can expand the scope of testing to HIV-negative partners and social contacts of key populations members, thus making testing services more acceptable and normalizing their use. In this guideline, WHO reviewed the evidence on social-network-based approaches for key populations and issued a new recommendation (see Section 5.3.5).

Box 5.10. Methods for delivering HIV partner services

Partner services are a process whereby a trained provider offers voluntary HTS to sexual and/or drug injecting partner(s) of consenting HIV-positive clients.

Partner services can be delivered in many ways, including patient referral and provider-assisted referral.

In **patient referral** (also called passive referral) a trained provider encourages HIV-positive clients to disclose their status to their sexual and/or drug injecting partners by themselves and to suggest HTS to the partner(s). Patient referral involves advice from the trained provider regarding the need for partner(s) to get tested, strategies for disclosing HIV-positive status safely and where and how the partner(s) can access HTS. HIV-positive clients may inform their partners either in person or by other means, such as a telephone call, text message or email.

In **enhanced patient referral**, the trained provider uses various support tools to facilitate disclosure and the offer of HTS by HIV-positive clients to their partner(s). These tools may include providing written information, leaflets and a referral slip or card for the partner(s), use of web-based messaging platforms to inform the partner(s) anonymously, as well as providing HIVST kits to HIV-positive clients to give to their partner(s) to test themselves for HIV.

Box 5.10. Methods for delivering HIV partner services, continued

In **provider-assisted referral** (also called assisted partner notification), a trained provider asks people with HIV about their sexual and/or drug injecting partners and then, with the consent of the HIV-positive client, informs the partners of their potential exposure to HIV. The provider then offers voluntary HTS to these partners. The provider can contact partner(s) by telephone, email or in person and offer them home-based HTS or invite them to visit a facility to receive HTS.

Where feasible and acceptable to the client, provider-assisted referral should be prioritized, as it is more effective and provides the opportunity to offer comprehensive prevention interventions to partners who are HIV-negative but remain vulnerable to HIV acquisition.

Provider-assisted referral can be offered at the time of diagnosis of the HIV-positive client and periodically through the course of the client's engagement with the health-care system. The provider-assisted referral method and timing can be adapted to suit the client's needs and preferences as follows:

- In **provider-assisted delayed referral** (also called contract referral), HIV-positive clients enter into an agreement with a trained provider to disclose their status to their sexual and/or drug injecting partners by themselves and to suggest HTS to them *within an agreed period*. If the partner(s) of the HIV-positive client does not access HIV testing services or contact the health-care provider within that period, the provider will contact the partner(s) directly and offer voluntary HTS. This can be useful when provider-assisted referral is not feasible at the time of diagnosis of the HIV-positive client, for example, when the client is not ready and needs time to absorb the diagnosis.
- In **provider–patient referral** a trained provider accompanies and provides support to HIV-positive clients when they disclose their status and the potential exposure to HIV to the clients' partner(s). The provider then offers voluntary HTS to the partner(s). This can be useful when the client prefers to disclose their status to a partner but needs support from a provider to offer voluntary HTS.

Social network-based HIV testing is an extension of HIV partner services. A trained provider asks people with HIV or those who are HIV-negative and at ongoing risk of HIV to encourage and invite individuals in their sexual, drug injecting or social networks to participate in voluntary HTS. A social network refers to a group of individuals linked by a common set of relationships or behaviours and includes social contacts as well as sexual and drug injecting partners. Testing may be offered for either limited times (often called "waves") or continuously depending on resource availability. Social network-based approaches to HIV testing are a particularly useful option for reaching people in key populations. Social network-based HIV testing can involve distribution of HIVST kits (see section 5.3.5).

Note: When conducting partner services, it is also important to offer HIV testing services to the biological children of the HIV-positive client, when their status is unknown. All infants exposed to HIV during pregnancy (that is, born to HIV-positive mothers) or breastfeeding should receive HIV testing to ascertain their HIV status and to start ART immediately if HIV-positive. Because of the persistence of maternal antibodies, antibody tests cannot be used, and virological testing such as nucleic acid testing (NAT), is required instead for infants under two years of age (see Chapter 6).

5.3.5 Social network-based HIV testing approaches: evidence and recommendation

Background and rationale

Globally, adoption of HIV partner services policy and implementation is increasing. As of July 2019, nearly three years after the 2016 WHO recommendation, 57% (73/128) of reporting countries had a policy on HIV partner services and were using provider-assisted referral, an increase from 45% in 2017 *(44).*

Although partner services are safe and effective, implementation among key populations remains limited.

Despite such progress, members of key populations and their partners do not seem to be fully benefiting from HIV partner services and provider-assisted referral *(53, 181).* Although partner services are safe, feasible and effective among key population members and their partners *(53, 182),* implementation remains limited. This is often attributed to policy and structural barriers, confidentiality concerns and the reluctance of key population members to identify their partners to providers due to fear of stigma, discrimination and lack of confidentiality *(181, 183).*

Social network-based HIV testing approaches have been proposed as a complementary approach to address some of the challenges in scaling up HIV partner services among key populations, particularly challenges of confidentiality. By addressing confidentiality concerns and broadening the reach of partner services to include both HIV-positive and HIV-negative members of key populations, their partners, social contacts and networks, social network-based HIV testing approaches can improve the acceptability of partner services and so reach more people who may not otherwise test for HIV.

WHO conducted a systematic review to develop new guidance on social network-based HIV testing approaches. In this guideline WHO conditionally recommends social network-based HIV testing as an approach for key populations as part of a comprehensive package of care and prevention. The following section summarizes the results of the systematic review and the new WHO recommendation (see also see Web Annex C).

Review of the evidence: systematic review on social network-based HIV testing approaches among key populations.

The systematic review included 17 studies: 14 observational comparative studies *(184-197)* and three non-comparative studies *(198-200).* No eligible RCTs were identified. Eleven studies were conducted among men who have sex with men, three of which included transgender women; two were among people who inject drugs; one among female sex workers; and one study included both men who have sex with men and female sex workers. Box 5.11 summarizes key findings from the systematic review.

The evidence reviewed showed that social network-based HIV testing approaches may result in higher **HIV positivity** than other HTS approaches, suggesting its potential for identifying additional HIV infections. Meta-analyses showed that social network-based HIV testing tends to have a higher HIV-positivity than standard HTS or venue-based testing. The quality of evidence was very low.

Box 5.11. Key findings from the systematic review

Overall, studies included in the review showed that, among partners and contacts, social network-based HIV testing approaches:

- may increase HIV diagnoses and identify additional people with HIV;
- may increase the acceptability of HIV partner services;
- are feasible to implement;
- seldom result in social harm or adverse events;
- can be an efficient use of resources when they focus on people with high ongoing HIV risk.

Social network-based HIV testing approaches also tend to reach more **first-time testers** than standard HTS or venue-based testing, but evidence is uncertain because of wide range of estimates and very low quality. Evidence on effect of social network-based approaches on testing **uptake** is also inconclusive. A meta-analysis showed that uptake of HIV testing tended to be lower among contacts of key population members receiving social network-based HIV testing approaches than among those receiving standard HTS, with wide range of estimates and very low-quality of evidence. The studies suggest it is feasible for key population participants to recruit or invite their contacts for HTS.

Evidence on **linkage** to post-test services with social network-based HIV testing is lacking. Findings from one study suggest similar linkage to care for those diagnosed HIV-positive through online or in-person social network-based HIV testing approaches *(185).*

Social harm among contacts of people from key populations is infrequent. Across two studies, 5.5% of participants (7 of 128) reported an adverse event – which included five verbal arguments among men who have sex with men and two incidents of client-related violence among sex workers *(198, 200).* These incidents of violence among sex workers took place in a context of high rates of background violence (at baseline 41% reported a history of partner violence) *(200).*

Review of **values and preferences** for social network-based approaches identified 14 studies among men who have sex with men (n=10; one study also included transgender people) and female sex workers (n=4) *(188, 198, 201-212).* The studies demonstrated acceptability of social network-based approaches among intended users, particularly for approaches involving distribution of HIVST kits.

A considerable proportion of men who have sex with men in two studies expressed they would recruit their partners or contacts for HTS, and in some instances it would depend on the recruitment method *(205, 210).* In one study, high-risk HIV-negative men who have sex with men were given HIVST kits for their partners *(198)*. In this study 27 index participants offered HIVST kits to 124 partners, and 101 accepted the kits. Some men who have sex with men expressed concerns around using HIVST kits with partners due to fear of anger or other negative reaction from partners and not wanting to disclose their own results to them. Participants felt that using HIVST kits for testing immediately before sex was not ideal and they reported some anxiety while waiting for results *(198)*.

Female sex workers trained as peer educators acknowledged the importance of encouraging their sexual partners and social contacts to get tested for HIV *(188, 204)*. In another study, sex workers indicated that they would be receptive to trained peers providing pre-test information but not performing HIV testing *(206)*. In a study in which sex workers in Kenya distributed HIVST kits to their social and sexual contacts, participants reported that HIVST was easy to perform and that their contacts valued learning their HIV status *(207)*. In this study two of 16 female sex workers who suggested testing to their clients reported verbal and/or sexual abuse *(207)*.

There is limited evidence to date on the values and preferences related to social network-based testing among sex workers and other key populations including transgender people, people who inject drugs and people in prisons and other close settings. Further studies and implementation experiences will be important to understand potential benefits and harms of this approach for these populations.

Feasibility and resource use

The review identified studies of social network-based HIV testing approaches that were conducted in a range of geographic settings and key population groups. This diversity indicates that social network-based HIV testing approaches are feasible to implement among key populations, particularly when HIVST kits are used and in the context of partner services.

Three studies reported on the costs of social network-based HIV testing, two from the USA and one from India. The cost per contact tested was US$ 191 in the USA *(213)*. The cost of a new HIV diagnosis varied widely by population – US$ 189–61 165 for men who have sex with men compared with US$ 51–2072 for people who inject drugs in India *(214)*. The costs seemed to be driven by the HIV positivity rate among contacts.

One study in the USA reported that social network-based HIV testing among men who have sex with men was cost-saving compared with standard HTS *(215)*. The identification of new HIV infections was largely responsible for cost savings *(215)*.

Recommendation

Considering the evidence reviewed and the information on user acceptability, feasibility and resource needs, the GDG deemed that the overall benefits of social network-based testing are likely to outweigh the potential harms and risks. By consensus, the GDG decided to make a conditional recommendation on social network-based HIV testing (Box 5.12). The strength of recommendation and quality of evidence were determined through the GRADE approach.[6]

Box 5.12. WHO recommendation on social network HIV testing approaches

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

6 The Grading of Recommendations Assessment, Development and Evaluation (GRADE) for systematic reviews. See WHO handbook for guideline development, 2nd edition. https://apps.who.int/iris/handle/10665/145714.

Implementation considerations for partner services and social network-based HIV testing approaches

It is important to optimize partner services and social network-based HIV testing approaches to maximize impact. Partner services can be delivered in different ways, which include patient referral and provider-assisted referral, as summarized in Box 5.10. In addition to conventional partner services, social network-based testing approaches can be offered to key populations, where supported by national policy. To date most evidence of effectiveness of social network-based HIV testing approaches is from men who have sex with men with some evidence from other key populations including transgender people, people who inject drug and female sex workers. Involvement of networks and community groups in the design, development and implementation should be central if social network-based approaches are considered for key populations.

Considerations for partner services and social network-based HIV testing approaches include the following:

- It is critical to **respect and protect the privacy and confidentiality** of clients and their partners when providing partner services including social network-based approaches to key populations. This is particularly important when partners have not yet mutually disclosed their HIV status.
- It is important to **ensure that all partner services are voluntary.** Whenever partner services and social network-based approaches are offered, the client should be informed of their benefits and cautions and assure that their decisions about contacting partners and other people from their social networks are voluntary and not pressured.

> Partner services and social network-based approaches should always be voluntary. WHO does not support mandatory or forced partner services or HTS.

- Partner services and social network-based approaches can be **differentiated and adapted** according to the local context, setting and clients' preferences. While clients should be informed and encouraged to use provider-assisted referral, they should have the **opportunity to choose from all available options** for partner services or to decline it altogether. They can choose different methods for different partners. For example, they may prefer to inform their primary partners themselves (patient referral), but they may not be comfortable informing other partners and instead opt for provider-assisted referral.
- Where feasible and supported by national policy, social network-based HIV testing approaches can be offered to **both HIV-positive and HIV-negative members of key populations**. These can be particularly helpful where clients from key populations have been reluctant to take up the offer of provider-assisted referral because it requires disclosing their partners to providers, or for fear of stigma, discrimination or prosecution.
- All members of key populations newly diagnosed with HIV can be offered voluntary partner services, including social network-based approaches where appropriate, **at the time of diagnosis and periodically thereafter**, as needed; clients' willingness to accept partner services may change over time, or they may have new partners.

- When implementing social network-based HIV testing, consider whether it is beneficial to offer it for a **limited duration (or waves) or on an ongoing basis**. Social network-based approaches will be **most effective when focused** on networks of higher-risk people in key populations. Longer duration or more waves generally allow deeper penetration into these social networks and, thus, may identify more people with undiagnosed HIV, but they that will require more resources.
- **Providers must be aware of the potential for partner, sexual violence and abuse and must support clients in making decisions that ensure their safety.** People with anxieties about a partner's or social contact's reaction to offer of HTS should be able and supported to decline partner services. People from key populations, particularly sex workers, often experience sexual violence and other abuse. Making sure that services are voluntary and informed is critical to avoid any adverse consequences. Involvement of local sex worker networks and community members along with careful monitoring of any unintended adverse outcomes will be critical, so that programmes can be adjusted to address these. Women who disclose previous partner violence should be offered immediate first-line support by the health-care provider or another provider within the same health service or in another easily accessible service.
- **Community engagement, awareness and support** are critical to develop and effectively implement partner services, including social network-based HIV testing. It is particularly important to empower people from key populations and to ensure that they are educated about the potential benefits of and cautions with partner services.
- **Ongoing M&E** of approaches to implementing partner services are needed to improve service delivery and optimize their impact. This will require defining and collecting relevant indicators and developing a monitoring and evaluation plan (see Web Annex H). It is also important to monitor for social harms and, if unintended adverse outcomes are identified, to review and adjust programmes promptly.
- Where feasible, **integration of partner services** with partner services or contact tracing for other diseases can be considered, depending on the setting and epidemic, such as testing for other STIs, TB and viral hepatitis, to improve efficiency and optimize resource use.

Promising models and tools

From the evidence reviewed, several promising social network-based HIV testing models and tools emerged that can be considered. Other models suited to local context also can be considered and adapted as evidence and experiences grow.

- **Peer educators or recruiters** can effectively implement social network-based HIV testing. For example, in three west and central African countries, distribution of coupons for free HTS by peer outreach workers resulted in identification of additional HIV infections among sex workers. Both men who have sex with men and female sex workers have expressed support for social network-based HIV testing to encourage peers to test for HIV.
- **Distribution of HIVST kits to partners and social contacts** is a promising way to operationalize social network-based HIV testing. Distribution of HIVST kits by HIV-positive and HIV-negative clients to their partners and social networks is an acceptable

and feasible approach and may improve testing uptake. Using HIVST kits may improve the acceptability and coverage of partner services and make them more efficient. This approach should be accompanied by information and support tools to facilitate linkage to prevention, treatment and care services (see section 5.3.3).

- **New tools and technologies**, such as digital and social media, text messaging and other web-based platforms, to reach social networks, can be considered, and may improve acceptability of partner services especially among young key populations. Some people may prefer in-person contact, telephone calls or email.
- Use of **anonymous methods** for partner services and social network-based approaches may be appropriate to protect confidentiality, particularly for reaching adolescents and young key populations and in settings where key populations experience stigma, discrimination and criminalization.

Training of providers

Providers who deliver partner services, including social network-based approaches, need adequate training and capacity building, which should develop the knowledge, skills and capacity of the provider in these areas:

- **offering partner services in non-judgemental ways** including how to identify clients who would benefit from these services, how to engage with clients in discussion about partners and social contacts, how to locate partners and social contacts and how to offer them voluntary HTS or to support clients in offering HTS, and how to facilitate mutual disclosure for couples;
- **documenting and reporting** partner service attempts and outcomes (test uptake, test result and linkage), using standardized forms and links to index client records as part of routine programme monitoring (see Web Annex H);
- **monitoring and minimizing the risk of harm and violence** for clients and providers when delivering partner services, including ensuring the confidentiality of clients and their partners; if unintended adverse outcomes are identified these should be reported so programmes can be modified promptly;
- **awareness of legal and policy issues** that affect how providers discuss and offer HIV partner services, including social network-based HIV testing.

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IMPLEMENTATION CONSIDERATIONS FOR HIV TESTING SERVICES AMONG PRIORITY POPULATIONS

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KEY POINTS

- Efforts to provide and expand HIV testing services (HTS) should **prioritize populations most affected by and at high ongoing risk of HIV**, including those with specific individual or structural vulnerabilities. HTS efforts will work best when designed specifically to address each priority population's needs and preferences.
- **The populations that need to be considered for prioritization** in a particular setting depends on local epidemiology. This will often include key populations and their partners, men, adolescents and young people, pregnant women, infants and children, serodiscordant couples, sexual and drug injecting partners of people with HIV, as well as migrants, refugees, displaced populations and other vulnerable groups.
- **Key populations.** Key populations are often at high ongoing risk of HIV regardless of setting. Key populations include men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and transgender people. Everywhere, access to HTS and HIV prevention, treatment and care is inadequate for key populations. Voluntary HTS for key populations should be offered as part of comprehensive prevention services. Countries should prioritize, fund and support acceptable services for key populations and address the barriers that impede their access to HTS.
- **Men.** Globally, men with HIV are less likely to access testing, prevention, treatment and care than women. In many settings most members of key populations are men. In most high HIV burden settings, primarily southern Africa, HTS reaches fewer men than women, resulting in late diagnosis and initiation of treatment, advanced disease and HIV-related mortality. Programmes should consider HTS approaches designed for reaching men.
- **Adolescents and young people.** Adolescents (10–19 years of age) and young people (20–24 years of age), particularly adolescent girls and young women, remain especially vulnerable to HIV in high HIV burden settings in east and southern Africa. Adolescents and young key populations are often more vulnerable to HIV and have high HIV-related risk. Nonetheless, they are less likely to test than adults. Programmes should prioritize focused, adolescent-friendly approaches to reach adolescents and young people, particularly those from key population groups, in need of testing as determined by local epidemiology and context. Programmes are also encouraged to review and revise laws on age of consent to test for HIV.
- **Pregnant women.** WHO recommends pregnant women be tested for HIV, syphilis and hepatitis B at least once during pregnancy, preferably in the first trimester. In some resource-limited settings, programmes may need to use resources strategically for testing and retesting during pregnancy, focusing on women in geographic areas with high HIV burden, women from key populations, women who have partners with HIV or from a key population and women with high HIV risk for any other reason. Dual HIV/syphilis rapid testing can be considered as the first test in antenatal care, except for women with HIV taking antiretroviral therapy (ART) and women already diagnosed with and treated for syphilis during the current pregnancy.
- **Infants and children.** HIV-exposed infants should receive virological testing for HIV as early as possible so that ART can be started immediately, and morbidity and mortality, prevented. Approaches to increase HTS coverage among children, especially those exposed to HIV, are needed including through provider-assisted referral, and focused testing efforts in in-patient and nutrition wards in high HIV burden settings.
- **Couples and partners.** Uptake of couples and partner testing remains low in many settings despite its benefits and high impact for HIV prevention and treatment. Implementing partner services, including provider-assisted referral and HIV self-testing (HIVST), should be prioritized. Among key populations approaches can include social network-based HIV testing.
- **Migrants, refugees, displaced populations and other vulnerable groups.** Migrants from high HIV burden settings or from key populations may be at higher risk of HIV infection and face increased social vulnerability associated with the process of migration. It is important that HTS and onward prevention and treatment are made available, within a comprehensive package of health services, to migrants, refugees and asylum seekers. As with all HTS, mandatory or forced testing is never warranted.

6. IMPLEMENTATION CONSIDERATIONS FOR HIV TESTING SERVICES AMONG PRIORITY POPULATIONS

6.1 Who are priority populations?

Early in the HIV epidemic, countries with a "generalized" epidemic were often advised to focus on general population HIV interventions, and countries with a "concentrated" epidemic were advised to focus on key populations[1] and other country-specific priority populations with greater risk or vulnerabilities to HIV. However, due to shifts in epidemiology *(1, 2),* all settings must focus efforts increasingly on priority populations who remain underserved by existing approaches. Priority populations are those that: (1) are most affected by HIV and at high ongoing HIV risk; (2) are critical to achieving and sustaining low HIV incidence; and/or (3) have specific individual or structural HIV-related vulnerabilities (3). While key populations are a priority in all settings, other populations may be a priority based on country context, setting or local epidemiology.

HIV testing services (HTS) efforts will work best when designed specifically to address each priority population's diverse needs and preferences *(4, 5).* Focused HTS efforts may include a mixture of approaches to reach people with HIV who do not know their status, re-engage people with HIV who may have been lost to follow-up, as well as to initiate and monitor HIV prevention services such as prevention of mother-to-child transmission (PMTCT), harm reduction, pre-exposure prophylaxis (PrEP) and voluntary medical male circumcision (VMMC) in the 14 priority countries in East and southern Africa *(4-9).*

6.2 Delivering HTS for priority populations

This chapter highlights key considerations for implementation of HTS for priority populations. Chapter 5, describing service delivery approaches, presents more information on each HTS approach.

6.2.1 Key populations

All epidemic settings require greater focus on members of key populations.

As countries make progress toward achieving national goals, all epidemic settings require greater focus on members of key populations and their partners to identify the remaining HIV infections *(1, 2).* More than half of new HIV infections globally now occur among key populations – men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and

1 Men who have sex with men, people who inject drugs, people in prisons and closed settings, sex workers and transgender populations

transgender people – and their sexual partners *(10).* In all settings, a comprehensive HIV response must include key populations *(2, 10).*

Due to risk behaviours and vulnerabilities related to stigma, restrictive policies and punitive laws, members of key populations and their partners often have poor access to health services and are at high ongoing risk of HIV in all settings *(11, 12).*

HTS for key populations, as for all clients, must practice the "5 Cs" – Consent, Confidentiality, Counselling, provision of Correct test results and Connection to comprehensive prevention, treatment and care services *(3)*. HTS and other HIV services should operate on the principles of medical ethics, avoidance of stigma, non-discrimination and the right to health. Testing services for key populations should also adopt practices that prioritize improving accessibility and acceptability and the capacity of providers to serve the needs of specific key populations in their communities *(3).* Testing services that employ peer and lay providers (sometimes called community health workers) from key populations are often crucial to providing friendly and accessible services in community and facility settings. These trained community providers can deliver HTS and support engagement in HIV prevention and treatment services *(3, 13).*

To address the high burden of undiagnosed HIV among key populations, a strategic mix of differentiated, inclusive and non-stigmatizing HTS approaches is required according to the local context. HIV testing at least annually is advised for all people from key populations for reaching those with undiagnosed HIV as early as possible and engaging them in prevention, treatment and care. More frequent retesting, that is every 3–6 months, may be warranted based on individual risks factors. For some key populations, more frequent testing may be required as part of routine monitoring in HIV prevention services – for example, harm reduction services, PMTCT or quarterly retesting for those taking PrEP *(3)*.

Facility-based HTS that are designed to serve members of key populations include stand-alone needle and syringe programmes or drug treatment services, drop-in centres, "one-stop shop" services and clinics that cater to the particular needs of key populations. In many settings members of key populations routinely access health services, such as reproductive, maternal, newborn and child health (RMNCH), sexually transmitted infection (STI), tuberculosis (TB), hepatitis B virus (HBV) and hepatitis C virus (HCV) services, hormone therapy, opioid substitution therapy (OST), safe abortion services where legal, and other services. HTS integration with these services can create additional opportunities to offer HIV testing. HTS in facilities should be inclusive and accessible to key populations and be sure to offer HIV testing in a non-discriminatory or non-stigmatizing manner. Training and sensitization of the health workforce may help to provide friendly and non-judgemental services for key populations, which, in turn, will encourage members of these communities to seek testing.

People in prisons and other closed settings also need access to a comprehensive package of testing, treatment, care and prevention services. It is essential that services give accurate information, obtain informed consent, maintain confidentiality and ensure that use of services is voluntary. Discriminatory practices, such as forced segregation of prisoners diagnosed with HIV (unless as part of clinical management and efforts to prevent TB) must be avoided. Such practices are not effective in safeguarding health,

and they breach human rights. Also, linkage from testing to appropriate HIV prevention, treatment and care is essential. Those diagnosed with HIV must be linked to and provided with ART before release from prison, and continuity of care between prison and community must be assured in order to maintain viral suppression and prevent transmissions, as well as to prevent the development of HIV drug resistance *(12).*

Women from key populations, including pregnant women, should receive HTS as part of a comprehensive package of prevention and care with linkage to a full package of RMNCH services, as needed *(3, 14)*. See section 6.2.4 for further considerations for pregnant women.

Community-based HTS is recommended for reaching members of key populations and their partners who may often be hesitant or unable to access facility-based services *(3, 15, 16).*

Venue-based approaches, which identify "hotspots" and offer mobile or outreach testing for key populations, can be highly effective in reaching undiagnosed key populations and their partners. For example, in Malawi and Angola over 70% of individuals reached (included sex workers, men who have sex with men and transgender women) using a venue-based outreach in a hotspot were not aware of their HIV status *(17)*. It is important that community-based HTS among key populations and their partners are strategically designed and well-focused, as costs can be high *(18, 19).* See Chapter 5 for a summary of the full range of community-based HTS approaches.

HIV self-testing (HIVST) can be particularly effective for reaching members of key populations who may not test otherwise or who are at ongoing risk but test less frequently than recommended. There are many ways to implement and distribute HIVST kits among key populations, including through community and facility settings, online platforms, pharmacies and private sector settings (for example, kiosks or retail outlets), as well as through secondary distribution of test kits through partners or other contacts, and peer-distribution through sexual, drug injecting or social networks *(5, 20-24).* Providing choice in HIVST service delivery models can improve access for various key population groups.

When developing or adapting HIVST service delivery models, consulting and engaging key populations is critical. Providing clear information and communication to communities, including key populations, can increase education and awareness and prevent or mitigate the risk of misuse. Monitoring and addressing potential social harm is important *(5)*. See Chapter 5 for further discussion of HIVST.

Voluntary partner testing, either together or separately, is also recommended for key populations, with support for mutual disclosure where beneficial and as necessary. **Provider-assisted referral**, sometimes called assisted partner notification or index testing, in which the sexual and drug injecting partners of people with HIV, including members of key populations, are offered voluntary HTS by a trained provider, is recommended as part of a comprehensive package of care for all people with HIV *(24).* Testing biological children of members of key populations with HIV should also be considered as part of provider-assisted referral *(7, 24)*.

It is important that provider-assisted referral is always voluntary, never mandatory or coercive, and supports partners and contacts to receive the benefits of HIV testing, treatment and prevention services. Further, it must be implemented in ways that is safe for clients and protects against violence or persecution of key populations and people with HIV who may be socially marginalized or criminalized for their behaviours *(25)*. The provision of health services in a safe environment, without the involvement of law enforcement, is important to enable key populations and other vulnerable groups to access necessary services *(24)*. Raising community awareness and monitoring and addressing potential harms by modifying programmes are essential.

Social network-based HIV testing approaches can be used to increase testing through the social, sexual or drug injecting contacts of both HIV-positive and HIV-negative members of key populations *(26).* WHO now recommends social network-based approaches can be offered within a package of partner services for key populations, particularly where uptake of provider-assisted referral among key populations is low. See Box 6.1; also, Chapter 5 describes the evidence and implementation considerations related to this guidance.

Integrating HTS with other testing and prevention services for key populations can increase benefits. Opportunities for integration need to be maximized, particularly for testing and screening for STIs, TB, and viral hepatitis. High rates of these conditions have been reported among key populations, including those taking PrEP *(27)* – specifically, hepatitis C among people who inject drugs *(28)*, TB among people in prisons *(28, 29)* and syphilis and other STIs among sex workers, men who have sex with men and transgender people *(10)*. According to a recent systematic review, community-based HTS offering multi-disease testing, including testing for STIs and HIV, achieve high uptake and HIV-case finding among key populations *(19)*. HTS also provides an opportunity to deliver effective prevention services – for example, distribution of condoms with lubricants, delivery of reproductive health services or provision of needle syringe programmes and opioid substitution therapy (OST).

Box 6.1. Summary of WHO recommendations on HTS for key populations

- NEW Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention *(conditional recommendation, very low-quality evidence).*
- Updated HIV self-testing is recommended as an approach to HIV testing services *(strong recommendation, moderate-quality evidence).*
- Lay providers who are trained and supervised can independently conduct safe and effective HIV testing services using rapid diagnostic tests *(strong recommendation, moderate-quality evidence).*

  Key population peers can be trained to function as lay providers.
- Voluntary HIV testing should be routinely offered for all clients from key populations in all clinical settings, including those for STIs, viral hepatitis, TB, immunization, malnutrition and ANC.
- Community-based HIV testing, with linkage to prevention, treatment and care, should be offered, in addition to routinely offering HTS in facilities, for key populations in all settings *(strong recommendation, low-quality evidence).*

Box 6.1. Summary of WHO recommendations on HTS for key populations, contiuned

- Couples and partners should be offered HTS with support for mutual disclosure. This applies also to couples and partners from key populations *(strong recommendation, low-quality evidence).*
- 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-quality evidence).*

Recommendations on testing in pregnancy

- All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)[2] at least once and as early as possible *(syphilis testing: strong recommendation, moderate-quality evidence; HBsAg[2]: strong recommendation, low-quality evidence).*
  NEW Dual HIV/syphilis rapid diagnostic tests (RDTs) can be the first test in HIV testing strategies and algorithms in all ANC.
- Retest all pregnant or postpartum women of negative or unknown status from key populations, or who have partners with HIV who are not virally suppressed from key populations, in the third trimester. If first test and/or retesting in late pregnancy is missed, catch-up testing is needed.
  An additional retest in the post-partum period could be considered among women from key populations and at high ongoing risk. Countries could also consider an additional post-partum test in specific districts or provinces with high HIV burden or incidence.

Sources: WHO, 2015 *(3);* WHO, 2016 *(24);* WHO, 2016 *(12);* WHO, 2017 *(14);* WHO, 2017 *(30)*

6.2.2 Men

Globally, men with HIV are less likely than women to know their status, be on treatment and be virally suppressed *(10)*. In 2018 an estimated 55% of all adult men with HIV were receiving ART compared with 68% of women *(10)* (Fig. 6.1). Such gaps are greatest in sub-Saharan Africa, where population-based surveys consistently find that fewer men than women with HIV know their status and are on treatment *(10, 31-34)*. Consequently, in many settings HIV-related morbidity and mortality rates are higher among men than women *(10, 35, 36)*. Men from key populations bear significant HIV burden, and many are undiagnosed. Outside of Africa, men from key populations account for more new HIV infections than women from key populations *(37)*. These gaps compromise efforts to achieve global HIV testing, treatment and prevention targets *(38, 39).*

There are multiple reasons for men's lower uptake of health services than women leading to poorer health outcomes among men. Health services in many settings are structured to serve women and children. As a result many HIV programmes have effectively integrated HIV testing and related services into ANC *(10, 40)*, but not

2 Particularly in settings with a ≥2% HBsAg seroprevalence in the general population.

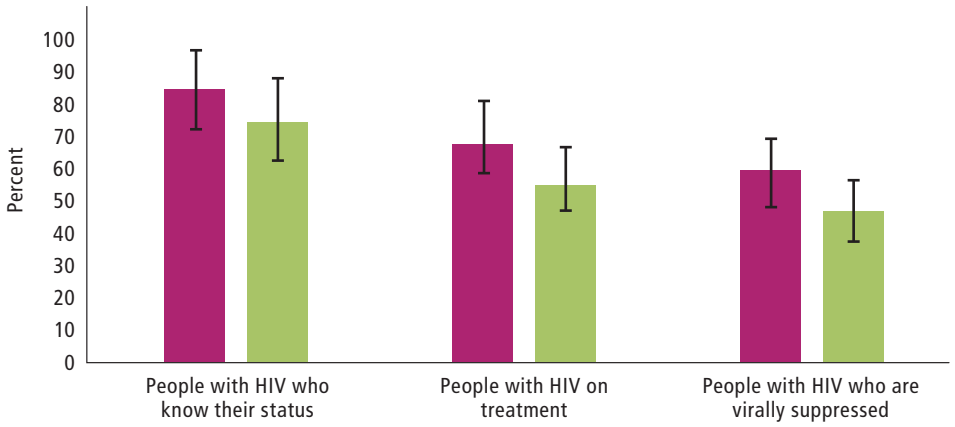
consistently into other relevant clinical services *(41, 42)*. This results in fewer opportunities for reaching men and contributes to perceptions that health services are not friendly to men and are primarily for women and children *(43-46)*. Other barriers that men face include behavioural and structural factors such as fear, stigma and direct and opportunity costs of accessing services *(43-47).*

Differentiated HTS approaches, using a mix of facility-based and community-based approaches, are important for reaching men. Selecting a strategic combination of service delivery approaches for men requires thorough situational analysis and considering men's preferences, local context, epidemiology and available resources. In high HIV burden settings such as those of southern Africa, efforts to engage men from both general and key population groups are needed. In low HIV burden settings, approaches need to focus specifically on men from key populations including clients of sex workers and men with STIs or with confirmed or suspected TB, as well as men with partners with HIV who are not on ART and virally suppressed. Across all HTS approaches, men, like women diagnosed with HIV may need support to link to ART as soon as possible.

Men can be offered HTS as part of **HIV prevention interventions**. For example, HTS is a part of VMMC services, which are a priority in 14 high HIV burden African countries *(9)*. In all settings men from key populations and HIV-negative men in serodiscordant relationships should be engaged in effective HIV prevention and test at least annually *(3).* Also, men taking pre-exposure prophylaxis (PrEP) need quarterly HTS integrated with testing and screening for STIs and viral hepatitis *(8).*

Facility-based HTS continue to be an important location where men access services, in many cases when ill and with advanced-stage HIV disease *(48, 49)*. At the same time, in high HIV burden settings, it is important that health services routinely offer HTS to men *(3).*

Fig. 6.1. HIV testing and treatment cascade, 15 years and older, global, 2018



Source: UNAIDS, 2019 *(10)*

In all settings men who have HIV-related symptoms, TB, viral hepatitis, STIs or other indicator conditions should be offered HIV testing *(3).* HTS in facilities should be inclusive, friendly and accessible to men, including those from key populations.

Men may also access facility-based HTS through partner testing, particularly in high HIV burden settings and during a partner's pregnancy *(10, 50).* WHO recommends couples and partner testing (either together or separately), especially for high HIV burden settings, with support for mutual disclosure where beneficial and desired by clients *(3)*. While some programmes have successfully introduced couples and partner testing, implementation and uptake remain low globally *(3, 51, 52)*. WHO recommends **provider-assisted referral** as part of a comprehensive package of care for men with HIV or men whose partners are living with HIV *(24).* Provider-assisted referral should be offered also to men diagnosed with other STIs or viral hepatitis *(14, 24, 53)*. Social network-based HIV testing approaches can be considered for men from key populations where feasible and supported by national policy. **Secondary distribution of HIVST kits** by ANC women to their male partners and by key populations peers to their partners and social contacts is also effective in increasing HTS uptake among men *(5, 24).*

Community-based HTS is important for reaching men because in many settings they are less likely than women to use health facilities. Community-based approaches may be particularly useful for reaching men who have never tested and men from or with partners from key populations *(19, 54, 55).* Focused community and peer mobilization and mobile outreach with HIVST distribution may facilitate testing for men *(56)* (see Chapters 3 and 5).

Community-based HTS has increased treatment coverage, reduced mortality and lowered HIV prevalence.

In southern Africa combination prevention trials have highlighted the benefits of widespread implementation of community-based HTS (primarily home-based HTS) followed by rapid ART initiation. This sustained implementation home-based testing has increased treatment coverage *(57-59)*, reduced mortality *(60)* and, as a study in Zambia shows, reduced incidence *(57, 58)*. In high HIV burden settings, such as southern Africa, mobile outreach in the evenings (after work) or on weekends, community-delivered HIVST (by partner or provider) and provider-assisted referral have proved useful for reaching men *(15, 20, 54, 61, 62)* (see Chapter 5).

Across all community-based HTS approaches, programmes will need to carefully consider and implement methods to facilitate linkage. Without linkage, men with HIV may not benefit from early ART initiation (see Chapter 4).

Workplaces also can be important venues for reaching men. It is expected that the number of people with HIV, many of whom are men, in the workforce will reach 29.9 million globally by 2020 *(63)*. HIV testing initiatives at workplaces have identified many previously undiagnosed infections. For example, the International Labour Organization (ILO) initiative Voluntary Counselling and Testing for Workers – VCT@WORK – has tested more than 4.3 million workers in a range of workplaces and industries in 18 countries over three and a half years – 69% of them men. Of those tested, 2.4% were HIV-positive *(64).*

In high HIV burden countries, workplace HTS that involve **HIVST distribution** may be particularly effective for reaching men with high ongoing risk who may not test otherwise, such as those employed in mining companies, transport and logistics, the military and other uniformed services. For example, in South Africa, when HIVST was implemented in a mining company, 2257 employees collected 3202 HIVST kits (945 were assumed to have been obtained for partners). Of those collecting kits, 42% had never tested or had not tested in the preceding 12 months, and 16% of those who reported their results were HIV-positive *(64).* Whenever providing workplace HTS, with or without HIVST, it is critical to implement services within a framework of workplace policies that protect workers who test HIV-positive from losing their jobs and from other discrimination *(64).*

Across all HTS approaches focused on reaching men, lay provider-delivered HTS should be considered, as it may facilitate uptake of HTS and provider-assisted referral and increase the affordability of HTS *(3, 24, 65, 66)*. See Chapters 3 and 5 for details on creating demand and service delivery.

While scale-up of HTS approaches for men has many benefits, it can be costly; concerted efforts to optimize resource use and efficiency are needed. Recent mathematical modelling suggests that in East and southern Africa, where HIV burden is high and male

Box 6.2. Summary of WHO HTS recommendations for men

- **Updated** HIV self-testing is recommended as an approach to HIV testing services *(strong recommendation, moderate-quality evidence).*
- In high HIV burden settings, HIV testing should be offered to all populations – including men – in all services, including those for STIs, viral hepatitis, TB, ANC (through partner service) and all services for key populations.
- In low HIV burden settings, HIV testing should be offered to all clients from key populations – including men – or who present with medical conditions or symptoms that may indicate HIV infection, including viral hepatitis, STIs, diagnosed or presumptive tuberculosis (TB), or other indicator conditions.
- Couples and partners should be offered HTS with support for mutual disclosure. This recommendation applies also to couples and partners from key populations *(strong recommendation, low-quality evidence).*
- Voluntary provider-assisted referral should be offered as part of a comprehensive package of testing and care offered to people with HIV, including men *(strong recommendation, moderate-quality evidence).*
- In high HIV burden settings, community-based HIV testing with linkage to prevention, treatment and care should be offered, in addition to routinely offering HTS in facilities, particularly for key populations *(strong recommendation, low-quality evidence).*
- In low HIV burden settings, community-based HIV testing, with linkage to prevention, treatment and care, in addition to facility-based testing, should be routinely offered to key populations *(strong recommendation, low-quality evidence).*

Sources: WHO, 2007 *(69);* WHO 2007 *(70);* WHO, 2015 *(3);* WHO, 2016 *(24);* WHO, 2016 *(12).*

testing and treatment coverage is low, additional investment in testing for men would be cost-effective if focused such as limiting implementation during specific time period *(67, 68).* Similar modelling among key populations including men in low burden settings also found that HTS can be cost-effective *(2)*.

6.2.3 Adolescents and young people

Despite their greater vulnerability, adolescents are less likely to be tested than adults.

In some settings adolescents (that is, people 10–19 years of age) and young people (15-24 years) remain particularly vulnerable to HIV acquisition. This vulnerability stems from social and contextual factors such as age and sex, gender, social and cultural norms and value systems about sexual activity, location (where the adolescent or young person lives, learns and earns), economic and educational status and sexual orientation. Nonetheless, adolescents and young people are less likely to be tested than adults; many remain undiagnosed and, thus, do not receive treatment *(10, 31)*. While there have been important strides for adolescents and greater recognition of their particular needs, an estimated 6000 new infections occur among adolescent girls and young women each week *(10).*

The gap in knowledge of HIV status is even greater among adolescents from key populations *(12, 71).* Such challenges are due partly to poor implementation of combination HIV prevention packages for young people, including testing in high incidence settings such as in southern Africa and among young members of key populations everywhere *(10, 72).*

Adolescents and young people may benefit from HTS as part of broader HIV prevention and sexual and reproductive health interventions and as part of focused outreach efforts to reach those with undiagnosed HIV infection *(73).* Among adolescents and young people HTS should be prioritized for:

- perinatally HIV-infected persons who were not diagnosed in infancy and have survived to adolescence;
- adolescent and young key population;
- adolescents and young people who are vulnerable and need special attention, such as those living on the streets, orphans, adolescents in child-headed households, girls engaging in sex with older men or in multiple or concurrent sexual partnerships and adolescents and young people who are sexually exploited; and
- all adolescent girls and young women in high HIV burden settings, such as southern Africa *(3).*

It is important to focus HTS on adolescents and young people in high HIV burden settings. Routinely offering HTS to all adolescents and young people in low HIV burden settings would identify very few HIV infections and may not be an effective investment in many resource-limited contexts. Instead, testing for adolescents and young people in low HIV burden settings should focus on those with particular vulnerabilities, such as young people in key populations.

Engaging adolescents and young people in HTS, and in prevention, treatment and care, requires strategies designed specifically to reach them. All HTS for adolescents and young people, whether in health facilities or the community, should be adolescent-friendly and should address their psychological and physical health needs. HTS for adolescents should be designed to improve accessibility and offer HIV testing in a non-judgemental, non-discriminatory and non-stigmatizing manner. For example, care should be taken to provide services in a confidential environment, not distributing HIVST kits in the presence of parents or guardians nor delivering provider-assisted referral with the involvement of law enforcement *(5)*. Referral and linkage pathways to HIV prevention, treatment and care are crucial, as is linkage to other adolescent-specific services, including sexual and reproductive health services. In some settings specific health education campaigns using social media or web-based approaches, developed in consultation with adolescents' and youth groups including those from key populations, may reduce barriers to access HTS and other services. All services for adolescents should follow the WHO standards for adolescent health services that define the required level of quality in the delivery of services for adolescents *(74).*

Both facility and community-based HTS can be offered to adolescents as part of sexual and reproductive health and HIV prevention packages for adolescents *(3)*. In high HIV burden settings, such as southern Africa, HTS may also be a part of HIV prevention efforts including VMMC services for adolescent boys and young men *(9)* and in sexual and reproductive health, contraception and family planning services *(75)*. In all settings HIV-negative adolescents from key populations should test at least annually *(3).* Adolescents and young people taking PrEP should receive quarterly HTS, alongside testing and screening for STIs, as part of quarterly facility visits *(8)*. Integration of HIV testing and prevention with sexual and reproductive health services may help to address the diverse needs of sexually active adolescents and young people.

To improve access to HTS for adolescents and young people, focused **community-based outreach** and **HIVST** can be used *(3, 24)*. HIVST has been shown to be effective and acceptable among adolescents and young people including young key populations. According to a recent systematic review, introducing HIVST more than doubles uptake of HTS among adolescents and young people (ages 15–24) compared to standard facility-based HTS *(20)*. Some adolescents and young people may want additional support when performing HIVST and for linking to services after self-testing. Providing support from a trained peer and peer-navigator to support linkage can be considered *(20).*

Introducing self-testing more than doubles uptake of HTS among adolescents and young people.

Adolescents who test HIV-positive may need additional support with disclosure *(3)*, and adolescents may especially need emotional support when potential HIV exposure is disclosed to them *(24, 76)*. When appropriate, and only with the adolescent's consent, providers can engage trusted adults, who may be parents, other family members, teachers or community members, to support adolescents as they learn to manage living with HIV.

Provider-assisted referral should actively engage adolescents with HIV and should offer methods and options informed by adolescents' and young people's preferences on when and how to contact partners *(24)*. Given its effectiveness, whenever possible, programmes should first offer and encourage provider assistance to contact partners of people with HIV *(24)*. Issues of voluntarism, confidentiality and disclosure are especially important for adolescents when offering testing for sexual or drug-injecting partners. Some young people may prefer that partners and other contacts be reached via mobile phone text messaging or other online services rather than through face-to-face notification options *(24, 77-79)*. Among adolescents in and young key populations, **social network-based approaches** may also be considered including the use of HIVST kits to their partners and contacts *(26)*.

Provider-assisted referral for adolescents and young people and their partners requires the provider to engage sensitively and non-judgmentally in a discussion about sexual partner(s), to support mutual disclosure and to recognize and minimize risks of harm and partner violence *(24)*. Providing health services to adolescents in a safe environment, without the involvement of law enforcement, is important to enable this vulnerable group to access lifesaving ART if diagnosed HIV-positive or prevention services if HIV-negative *(24)*.

Risk-based **screening tools** to "screen in" or identify adolescents in need of HTS, who may not have tested otherwise, could be considered to optimize HTS in some settings *(81)*. Such tools ask questions about a person's HIV risk. In high HIV burden settings, however, tools that are designed to "screen out" or exclude individuals from HIV testing may not be appropriate; they could be misused, may deter uptake of testing and may miss adolescents in need of testing *(81)*. See Chapter 7 for considerations related to screening tools.

Policies on **age of consent** can impede adolescents' access to HTS and other health services, particularly for adolescents from key populations *(3, 82)*. Age of consent for HTS varies from country to country *(80)* (Box 6.3).

Box 6.3. WHO policy review on age of consent for HTS

According to a 2019 review and analysis of national policies on age of consent for HTS in sub-Saharan Africa, only 66% of country policies (23/35) allowed HTS for adolescents younger than 16 years of age without consent of a parent. Within the region there were considerably fewer country policies allowing HTS for adolescents younger than 16 years of age in west and central Africa (7/16, or 44%) than in east and southern Africa (16/19, or 84%).

Source: WHO, 2019 *(80)*.

WHO recommends that, as much as possible, adolescents themselves be involved in the decision to accept HTS *(3)*. Governments should review age of consent policies and revise where needed, recognizing adolescents' right to make choices about their own health and well-being (with consideration for different levels of maturity and understanding) *(3).* Authorities also should consider the role of surrogate decision-makers in HTS for adolescents without parents or for those unwilling to involve parents *(3)*.

HTS providers should be aware of country laws and policies governing the age of consent and develop appropriate procedures to ensure that children and adolescents have access to HTS.

Box 6.4. Summary of WHO recommendations and good practice statement on HTS for adolescents and young people

- NEW Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention *(conditional recommendation, very low-quality evidence).*
- Updated **HIV self-testing** should be offered as an HIV testing approach *(strong recommendation, moderate-quality evidence).*
- In all settings, HTS with linkages to prevention, treatment and care, are recommended for adolescents from key populations *(strong recommendation, very low-quality evidence).*
- In high HIV burden settings, HTS should be offered, with linkage to prevention, treatment and care, to all adolescents *(strong recommendation, very low-quality evidence).*
- In low HIV burden settings, WHO suggests that HTS with linkage to prevention, treatment and care should be accessible to all adolescents *(conditional recommendation, very low-quality evidence).*
- In all settings WHO suggests that adolescents be counselled about the potential benefits and risks of disclosure of HIV-positive status and empowered and supported to determine if, when, how and to whom to disclose *(conditional recommendation, very low-quality evidence).*
- Provider-assisted referral should be offered to people with HIV as part of a voluntary comprehensive package of testing and care *(strong recommendation, moderate-quality evidence).*

Good practice statement

- Governments should revisit age of consent policies, considering the need to uphold adolescents' rights to make choices about their own health and well-being (with consideration for different levels of maturity and understanding).

Sources: WHO, 2013 *(83);* WHO, 2015 *(3);* WHO, 2016 *(24);* WHO, 2016 *(12).*

6.2.4 Pregnant and postpartum women

Globally, there are 1.4 million new maternal HIV infections and 988 000 new maternal syphilis infections each year and 65 million women of childbearing age with chronic HBV infection *(10, 84, 85)*. Elimination of mother-to-child transmission (EMTCT) of HIV, syphilis and HBV is a global health priority *(86)*. HIV and syphilis testing as early as possible in pregnancy enables pregnant women to benefit from prevention, treatment and care and reduces the risk of transmission to their infants and sexual partners. Early treatment for HIV and syphilis and use of PMTCT interventions (antivirals and birth dose with infant HBV vaccine) and identification of those women in need of long-term treatment for chronic HBV will lead to the best health outcomes for mothers and children. ART is most effective in preventing HIV transmission from mothers to infants when begun before or early in pregnancy. These services can be delivered at ANC or through safe abortion services where legal. Linkage to the full package of RMNCH services is essential for all women and HIV-exposed infants regardless of their HIV status.

All RMNCH and ANC services should offer HTS, syphilis and HBsAg testing (particularly in settings with a HBsAg prevalence ≥2% in the general population) at least once, preferably in the first trimester or as early as possible during pregnancy *(3, 14, 87, 88).* Those who test positive should be linked promptly to care, treatment and prevention services. Dual HIV/syphilis RDTs can be used as the first test in antenatal care in all settings. Dual HIV/syphilis RDTs can be cost saving in all settings *(89)*. See annex G for further details.

Further WHO guidance on preventing mother-to-child transmission of HBV is available: https://www.who.int/publications/i/item/978-92-4-000270-8.

Maternal HIV **retesting**, in pregnancy and breastfeeding period, is recommended for all women only in high HIV burden settings *(3, 90)*. In these settings, when women receive their first HIV test in early pregnancy, they should be counselled about the risks of HIV acquisition and the benefits of retesting for their own and their baby's health, the retesting schedule and the importance of mothers taking their children to services in the first year of life *(3)*. When HIV testing opportunities are missed or delayed in early pregnancy, the third trimester of pregnancy or during the postpartum period, women should receive catch-up testing at the earliest possible visit.

In low HIV burden settings, maternal retesting in third trimester is recommended only for women at high ongoing HIV risk – those from key populations or whose partners are from key populations or have HIV and are not on ART and virally suppressed. In low HIV burden settings, offering retesting to all pregnant women is not cost-effective and may not be good use of resources unless as part of efforts to achieve eMTCT *(3, 90).* In some resource-limited settings, particularly those with low HIV burden, programmes may need to optimize resource use by focusing HTS in pregnancy on geographical areas with higher prevalence or women with high ongoing risk.

Recent mathematical modelling suggests that the **optimal time point for retesting** is a second test during late-pregnancy – at a **third trimester visit**. Countries can consider an additional retest in the post-partum period, for example one additional retest at 14 weeks, six months or nine-months post-partum in districts or provinces with high HIV burden and among key populations or women with partners with HIV who are not virally suppressed (Table 6.1) *(90).* The postpartum maternal retest may be delivered along with infant immunization services. More details are available in Annex F.

Table 6.1. Recommended time points for HIV retesting for pregnant and postpartum women

	Time points		
Setting	Early in pregnancy (first antenatal care visit)	Late in pregnancy (third trimester ANC visit)	1 additional postpartum retest (14 weeks, six-month or nine-months post-partum)
High HIV burden settings	All	All	Can be considered for those at ongoing high risk
Low HIV burden settings	All pregnant women as part of EMTCT, otherwise focused on those at high ongoing risk	Can be considered for those at high ongoing risk	Can be considered for those at high ongoing risk
Among key population groups and their partners	All settings	All settings	All settings

Dual HIV/syphilis RDTs can be used as the first test in ANC. To optimize implementation and delivery, supply chain management, training and verification of testing algorithms need to be considered. Pregnant women who have already been diagnosed with HIV and are on ART women already diagnosed with and treated for syphilis during their current pregnancy should not be tested with a dual HIV/syphilis RDT. Instead, women should be tested for HIV and syphilis using two different tests according to national algorithm.

As with all other populations, pregnant and breastfeeding women with HIV should start ART immediately or as soon as possible after an HIV-positive diagnosis, regardless of WHO clinical stage or CD4 cell count, and continue treatment for life *(91, 92).*

Pregnant women who are HIV-negative but at ongoing risk should be linked to comprehensive HIV prevention services. It is safe for pregnant and breastfeeding women to start or continue taking PrEP (30). Pregnant and breastfeeding women taking PrEP should receive HIV testing, alongside testing for STIs, at quarterly facility visits *(93).*

Related testing. HTS may serve as an entry point for a broad range of pregnancy care and prevention services, some of which will help prevent HIV infection among women and their children. These services may include screening and treatment for other infections (STIs, hepatitis and TB), HIV prevention and sexual and reproductive health including contraception/family planning. The presence of STIs increases the risk of HIV acquisition.

The presence of undetected TB among HIV-positive pregnant women increases the rate of HIV transmission to infants and increases mortality among mothers and infants *(94).* Those who inject drugs may also benefit from screening for hepatitis C *(3, 95).*

ANC visits also provide an important opportunity to offer and encourage **partner testing**. Partner testing, either together or separately, is also recommended for all pregnant women in high HIV burden settings and for women from key populations or in serodiscordant couples in all settings, with support for mutual disclosure where beneficial *(3).* While some programmes have successfully introduced couples and partner testing, implementation and uptake remain low globally *(3, 51, 52).* WHO recommends **provider-assisted referral** as part of a comprehensive package of care for all people with HIV, including pregnant women with HIV *(24).* Biological children of women diagnosed with HIV should be offered HTS as part of a package with provider-assisted referral when their status is unknown *(91, 96).* Distribution of **HIVST** kits by ANC clients to their male partners improves HTS uptake among male partners and can be considered.

Programmes need to ensure that HTS, as well as related testing, treatment and prevention services, reach pregnant and postpartum women from key populations, including those in prisons and closed settings. Measures must be taken, however, to prevent mandatory or forced testing, whether intentional or unintentional. These measures include regular mentoring and supervision of staff, retraining where necessary and monitoring of HTS procedures to ensure their acceptability to pregnant women *(3)*.

Box 6.5. WHO recommendations and good practice statements on HTS for pregnant and postpartum women

- **Updated** HIV self-testing should be offered as an HIV testing approach *(strong recommendation, moderate-quality evidence).*
- All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)[1] at least once and as early as possible, ideally at the first antenatal care visit (syphilis: strong recommendation, moderate-quality evidence; HBsAg1: strong recommendation, low-quality evidence).
- In resource-limited settings programmes may need to rationalize resources by focusing HTS on women at greatest risk. Therefore:
  - In high HIV burden settings, following initial HTS in pregnancy at first ANC visit, retesting is advised in the third trimester. (Catch-up testing following a missed or delayed first test or retest is needed.) Countries can consider one additional retest in the post-partum period, such as at 14 weeks, six months or nine months in high HIV burden or incidence districts or provinces, key populations or women with partners with HIV wo are not virally suppressed.
  - In low HIV burden settings, retesting all pregnant women is not warranted unless focused among women from key populations or at high ongoing risk, such as those from key populations or with partners with HIV who are not virally suppressed. Countries could consider one additional retest in the post-partum period, such as at 14 weeks, six months or nine months for women in high HIV burden or incidence districts or provinces, key populations or women with partners with HIV who are not virally suppressed.

1 Particularly in settings with a ≥2% HBsAg seroprevalence in the general population.

Box 6.5. WHO recommendations and good practice statements on HTS for pregnant and postpartum women, contiuned

- Dual HIV/syphilis RDTs can be the first test in HIV testing strategies and algorithms in ANC settings.

- Provider-assisted referral services should be to offered to all people with HIV as part of a voluntary comprehensive package of testing and care *(strong recommendation, moderate-quality evidence).*
- Couples and partner testing services are recommended in antenatal care settings, particularly high HIV burden settings, facilitating interventions including prevention in serodiscordant couples in all settings *(strong recommendation, very low-quality evidence).*

Good practice statement

- Women at substantial risk of HIV acquisition can start or continue PrEP during pregnancy and breastfeeding. Women taking PrEP should receive HTS alongside screening and testing for STIs, as part of quarterly facility visits.
- Women with HIV, including those that are or who may become pregnant, need information about the benefits and risks of ART and medical guidance appropriate to their situation and support in making voluntary choices about initiating therapy, continuation and adherence/retention in care, as applicable. Health workers must help women to address their health-care needs and those of their children.
- Pregnant women without any serological markers for HBV can be offered HBV vaccination. Follow-up should continue through the breastfeeding period to ensure that infants born to mothers with chronic HBV infection receive the recommended three doses of vaccine, especially if they did not receive the HBV birth-dose vaccination.
- Further guidance on HBV is available: https://www.who.int/publications/i/item/978-92-4-000270-8.

Sources: WHO, 2007 *(97)*; WHO, 2007 (70);WHO, 2015(3); WHO, 2016 *(12)*; WHO, 2016 *(91);* WHO, 2016 *(14)*; WHO, 2017 *(87, 98)*; WHO, 2017 *(93)*; WHO, 2017 *(99)*; WHO, 2017 *(30);* WHO, 2019 *(100).*

6.2.5 Infants and children

In the first year of life mortality is very high – approximately 30% – among HIV-infected infants who remain untreated *(101)*. Timely HIV testing of HIV-exposed infants (born to HIV-positive mothers), prompt return of test results and immediate treatment for those with HIV are critical. Early treatment among infants has demonstrated improved survival and clinical outcomes overall, with substantial impact on the HIV reservoirs and future disease progression.

All HIV-exposed infants should receive HIV testing to ascertain their HIV status and to start ART immediately if HIV-positive. Because of the persistence of maternal antibodies, virological testing such as nucleic acid testing (NAT) technologies is required for infants under 18 months of age *(102).* After this period serology tests, including RDTs, can be used *(103)*. See Chapter 8 for details on how to diagnose HIV in infants.

Less than one third of perinatally infected infants are linked to services and initiate ART in a timely manner.

Access to early infant diagnosis (EID) – that is, use of NAT technologies among HIV-exposed infants within two months of birth – has improved. Despite progress, in 2018 only 56% of all HIV-exposed infants received EID by the second month of age *(104)*. For infants who are tested, delays in obtaining results and further losses in the treatment cascade still occur. As a result, less than one third of perinatally infected infants are linked to services and initiate ART in a timely manner *(91)*.

Usually, EID is possible only for infants whose mothers have received PMTCT services. Many mothers with HIV do not receive these services, and some infants whose mothers have received PMTCT services are lost to follow-up *(102)*. As EID is further scaled up, efforts are needed to improve uptake of NAT at 4–6 weeks, strengthen retention along the testing-to-treatment cascade, confirm positive NAT results with a second sample and ensure that infants who test negative by NAT are retained in care until a final diagnosis is made at the end of the period of risk for transmission from breastfeeding.

NAT at birth can be considered to improve the coverage of EID in HIV-exposed infants. Such an approach, conditionally recommended by WHO, consists of NAT at birth or within two days of birth in addition to existing EID approaches *(12, 102).* WHO suggest birth NAT in conjunction with broader efforts to optimize and scale up existing EID approaches as well as efforts to retain infants in the testing-to-treatment cascade until the end of the period of risk for transmission. Mathematical modelling suggests that, where resources are limited and uptake or retention in the testing cascade is suboptimal, EID for of infants at six weeks should be prioritized over adding NAT at birth. The programmatic decision of whether to add NAT at birth will need to consider current national PMTCT coverage, HIV transmission risk to infants, uptake and retention in the infant testing cascade and available resources and funding priorities *(12, 102).*

In all settings, HTS should be offered to all biological infants and young children with an HIV-positive parent and whose HIV status is unknown (often termed "family-based index case testing") as part of a package of provider-assisted referral *(12, 24, 96, 102).* Additional support may be required for orphans and vulnerable children in high HIV burden settings, where one or both parents may have died *(3)*. Lay providers who deliver testing through community outreach may be particularly important for increasing coverage among HIV-exposed children ages two years and older. Some programmes are currently assessing the use of oral fluid-based RDTs for testing of children by trained lay providers to improve the acceptability and feasibility. However, it is important that children tested are not on treatment or on enhanced postnatal prophylaxis regimens *(105)*.

Routine offer of HTS remains an important strategy for infants and children in high HIV burden settings, particularly for HIV-exposed, sick or hospitalized children. In high HIV burden settings, WHO recommends routine facility-based HTS for infants and children with unknown HIV status who are admitted for inpatient care or are attending malnutrition clinics *(12, 102)*. WHO also suggests offering HTS to infants and children with unknown HIV status in outpatient or immunization clinics in high HIV burden settings *(12, 102).*

> WHO recommends routine facility-based HTS in inpatient care and malnutrition clinics for infants and children with unknown HIV status in high HIV burden settings.

Using **risk-based screening tools or questionnaires** for older children can increase the number of children receiving testing. These tools can remind providers to offer testing to children with certain HIV risks or indicator conditions who might not otherwise be offered testing *(81).* For example, in Nigeria, where routine HTS among older children is not provided, the introduction of a validated screening tool increased testing coverage among sick and hospitalized children by 27% and the number of children newly diagnosed with HIV increased by 36% *(81).* In some settings, such as high HIV burden settings, however, tools that seek to "screen out" those in need of testing may not be appropriate, as they could be misused, may deter uptake and may miss children in need of testing *(81).* See Chapter 7 for further details and considerations on screening tools.

Box 6.6. Summary of WHO recommendations and good practice statements on HTS for infants and children

- In high HIV burden settings, infants and children with unknown HIV status who are admitted for inpatient care or attending malnutrition clinics should be routinely offered HIV testing *(strong recommendation, low-quality evidence).*
- In high HIV burden settings, infants and children with unknown HIV status should be offered HIV testing in outpatient or immunization clinics *(conditional recommendation, low-quality evidence).*
- Addition of nucleic acid testing (NAT) at birth to existing early infant diagnosis (EID) testing approaches can be considered to identify HIV infection in HIV-exposed infants *(conditional recommendation, low-quality evidence).*
- NAT technologies that are developed and validated for use at or near the point-of-care can be used for early infant HIV testing *(conditional recommendation, low-quality evidence).*
- HIV virological testing should be used to diagnose HIV infection in infants and children below 18 months of age *(strong recommendation, high-quality evidence).*
- All HIV-exposed infants should have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter *(strong recommendation, high-quality evidence).*

Box 6.6. Summary of WHO recommendations and good practice statements on HTS for infants and children, contiuned

- In infants with an initial positive virological test result, it is recommended that ART be started without delay and, at the same time, a second specimen be collected to confirm the initial positive virological test result. Do not delay ART. Immediate initiation of ART saves lives and should not be delayed while waiting for the results of the confirmatory test *(strong recommendation, high-quality evidence).*
- It is recommended that test results from virological testing in infants be returned to the clinic and child/mother/caregiver as soon as possible, but at the very latest within four weeks of specimen collection. Positive test results should be fast-tracked to the mother–baby pair as soon as possible to enable prompt initiation of ART *(strong recommendation, high-quality evidence).*
- It is recommended that all infants with unknown or uncertain HIV exposure being seen in health-care facilities at or around birth or at the first postnatal visit (usually four to six weeks) or other child health visit have their HIV exposure status ascertained *(strong recommendation, high-quality evidence).*
- It is recommended that HIV-exposed infants who are well undergo HIV serological testing at around nine months of age (or at the time of the last immunization visit). Infants who have reactive serological assays at nine months should have a virological test to identify HIV infection and the need for ART *(strong recommendation, low-quality evidence).*
- It is recommended that infants with signs or symptoms suggestive of HIV infection undergo HIV serological testing and, if positive (reactive), virological testing *(strong recommendation, low-quality evidence).*
- It is recommended that children (18 months or older) with suspected HIV infection or HIV exposure have HIV serological testing performed according to the standard diagnostic HIV serological testing algorithm used in adults *(strong recommendation, high-quality evidence).*

Good practice statement

- In all settings biological children of a parent living with HIV (or who may have died of HIV) should be routinely offered HTS and, if found to be either infected or at high risk of infection through breastfeeding, should be linked to services for treatment or prevention and offered a broader package of voluntary provider-assisted referral.
- National regulatory agencies are encouraged not to delay adoption of point-of-care EID by conducting further evaluations but instead to adopt a rapid and streamlined registration and national approval process for immediate implementation.

Sources: WHO, 2015 *(3);* WHO, 2016 *(12, 102);* WHO, 2017 *(30)*

6.2.6 Couples and partners

Testing partners of people with HIV is an effective way to reach people at high risk of HIV infection. It efficiently identifies additional people with HIV not yet diagnosed or on ART– particularly male partners in high HIV burden settings, who are substantially less likely to test than women. It also helps to offer HTS to sexual and/or drug-injecting partners of people with HIV from key populations who may not otherwise test *(3, 24, 26)*. HTS creates the opportunity to link couples to prevention interventions including PrEP and to safer conception or contraception *(30, 93).* It also can facilitate uptake of and adherence to ART among HIV-positive partners and to PMTCT among HIV-positive pregnant women *(3)*. As with all HTS approaches, couples and partner HTS must be voluntary and not forced, and providers must recognize that some clients will not want to involve partners.

Partner testing. HTS for the partners of women attending ANC is a focus in the 21 priority EMTCT countries in Africa.[3] Couples and partners from key population groups or in serodiscordant relationships, however, should be prioritized in all settings *(3)*.

Among couples or partners, serodiscordance is common: It is estimated that in one half to two thirds of couples where one partner has HIV, the other does not *(106)*. Many people, however, do not know their partner's HIV status. In most countries fewer than 20% of couples and partners test together *(52)*. Even in countries where partner testing is included in the national policy, it has seldom been prioritized or widely implemented.

WHO developed recommendations in 2016 on **provider-assisted referral as a preferred way to support partner testing** as part of a voluntary comprehensive package of care to reach partners *(24)*. **Provider-assisted referral**, in which a trained provider, with consent of the index client, offers HTS to sexual and drug injecting partners, has been shown to lead to greater uptake as well as identification of additional HIV infections compared to patient referral *(62).*

HIVST has emerged as a safe, acceptable and effective way to reach partners of HIV-negative ANC clients as well as partners of people diagnosed HIV-positive at facilities *(5, 20)* (see Chapter 5).

Partner testing for members of key populations is also a priority. **Social network-based approaches** can also be used to promote HTS among sexual and drug-injecting partners and social contacts of members of key populations *(20, 107).*

Vulnerable and affected populations should be engaged in designing and implementing partner services, which may include provider-assisted referral, social network-based approaches and use of HIVST kits. Programmes are encouraged to offer options based on clients' preferences, such as whether the client would like to contact partners and how partners could be reached – for example, by telephone, social media or home visit. However, given its effectiveness, whenever possible, programmes should offer provider-assisted referral to contact partners of people with HIV *(20, 107).*

3 The 21 priority EMTCT countries are Angola, Botswana, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Eswatini, Ethiopia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

Wherever possible, programmes delivering provider-assisted referral among couples and partners should consider also offering assisted referral for other STIs and viral hepatitis *(53)*, particularly for couples from key populations or when a woman is pregnant or breastfeeding. Testing biological children of people with HIV whose status is unknown should also be considered as part of a voluntary provider-assisted referral package *(3, 24, 91, 96).*

Providers must provide information to couples and partners, particularly those with serodiscordant status, to understand their results *(3, 108, 109)*. It is necessary to provide the latest information on HIV prevention, treatment and sexual and reproductive health options, as well as educational messages about how PrEP prevents HIV acquisition and how ART reduces the risk of HIV transmission to their children and sexual partners. See Chapters 3 and 4 on information and counselling messages before and after HTS.

Partner violence. Partner testing, either together or separately, is recommended, with support for mutual disclosure where beneficial *(3).* Care is needed when delivering testing for couples and partners to minimize the risk of partner violence *(110)*.

WHO recommends that service providers supporting women with HIV who are considering voluntary or mutual disclosure should discuss with them the potential benefits and risks including the potential for violence and options for safe disclosure *(24, 111, 112).* For women who fear or who are experiencing violence, safety assessment and planning are crucial. Options include mediated disclosure, delayed disclosure and, when there is risk of severe violence, a decision not to disclose *(113).* When women report IPV, mutual disclosure is not recommended. Training for those who provide HTS should cover, as appropriate, how to discuss and respond to the potential for violence and procedures for assuring that people experiencing violence receive care and support.

In the context of planning whether and how to disclose HIV-positive status, the focus of discussion with all women should be on whether they foresee a potential for IPV. Tools are available to help a woman assess the potential for violence on the basis of her partner's past behaviour *(111).* If a woman has experienced violence by her current partner in the past, the chances are heightened that they may become violent when she discloses her HIV-positive status. Not only women and girls generally, but also some members of key populations, regardless of gender, may be particularly at risk of violence when they disclose HIV-positive status, and discussion of this possibility should be part of planning about disclosure. The same guidance on responding to violence and sexual abuse applies to key populations as to women *(112)* and to adolescents and children *(111, 114).*

WHO does not recommend asking all women whether they are experiencing or have experienced partner violence. Rather, WHO recommends asking about violence as a part of clinical enquiry – that is, when signs and symptoms might be the result of violence. In addition, minimum systems requirements must be met – a private and confidential space, a trained provider, a standard operating procedure in place and a referral mechanism for violence support services in place *(111)*.

Those who disclose history of IPV should be referred to available violence response services. Anyone who discloses violence must be offered, at minimum, first-line support (which is an adaptation of psychological first aid), treatment for presenting health conditions and referrals to additional services that they may need *(112).*

Box 6.7. WHO recommendations and good practice statements on HTS for couples and partners

- NEW Social network-based approaches can be offered as part of a comprehensive package of testing and care for key populations *(conditional recommendation, very low-quality evidence).*
- Updated HIV self-testing should be offered as an HIV testing approach *(strong recommendation, moderate-quality evidence).*
- Couples and partners should be offered voluntary HTS with support for mutual disclosure. This applies also to couples and partners from key populations *(strong recommendation, low-quality evidence).*
- Couples and partners in antenatal care settings should be offered voluntary HTS with support for mutual disclosure *(strong recommendation, low-quality evidence).*
- Voluntary provider-assisted referral should be offered to people with HIV as part of a comprehensive package of testing and care *(strong recommendation, moderate-quality evidence).*
- WHO recommends that policy-makers and service providers who support women living with HIV who are considering voluntary HIV disclosure should recognize that many fear, or are experiencing, or are at risk of intimate partner violence *(strong recommendation, low-quality evidence).*
- WHO recommends that interventions and services supporting women with HIV who are considering voluntary HIV disclosure should include discussions about the challenges of their current situation, the potential associated risk of violence, and actions to disclose more safely, and facilitate links to available violence prevention and care services *(strong recommendation, low-quality evidence).*
- WHO recommends that, for those who disclose sexual abuse within the first five days of it occurring, clinical care should include first-line support, HIV post-exposure prophylaxis (PEP) (in the first 72 hours), STI prophylaxis or presumptive treatment, emergency contraception (in the first 120 hours) and access to safe abortion as law allows and hepatitis B vaccination.
- Women who disclose any form of violence by an intimate partner (or other family member) or sexual assault by any perpetrator should be offered immediate support. Health-care providers should, as a minimum, offer first-line support when women disclose violence. If health-care providers are unable to provide first-line support, they should ensure that someone else (within their health-care setting or another that is easily accessible) is immediately available to do so *(strong recommendation, indirect evidence).*
- Health-care providers should ask about exposure to intimate partner violence when assessing conditions that may be caused or complicated by intimate partner violence, in order to improve diagnosis/identification and subsequent care *(strong recommendation, indirect evidence).*

Box 6.7. WHO recommendations and good practice statements on HTS for couples and partners, continued

- For children and adolescents who have been sexually abused, WHO recommends that, in addition to HIV PEP and emergency contraception (which can be offered to pre-pubertal girls), STI presumptive treatment or syndromic management is suggested in settings where laboratory testing is not feasible *(conditional recommendation, very low-quality evidence)*. Additionally, adolescent girls (ages 9–14 years) should be offered HPV vaccination as per national guidance *(strong recommendation, moderate-quality evidence).*

Good practice statement

- Extending provider-assisted referral to the biological children of people with HIV may also be considered as part of a voluntary provider-assisted referral package.
- Mandatory or coercive testing is never warranted. In consultation with the client, the provider should assess the risk of harm, the most appropriate approach for couple and partner testing, including more supportive options such as provider assistance, and situations that make couple or partner testing inadvisable.
- Providing the latest information on HIV prevention, treatment and sexual and reproductive health options, as well as educational messages about how PrEP prevents HIV acquisition and how ART reduces the risk of HIV transmission to children and sexual partners is necessary. Delivering these messages may be important to prevent potential social harm among couples, particularly those that are serodiscordant.

Sources: WHO, 2015 *(3);* WHO, 2016 *(24);* WHO, 2016 *(91);* WHO, 2017 (*8).*

6.2.7 Vulnerable groups and other populations, including migrants, refugees and displaced persons

Migration and displacement can place people in situations of higher risk of HIV through sexual or drug-use behaviours. In many countries refugees and migrants face complex obstacles, including lack of access to health-care services and social protections. Indeed, the processes of migration and seeking asylum can increase the risk of HIV and other infections through social disruption, unsafe living conditions, language barriers, fear of being deported, limited understanding and knowledge of the health and legal systems in the transit and host countries, legal issues and lack of required documentation, lack of social capital and discrimination in access to services. These conditions also can lead to late diagnosis, avoiding seeking treatment, treatment interruptions and treatment discontinuation.

It is important that HIV testing and linkage to prevention and treatment, within a comprehensive package of health services, are made available to migrants, mobile workers, refugees, asylum seekers, trafficked and other displaced people in need of these services, particularly in high HIV burden settings or for migrants from high

burden countries *(115).* Facility and community-based HTS, including the offer of HIVST and provider-assisted referral as needed, should be available, free of coercion, for all these migrants.

The risk of HIV infection among migrants, refugees, trafficked and other displaced populations varies depending on geographical location and specific situation. Some migrants from key populations, vulnerable groups or in high-risk situations related to their migration—for example, during border-crossings, in situations of exploitation or economic distress—may have increased risk for acquiring HIV and be in need of comprehensive services *(116)*. Comprehensive HIV prevention and treatment services must account for the specific needs of these vulnerable groups. A situational analysis is helpful to inform how to adapt services to reach the vulnerable groups at highest risk and ensure that these services are accessible, acceptable and appropriate.

It will be important to ensure that HTS for these groups are delivered within a human rights framework. Some jurisdictions mandate HIV testing of immigrants. This requirement is not justified, and it can jeopardize voluntary access to health services in general and to HIV testing services.

HTS should never be mandatory. Policies and practices to protect vulnerable populations from mandatory or compulsory testing are needed, as well as monitoring and accountability for policies already in place.

Other vulnerable populations

Other vulnerable populations are groups of people who are particularly vulnerable to HIV infection in certain situations or contexts but are not affected uniformly across all countries and epidemics. Depending on context, these may include orphans, street children, people with disabilities, and mobile or seasonal workers. Also, workers in certain industries, such as fisher folk and long-distance drivers, may face increased vulnerability to HIV. These vulnerable groups are often hard to reach and, typically, seldom use conventional HIV services.

To address the needs of vulnerable populations, countries need to conduct situational analyses to understand their epidemic, the local context and to identity these groups. Such analyses can help to establish who, in addition to key populations, is at highest HIV risk and in need of services. Based on these assessments, programmes can adapt HTS, either within or in addition to existing services, to address specific needs.

Box 6.8. Summary of good practice statements for migrants, refugees, displaced populations and other vulnerable groups

- In any circumstance HTS should not be mandatory, and policies and practices to protect vulnerable populations from mandatory or compulsory testing are needed.
- To address the needs of vulnerable populations, including migrants, countries need to conduct in-depth situational analysis to understand their epidemic, the local context and to identity these groups, in addition to key populations, that are at highest risk and in need of services. Based on these assessments, programmes can adapt HTS approaches, either within or in addition to existing services, to address needs.

Sources: WHO, 2014 *(116);* WHO, 2015 *(3).*

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KEY POINTS

- HIV testing services (HTS) need to **prioritize reaching the largest number of people with HIV who remain undiagnosed** and reaching the **population groups with higher HIV risk where the gap in knowledge of HIV status is greatest.** These include members of key populations and their partners in all regions and, in East and southern Africa, men and young women.
- Conducting an **in-depth HTS situational analysis** is the first step when evaluating how to optimize HTS – including modifying existing HTS, introducing new HTS approaches and selecting an optimal combination of HTS approaches to address the needs of different populations. Such analyses will vary by country and setting but typically include review of national HIV epidemiological data, programme data, financial resources, costs and relevant laws and policies.
- Programmes need to prioritize HTS approaches and optimize resources depending on their local context, HIV epidemiology and burden. In the context of HTS programming and planning, **high HIV burden** refers in this document to settings with ≥5% national HIV prevalence and subpopulations and geographic settings where HIV prevalence and/or incidence is higher than nationally. **Low HIV burden** settings refer to settings with <5% HIV prevalence but where certain populations (primarily key populations and their partners) and geographic settings may have higher HIV prevalence and/or incidence than nationally. The HIV response needs to prioritize these populations and areas. Countries also can review their **treatment-adjusted HIV prevalence** as an indication of the proportion of people who are undiagnosed or diagnosed but not currently on treatment.
- **Focused HTS approaches are needed**, particularly in resource-limited settings. HTS can be optimized by prioritizing approaches such as partner services and provider-assisted referral (including index testing) and focusing testing in specific health services, priority populations and geographic settings.
- For efficient use of resources, programmes need to optimize the frequency of HIV retesting. Globally, **most people who have an HIV-negative test will not need retesting.** Annual retesting is needed only for key populations and sexually active people in high HIV burden settings. More frequent retesting may be needed for people with ongoing HIV-related risk or for monitoring the effectiveness of HIV prevention interventions such as pre-exposure prophylaxis (PrEP).
- In low HIV burden settings, programmes can consider the use of validated **screening tools or questionnaires** to identify people who would benefit from HTS and who would not otherwise be offered testing. **Programmes should be judicious, however, when using validated tools or questionnaires that exclude people from the offer of HTS**, as HIV infections could be missed. Also, screening may not be feasible in some settings and could discourage some people from testing; when these questionnaires include personal or sensitive questions, it is important to ensure confidentiality.

7. STRATEGIC PLANNING FOR EFFECTIVE AND EFFICIENT HIV TESTING SERVICES

7.1 Introduction

HIV testing services (HTS) and treatment have been scaled up worldwide. Now, in many settings, the vast majority of people with HIV know their status and are accessing treatment with antiretroviral therapy (ART).

As the coverage of HIV testing and ART continues to increase, fewer individuals with HIV will need testing, diagnosis, treatment and care. As a result, efforts to reach the remaining people with HIV who do not know their status is increasingly challenging and costly in many settings. To maximize impact and optimize resource use, countries, particularly low- and middle-income countries, need to select high impact, innovative and efficient HTS approaches to focus their efforts on reaching populations and settings where undiagnosed HIV infection is greatest *(1-4).*

Many people with HIV who do not know their status are members of key populations and their partners and, in East and southern Africa, men and young women *(5, 6).* Others not being reached are the partners of people with HIV and individuals with sexually transmitted infections (STIs) *(7, 8).* Individuals diagnosed with HIV during the pre-ART era (that is, before treatment was offered to all people with HIV regardless of clinical assessment) and those who know their HIV status but are not on ART may benefit from HTS to prompt them to initiate or re-engage in care. To encourage these individuals to initiate or re-initiate ART, they may need the latest information on the health and preventive benefits of treatment and of simplified treatment regimens *(9).*

To reach people in need of HIV testing and to improve programme efficiency and effectiveness, HTS need to be planned and delivered in a new way. This chapter discusses core principles for selecting which HTS approaches to use for reaching various populations that are the priority for HIV testing, treatment and prevention. This chapter also provides guidance on rationalizing the use of limited resources and implementing focused HTS to reach those in need of testing. Additional content addresses how to conduct an in-depth situational analysis for selecting HTS approaches and cost and resource considerations.

To reach people in need and to improve programme efficiency and effectiveness, HTS need to be planned and delivered in a new way.

7.2 Core principles when planning and implementing effective and efficient HIV testing services

Box 7.1 presents guiding principles for planning HTS.

Box 7.1. Guiding principles for planning HTS

For any HTS, service delivery models and approaches should focus on:

1. reaching the **largest number of people with HIV who remain undiagnosed** and reaching the **population groups with higher HIV risk where the gap in knowledge of HIV status is greatest;**
2. **increasing acceptability, equity and demand** for HTS to reach those left behind, including key populations;
3. **prioritizing approaches** that are most cost-effective and efficient;
4. achieving **national programme targets** (for example, the 90–90–90 targets and the fast-track prevention targets);
5. **facilitating linkage** to treatment for individuals who are diagnosed HIV-positive and providing appropriately tailored prevention for those who test HIV-negative.

Source: WHO, 2018 *(10)*.

Determining how to deliver HTS more effectively requires review of existing programmes and approaches used for: (1) mobilizing and creating demand for HTS, (2) implementing HTS and (3) facilitating timely linkage to treatment, care and prevention following HTS.

Selecting **what HTS approaches are needed** to reach the greatest number of people with HIV who remain undiagnosed requires in-depth knowledge and understanding of a country's epidemic – for example, national HIV prevalence and incidence, treatment-adjusted prevalence (which estimates the proportion of people with HIV in the testing population by excluding those on ART) and subnational variations in these indicators by region and populations, including key populations. An in-depth review and analysis of programme data and data from population-based surveys is needed to "know your epidemic" and to identify gaps and opportunities. This will provide a good understanding of HTS coverage, both nationally and subnationally, and identify where the greatest burden of undiagnosed HIV infection exists. This exercise can also help identify areas or populations where there is unnecessary testing and opportunities to scale back or stop some HTS approaches. Determining how to deliver HTS more effectively requires a review of existing programmes and approaches used for: (1) mobilizing and creating demand for HTS, (2) implementing HTS and (3) facilitating timely linkage to treatment, care and prevention following HTS (Table 7.1).

Through these analyses, programmes will be able to adapt and redesign HTS so that they can effectively and efficiently reach those in need of HIV testing, treatment, care and prevention.

Relevant guidance for each component is available in the following chapters:

- Pre-test services, including messages, mobilization and demand creation, are detailed in Chapter 3.
- Post-test services, including messages, counselling and linkage, are detailed in Chapter 4.
- Service delivery models and approaches for HTS are detailed in Chapter 5.
- Considerations for implementation among population groups are detailed in Chapter 6.
- Monitoring and evaluation for HTS is detailed in Annex H.

Information on developing differentiated service delivery approaches is also available in *Differentiated service delivery for HIV: Decision framework for HIV testing services (11)*.

Table 7.1. Building blocks for an HIV testing service delivery model

	Mobilizing and creating demand	HTS implementation	Linkage to care
When	Continuous, intermittent or focused	Time of day and frequency	Time period for linking and frequency of monitoring
Where	Location of mobilization activities	Health facility, other facility, community	Location of linkage activities
Who	Location of mobilization activities Who does the mobilizing? Who is the focus for messages and mobilization?	Who does the HIV testing? Who is the focus for testing?	Who supports linkage to prevention or ART initiation?
What	What package of services and demand creation interventions?	What HTS approach?	What linkage intervention?

Source: Adapted from IAS, 2018 *(11)*

7.2.1 Knowing your epidemic

WHO recommendations and guidance on HTS approaches to prioritize and implement in various settings are often based on whether settings have high HIV burden or low HIV burden *(9, 12-15)*. In the context of HTS programming and planning, in this document **high HIV burden** refers to settings with ≥5% national HIV prevalence and subpopulations and geographic settings where HIV prevalence and/or incidence is higher than nationally. **Low HIV burden** settings refer to settings with <5% HIV national prevalence but where certain populations (primarily key populations and their partners) and geographic settings may have higher HIV prevalence and/or incidence than nationally and, therefore, need priority in the HIV response.

As epidemics mature in countries and HTS and ART coverage increase, fewer people will remain to be diagnosed, and HIV-positivity in national HTS programmes ("HTS-positivity"; sometimes referred to as yield that is the proportion of people with HIV who are **newly** diagnosed) will decline, even when national HIV prevalence increases as more people live longer on ART. Countries also can review their **treatment-adjusted HIV prevalence** as an indication of the proportion of people who are undiagnosed or diagnosed but not on treatment (see Chapter 8 for details). While these categories are indicative, they can be helpful when considering how to optimize HTS approaches, including determining who, what, where and when to test (see Table 7.1) *(13).*

Within countries, HIV burden varies by region, province and smaller geographic areas and administrative units, such as metropolitan areas, and even among testing sites. A nuanced and closer look at HIV prevalence and burden in different populations and geographic areas facilitates effective planning to determine where the largest gaps in testing, treatment and prevention exist (see Box 7.2).

The tools for identifying such variations and use of available data for programming are improving. Programmes now often have data from several sources at their disposal, including surveillance, programme and survey data, which often allow disaggregating HIV prevalence and HTS-positivity by sex, age, population type and geography. Specific data sources typically include surveillance data from HIV testing among pregnant women, national household surveys, smaller studies among groups of interest such as key populations and modelling exercises such as Spectrum AIDS Impact Model (AIM) of the United Nations Joint Programme on HIV/AIDS (UNAIDS) *(16)*. Used on its own, any data source will have limitations. When used in combination, however, multiple data sources can present a reliable picture of the HIV situation in the country and reveal epidemiological trends when analysed appropriately.

Any data source if used on its own will have limitations. However, triangulation of data from multiple sources can present a reliable picture of the HIV situation in the country and provide epidemiological trends.

National population-based surveys tend to provide the most accurate national or regional prevalence estimates if response rates are high and no major biases or exclusions of specific population groups exist. A limitation of national household or population-based surveys is that they are typically not designed to identify key populations or other country-specific priority populations. To address this gap, other approaches or specific surveys/studies may be needed to obtain reliable information for these groups, where HIV prevalence and knowledge of HIV status can be considerably different from that in the general population.

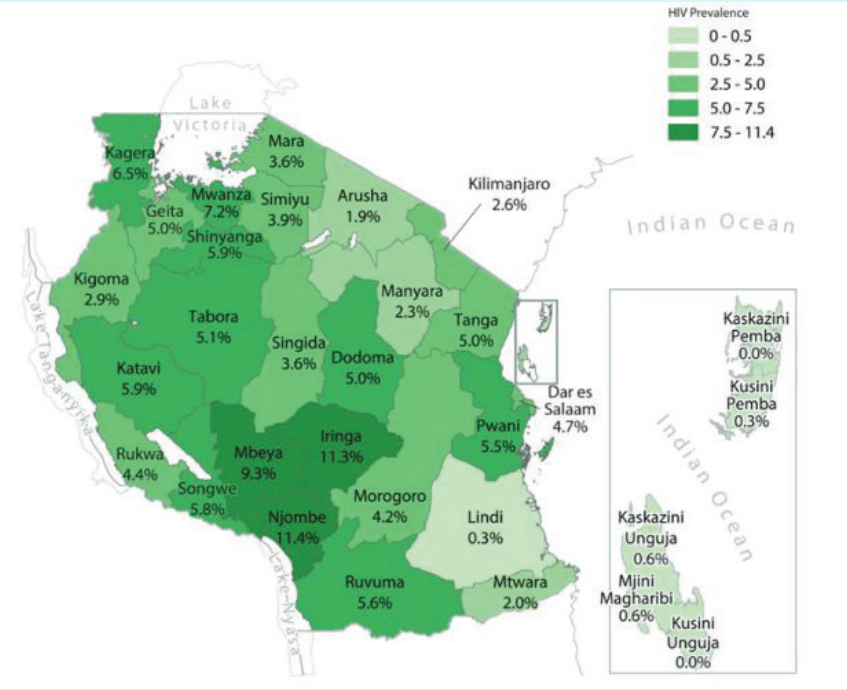
To obtain detailed information on HIV testing coverage and HTS-positivity, programme data at the provincial and district levels, and even at the facility level, should be reviewed.

Box 7.2. Variability in HIV prevalence by geography and HIV incidence by age and sex in the United Republic of Tanzania

According to 2016-2017 Population Health Impact Assessment (PHIA)[1] survey, HIV prevalence among adults ages 15 years and older in United Republic of Tanzania is 4.9%. *(17, 18).* This survey highlights marked variations in HIV prevalence by sex, age group and region.

HIV prevalence among adults in different regions of the country ranges from <1% in Lindi, Unguja, Mjini Magharibi and Pemba to over 11% in Njombe and Iringa (Fig. 7.1). There are differences in HIV prevalence by sex and age group, as well. The highest HIV prevalence is among females ages 45–49 years (12%) and among males ages 40–44 years (8.4%). In age groups between 15 and 39 years, HIV prevalence among women is more than double that among men in the same age groups. HIV incidence in adult women, ages 15–64 years, also is double the incidence in men in this age range (0.34% versus 0.17%).

Fig. 7.1. HIV prevalence among adults ages 15 years and older in the United Republic of Tanzania, by region



Source: Tanzania HIV Impact Survey, 2018 *(17)*

1 PHIA Project, https://phia.icap.columbia.edu/about/.

7.2.2 Considerations for routinely offering HIV testing services

When HTS is routinely offered, all people with unknown or HIV-negative status in a specified geographic location or setting are offered HIV testing. WHO suggests offering voluntary HTS routinely to all clients of unknown or HIV-negative status in high HIV burden settings. Routinely offered HTS can be delivered in health facilities or in the community. In some high HIV burden settings, community-based approaches such as home-based (door-to-door) HTS are conducted to reach all people in a geographic area.

In high burden setting with high testing and ART coverage, the HTS- positivity may be low, especially if testing is offered routinely to all people every time that they attend clinical services. Annual retesting is suggested in high burden settings for sexually active individuals, those at ongoing risk or as part of monitoring the effectiveness of HIV prevention interventions (see section 7.2.4 for guidance on optimal retesting frequency and Chapter 4 for post-test messages). Review of the HTS-positivity at testing sites and adjusting the frequency of offering testing may need to be considered to optimize retesting.

7.2.3 Considerations for focusing HIV testing services

Focused HTS seeks to reach specific populations or subgroups where HIV prevalence or treatment-adjusted prevalence remains high or to prioritize implementation in certain geographic areas or clinical settings according to local epidemiology and HIV testing coverage.

> Focused HTS approaches are needed to effectively reach population groups who are most at risk of acquiring HIV and where gaps in testing coverage are greatest.

Focused HTS can be delivered using a range of WHO-recommended HTS approaches, including facility-based, community-based, HIV partner services and HIV self-testing (HIVST). Box 7.3 summarizes how focused HTS approaches can be used to reach specific populations and settings.

Focused approaches are designed to reach certain populations not adequately served by existing HTS or where gaps in HTS coverage are greatest. While these efforts may seem costly, the cost needs to be considered in the context of improving access and equity for the populations served and the potential for identifying additional undiagnosed HIV infections. If a focused HTS approach leads to high HTS-positivity, either nationally or subnationally, the cost per person diagnosed HIV-positive may be lower than or comparable with other, less focused approaches even though the unit cost per test may be higher. Care is needed when implementing focused HTS approaches to ensure that they do not increase stigma and discrimination. Focused demand creation activities can also improve testing uptake among priority populations (see Chapter 3). Table 7.2 summarizes how to prioritize HTS by population.

Box 7.3. Approaches for focusing HIV testing services

Focusing HTS means selecting the most appropriate HTS approaches specific for specific priority populations and settings. Options include the following:

- **Provider-assisted referral** (often called assisted partner notification or index testing) reaches the sexual and drug-injecting partners of people with HIV. **Social network-based HIV testing approaches** can also reach sexual and drug-injecting partners as well as social contacts of HIV-positive and HIV-negative members of key populations with ongoing risk *(8, 19).* Chapter 5 presents additional considerations.
- **HTS in selected health facilities** can serve specific populations or areas with high HIV burden or unmet testing need. See considerations in Chapter 5.
- **HTS focused on certain populations** can reach those at high risk or with undiagnosed infections, such as a specific key population, sexual and social networks with ongoing HIV transmission risk, partners, family members, peers or social contacts of people with HIV. Other groups may include men and adolescents in high HIV burden settings and other underserved vulnerable groups (for example, migrant workers), depending on the local setting and context. Chapter 6 presents considerations for specific populations.
- **HTS focused on specific geographic areas or settings**, such as districts or areas with high HIV burden with ongoing transmission (for example, transport hubs, border crossings or specific urban locales where key population members work or reside) *(20).* Other examples include community-based testing and distribution of HIVST kits at workplaces, schools and educational establishments, sex-on-premises venues, mobile outreach and home-based testing in specific settings with low testing coverage and high HIV prevalence or incidence *(21).* Geographic prioritization may also be a way to gradually scale up and phase in new HTS approaches, increasing coverage as resources become available.

As for any HTS, focused HTS approaches require regular monitoring and review of data to determine if approaches are reaching the intended populations and areas. Approaches need to be modified if they are not achieving their goals. Subnational or site-level programme data and data from other sources, such as surveys, may be needed to gauge progress.

HTS can also focus on people who present with clinical conditions suggestive of HIV infection, high risk groups with co-infections and people who would not otherwise be offered testing. Considerations for such approaches are summarized below.

Table 7.2. HTS approaches to consider for selected priority populations

Priority population	Facility-based	Community-based	HIV self-testing	Social network-based testing for key populations
Key populations	Routine in all facilities and testing sites serving key populations	Mobile or outreach testing for key populations in all settings	Offer in all settings	Offer to partners and social contacts of HIV-positive, and, if at ongoing risk, HIV-negative, members of key populations
Men	Routine in high HIV burden settings Focused in other settings, for example, indicator condition- or risk-based	Workplace testing in high burden settings	Peer distribution or distribution to male partners by antenatal care (ANC) clients in high burden settings	Offer to social contacts of men who have sex with men
Adolescents and young adults (ages 15–24 years)	Routine in high HIV burden settings Focused in other settings, for example, indicator condition- or risk-based	In high HIV burden offer in settings such as schools, other educational institution or sports festivals	Online distribution via social media in high burden settings; can be considered in facilities where testing may not routinely offered (i.e. family planning clinics) or as part of focused key populations outreach.	Offer to youth from key populations who test HIV-positive or HIV-negative
Pregnant and postpartum women	One test routinely in all settings Retesting: routine in late pregnancy in high HIV burden settings; focused in other settings, for example, pregnant women from key populations or who have partners with HIV or from key populations	In high HIV burden settings where women receive community-based postpartum care	Can be considered for retesting during the postpartum period or for women attending contraception/family planning services in high burden settings	Offer to pregnant women from key population groups
Infants and children	Routine in high HIV burden settings Focused in other settings, for example, children with a parent with HIV or indicator condition-based	HIV-exposed children and children with a parent with HIV	Using HIVST kits for testing infants and children is not currently recommended.	N/A

Note: Partner services, including voluntary provider-assisted referral should be offered to all people with HIV in order reach to their sexual and/or drug-injecting partners and biological children whose HIV status is unknown.

Indicator condition-guided HTS is the offer of HTS to individuals who present with specific clinical conditions indicative of an HIV infection, such as cervical or anal cancer/dysplasia, herpes zoster or unexplained fever *(22)*. This approach has been effectively implemented in routine health-care settings in Europe, where it is supported by WHO region-specific guidance *(22, 23)*. Analysis of data from 20 low HIV burden European countries found 3% HIV positivity when people with indicator conditions were offered HIV testing *(24).*

Programmes considering this approach need to provide staff training and may want to consider providing staff with an abbreviated list of indicator conditions specific to their setting. See *HIV indicator conditions: guidance for implementing HIV testing in adults in health care settings* for details *(22)*.

Indicator condition-guided HIV testing can be considered in both high and low HIV burden settings. It should be noted, however, that this approach has not been assessed in high burden settings in Africa. In such settings indicator condition-guided HTS can be an additional tool to minimize the chances of missing people with HIV, but it should not replace routinely offered testing where the latter is appropriate.

Symptoms and co-infection. Offering HIV testing to people with tuberculosis (TB) symptoms (also known as presumptive TB patients), diagnosed TB patients, people with an STI or viral hepatitis can be highly effective in identifying HIV infections. This is appropriate in both high and low HIV burden settings and for specific populations and areas depending on HIV epidemiology – for example, populations with high burden of both HIV and hepatitis C infections such as people who inject drugs and people in prisons and other closed settings. In many high HIV burden settings, HIV testing has been integrated into TB settings but not so much into other settings such as STI and hepatitis services.

Risk-based screening tools or questionnaires have been developed and used in some settings to "screen in", or identify, people who would benefit from HTS in settings where HIV testing is not routinely offered or, to maintain or improve efficiency, to "screen out", or exclude, people from HTS in settings where HTS has been offered routinely but HTS-positivity is low.

Some evidence suggests the utility of tools or questionnaires that prompt providers to offer testing to individuals with HIV-related risk factors when they would otherwise not be offered HIV testing *(25)*. For example, in Nigeria, where HTS is not routinely offered to older children, introduction of a validated screening tool increased HTS coverage among sick and hospitalized children by 27%, and the number of children newly diagnosed with HIV increased by 36% *(26)*. Individual risk-assessments or demographic characteristics have also been successfully used to determine who should be offered or encouraged to use a self-test. For example, in Brazil online self-assessment tools were used to prioritize HIVST distribution to men who have sex with men who had additional HIV risk factors *(27)*.

Where HTS is not routinely offered, including low HIV burden settings, validated screening tools may play a role in focusing the use of resources.

Use of tools that screen out people from the offer of HTS need careful consideration.

In settings and populations where HTS is not routinely offered, including low HIV burden areas, screening tools may have a role in focusing resources and scaling-up HTS strategically. These situations may include a country trying to increase HTS coverage in key entry points, such as outpatient settings but without resources to test everyone, a low-HIV burden setting where sick children with HIV risk factors are presenting but are not routinely offered HTS, or to rationalize the distribution of a limited number of available HIVST kits based on demographic risk factors.

There is less evidence, however, of the effectiveness of tools that screen out or exclude people from the offer of HTS *(25).* Programmes considering the use of such tools need to consider their use carefully, as these questionnaires may include questions that are personal or sensitive, which may deter some people from testing due to confidentiality concerns. Also, there may be potential for misuse, and these tools may miss some people at high ongoing risk who need testing.

Retesting those who last tested more than 12 months ago may improve HIV-positivity. For example, an assessment at seven testing sites in Kenya operationalizing this approach showed that the number of HIV tests performed would be substantially reduced and would result in a 2.4-fold increase in the proportion of people diagnosed HIV-positive among those tested (1.9% versus 0.8%; $P<0.001$). However, restricting HTS to those who had tested more than 12 months ago would have missed more than half (54.8%) of all new HIV-positive diagnoses in this setting *(28).*

Evidence-based tools that have been validated to ensure high specificity (that is, people screened out are actually HIV-negative) could be considered and adapted. Careful consideration is needed when introducing these tools, including ensuring client confidentiality and assessing their effect on service provision and patient flow. When utilized, it is critical to ensure that these tools do not increase stigma and discrimination or hinder access to HTS for those in greatest need. Engagement with affected populations and providers is also essential.

7.2.4 Retesting – when and who

Retesting among people who are HIV-negative or of unknown status has two key purposes: (1) monitoring the effectiveness of HIV prevention interventions and (2) identifying and treating new HIV infections as early as possible when prevention efforts fail *(13).*

Globally, most people who have an HIV-negative test will not need retesting *(13)*. In low HIV burden settings, one lifetime HIV test is sufficient for most people when there is no ongoing risk *(13, 29).*

Retesting people who are HIV-negative is needed only for people with ongoing HIV-related risk. Retesting is needed for HIV-negative individuals only when they report recent or ongoing HIV risk exposure. For most people who test HIV-negative, retesting to rule out being in the window period is not necessary and not a good use of resources, unless they report a recent potential HIV risk exposure.

Annual retesting. Only specific groups of people in high HIV burden settings or with other HIV-related risks need post-test counselling messages encouraging retesting at the appropriate intervals. WHO guidance recommends annual retesting for:

- **sexually active individuals in high HIV burden settings** and;
- people who have **ongoing HIV-related risks in all settings**. These include:
  - **key populations**, defined as men who have sex with men, people in prison or other closed settings, people who inject drugs, sex workers and transgender people;
  - **people with a known HIV-positive partner who is not virally suppressed on ART.**

Retesting in special groups. In certain situations individuals who have tested HIV-negative in the past should be considered for retesting. These include:

- **individuals presenting with a diagnosis or receiving treatment for STIs or viral hepatitis;**
- **individuals with a confirmed or presumptive TB diagnosis;**
- **outpatients presenting with clinical conditions or symptoms** indicative of HIV;
- **individuals with recent HIV risk exposure.**

More **frequent retesting** – that is every 3–6 months – may be warranted based on individual risks factors, particularly for people from key populations and as part of broader HIV prevention interventions – for instance, individuals taking PrEP, who require quarterly HIV testing, or members of key populations who present to services with an STI.

7.2.5 Testing pregnant and breastfeeding women

Pregnancy and breastfeeding are periods when many women face an increased risk of HIV acquisition, particularly those in high HIV burden settings, those who have partners with HIV and those from a key population.

All pregnant women in all settings should be offered testing for HIV, syphilis and hepatitis B surface antigen (HBsAg)[1] at least once and as early as possible during pregnancy, ideally at the first ANC visit. Dual/HIV syphilis rapid diagnostic tests (RDTs) can be considered as the first test in HIV testing strategies and algorithms at ANC in all settings.

In **high HIV burden settings**, retesting is advised in late pregnancy – at a **third trimester visit** – for all pregnant women of unknown or HIV-negative status. If either the first test or the retest is missed or delayed, "catch-up" testing is needed.

An additional retest for women of unknown or HIV-negative status in the postpartum period can be considered. Countries could consider an additional postpartum test in specific districts or provinces with high HIV burden or incidence and among women from key populations or who have partners with HIV that is not virally suppressed.

1 Particularly in settings with a ≥2% HBsAg seroprevalence in the general population.

In **low HIV burden settings**, focused retesting at a third trimester visit is advised for HIV-negative pregnant women with unknown or HIV-negative status who are in serodiscordant relationships in which the partner is not virally suppressed on ART, who are from key populations or who have other ongoing HIV-related risk. If either the first test or the retest is missed or delayed, "catch-up" testing is needed.

An additional retest for women of unknown or HIV-negative status in the postpartum period can be considered among women from key populations or who have partners with HIV on ART but not virally suppressed. Countries could also consider an additional postpartum test in specific districts or provinces with high HIV burden or incidence or to support efforts to eliminate mother-to-child transmission (eMTCT).

Importantly, in low HIV burden settings, retesting all pregnant and post-partum women is not advised.

Table 7.3 summarizes optimal time points for maternal HIV testing and retesting.

Table 7.3. Suggested optimal time points for maternal HIV testing and retesting

	Time points		
Setting	Early in pregnancy (first ANC visit)	Late in pregnancy (third trimester ANC visit)	One additional postpartum retest (14 weeks, six-month or nine-months postpartum)
High HIV burden settings	All	All	Can be considered for those at high ongoing risk
Low HIV burden settings	All pregnant women as part of eMTCT, otherwise focused on those at high ongoing risk	Can be considered for those at high ongoing risk	Can be considered for those at high ongoing risk
Key populations and their partners, or partner with HIV that is not virally suppressed, in all settings	All settings	All settings	All settings

See Box 7.4 for an example and the rationale for maternal testing and retesting among HIV-negative women. See Chapter 6 for other considerations for testing pregnant and postpartum women.

Box 7.4. Considerations for testing (and retesting) for HIV and syphilis in pregnancy and the postpartum period in high and low HIV burden settings

Mathematical modelling and cost-effectiveness analysis was conducted to assess:

1. Whether retesting women of unknown or HIV-negative status in late pregnancy and in the postpartum period is cost-effective in different epidemic settings and, if so, the most optimal time point or combinations of time points to retest.
2. Whether using a dual HIV/syphilis RDT as the first test in ANC is cost-effective in different epidemic settings and the utility of dual tests for retesting in late pregnancy.

To address these questions, four illustrative country scenarios were developed based on data from high HIV burden settings (Kenya and South Africa) and low HIV burden settings (Colombia and Ukraine), with national HIV prevalence of 6.2%, 30.0%, 0.4% and 0.7% and syphilis prevalence of 1.2%, 2.0%, 0.4% and 2.5%, in adults ages 15–49 years. Modelled HIV and syphilis testing coverage were based on national estimates. Costs considered included HIV and syphilis testing, consumables, labour and service delivery costs.

Key findings are summarized below. The full report, including methods, results and details on each country scenario appear in annexes F and G.

Key findings

- Maternal HIV retesting during pregnancy is cost-effective (<$500/disability-adjusted life year (DALY) averted) in high HIV burden countries (in this model, Kenya and South Africa).
- Retesting during late pregnancy (in the third trimester and catch-up testing for those initially missed) is the best single time to retest and averts over 20% of infant HIV infections attributed to incident maternal HIV infections.
- Retesting during pregnancy in low HIV burden countries is not cost-effective (in this model, Colombia or Ukraine).
- Dual HIV/syphilis testing at the first ANC visit is cost-saving in both high and low HIV burden settings.

Source: Meisner, 2019; Rodriguez, 2019 *(30, 31)*.

Retesting people with HIV not taking ART or receiving other HIV care. People with HIV who are not currently taking ART or receiving other HIV care may seek retesting to re-engage in care. These individuals may have been diagnosed in the pre-ART era and were not eligible to start treatment at the time of diagnosis. Furthermore, people retesting may include those who started ART but disengaged from care. For people with HIV who are retesting, efforts should focus on effective linkage to ART.

Retesting as part of efforts to provide an accurate HIV diagnosis, such as for those with an inconclusive test result, and verifying all HIV-positive diagnoses prior to ART initiation are detailed in Chapter 8.

Details on messages for clients about retesting, delivered as part of pre-test and post-test services, are available in Chapter 3 and Chapter 4.

7.3 Conducting in-depth situational analyses to optimize HTS delivery

Conducting an in-depth HTS situational analysis is the first step when planning to optimize testing approaches.

Conducting an in-depth HTS situational analysis is the first step when planning to optimize testing approaches. Such analyses will vary by country and setting but typically include a review of national HIV epidemiological, programme and survey data (as described in section 7.2.1 Knowing your epidemic), financial resources, costs and relevant laws and policies. The information reviewed should be disaggregated by sex, age, population type, geography and HTS approach (such as type of facility or community approach, provider-assisted referral and HIV self-testing), where feasible.

A situational analysis should also include review of complementary packages of services to facilitate linkage to care and create demand for HTS and of their effectiveness.

Where possible, multiple data sources should be used to triangulate and validate information. Considering this information in relation to HTS coverage and other contextual factors can provide valuable insight into where the largest gaps in service delivery exist and where HTS needs to be focused and differentiated.

Table 7.4 summarizes key data points and sources to consider. More guidance on indicators for routine monitoring appear in Annex H.

Ensuring that HIV testing programmes are reaching their intended populations and identifying previously undiagnosed HIV infections will require ongoing monitoring and evaluation. For long-term success, the impact of different HTS approaches on uptake, HTS-positivity, cost and changes in HIV prevalence in different populations must be evaluated and measured regularly, and programmes should be adjusted accordingly. Section 7.2.3 discusses strategies to focus HTS.

Table 7.4. HIV testing data and sources relevant to HTS situational analysis

Indicator	Data source(s)	Disaggregation	Use
HIV testing services data			
HIV prevalence (and/or HIV incidence)	Multiple sources can be used; consider triangulation. Possible sources: national population-based surveys; ANC surveillance data; programme data; special studies or projects among key populations; modelling exercises (for example, the UNAIDS Spectrum AIDS Impact Model (AIM))	National and subnational; sex and age group (5-year age groups or at least <15 and >15 years); pregnant women attending ANC; key population; other vulnerable and priority populations such as STI and TB patients	To quantify HIV burden in different geographies, demographics and populations
Number/proportion of people with HIV who know their HIV status	National population-based surveys; programme data	National and subnational; sex and age group; key population; other vulnerable and priority populations	To understand HIV testing coverage gaps in different geographies, demographics and populations.
Treatment-adjusted prevalence (proportion of people with HIV in the testing population, excluding those on ART)	National population-based surveys; programme data	National and subnational	To understand the burden of undiagnosed and untreated HIV in different geographies. Provides an indication of optimal HTS-positivity.
HIV testing coverage – ever-tested or tested in the past 12 months	Programme data; special surveys or reports; population-based surveys	General population with sex and age groups (5-year age groups or at least <15 and >15 years); key population; other vulnerable and priority populations; facility type (outpatient/inpatient, ANC, TB, STI, harm reduction, etc.)	To understand HIV testing coverage gaps for different populations and types of facilities; facility level retesting rates.
Mobilization and demand creation approaches	Programme data	General population with sex and age groups (5-year age groups or at least <15 and >15 years); key population; other vulnerable and priority populations	To understand the range of demand creation packages and approaches in use and their effectiveness and acceptability
HIV testing uptake – number/proportion of those offered HTS who accept it	Programme data (may not be readily available); special studies	General population with sex and age groups (5-year age groups or at least <15 and >15 years); key population; facility type; HTS approaches	To understand the effectiveness and acceptability of different HTS approaches and differences by facility type and populations

Indicator	Data source(s)	Disaggregation	Use
HTS-positivity – number/proportion HIV-positive among those tested	Programme data	Key population; other vulnerable and priority populations; facility type (outpatient/inpatient, ANC, TB, STI, harm reduction, etc.); HTS approaches	To assess how well the testing is focused on those in need; which HTS approaches are identifying more people with HIV or achieving high positivity rates
Number/ proportion of people diagnosed with HIV who are linked to HIV treatment and care	Population-based surveys; programme data; national registries	National and subnational	To assess the success of linkage interventions
Number/ proportion stock-outs of test kits	HTS site-level data (facility and community); central medical stores	National and subnational	To identify quality issues that may affect optimal HTS implementation, for example, people in need of HTS who could not get tested
Other HIV programme data			
ART coverage (number/ proportion of people on ART)	Programme data	National and subnational; key population; other vulnerable and priority populations.	To determine the gap in ART coverage among those diagnosed.
Policy and regulatory status			
National HTS policy and related laws and regulations	National guidelines, strategic plans and standard operating procedures		Policy support for differentiated HTS, for example, task sharing, lay provider testing, decentralization, HIVST, age of consent; identifying legal barriers
National product registration status	National regulatory documents; regulatory agency websites; ministry of health (MOH)		To identify product availability for specific HTS approaches, for example, HIVST
Quality assurance and post-market surveillance	Programme data, WHO prequalification, MOH and regulatory authorities	National and subnational	To ensure quality assurance, for example, verified national HIV testing algorithm and post-market surveillance for HIVST
Cost and resource use			
Resource availability	MOH and other ministries	Human and financial; national and subnational	To understand resources available for differentiated HTS and scale-up
Cost, budget impact and cost-effectiveness	Programme data; special studies; modelling exercises. Consider triangulation.	National and subnational; facility type (outpatient/ inpatient, ANC, TB, STI, harm reduction, etc.); HTS approaches	To understand costs per test and per positive case identified or linked to care/ ART; to identify service delivery models likely to be cost-effective if scaled up

7.3.1 Considering cost and resource needs for HTS

Some approaches – such as provider-assisted referral – may be costly to implement but more efficient in identifying individuals with undiagnosed HIV; thus, cost per person diagnosed HIV-positive may be lower or comparable to that of other HTS approaches.

HTS delivery costs, including cost per person tested and cost per person diagnosed HIV-positive, vary by approach and setting across countries and within countries. The cost of the HTS programme in a given setting will depend on such factors as HTS approach (facility versus community-based; routinely offered versus focused), type of staff involved (clinician versus lay provider); HIV epidemiology (high versus low burden); focus population (general population versus priority populations) and the nature of pre-test information and post-test counselling provided (concise versus long; in-person versus digital platforms). For example, an analysis of HTS costs in Botswana showed that cost per person tested ranged from US$ 5–75, varying depending on the HTS approach and where it was delivered (in the community or a facility), the number of people tested (for example, 1000 people or 100 000) and the type of providers who delivered services (32). Some approaches – such as provider-assisted referral – may be costly to implement but more efficient in identifying individuals with undiagnosed HIV; thus, cost per person diagnosed HIV-positive may be lower or comparable to that of other HTS approaches. To optimize HTS costs, it is useful to streamline and integrate services as well as to use lay providers, efficient and effective service delivery models, focused demand generation, rationalized pre-test information and post-test counselling and, in certain populations, promotion of HIVST *(13, 33).*

When introducing a new HTS approach, it is important to consider the full costs of the existing programme as well as the costs of adding the new HTS approach (that is, the incremental costs). Programmes should consider start-up costs for introducing new HTS approaches when directly comparing new HTS with existing HTS approaches. Because of these additional costs, newer HTS approaches may appear to be more costly than existing approaches in the short term but may prove to be less expensive in the long run if designed and implemented appropriately with focus on the appropriate areas and populations. Programmes can use cost per person diagnosed HIV-positive to compare the efficiency of HTS approaches.

The following broad categories can be used to calculate the total expected cost of an HTS approach (with or without linkage).

Direct medical costs

- personnel, including providers and supervisory staff – for example, staff salaries and allowances;
- fixed costs or capital expenses, often amortized over their useful life and discounted annually at 3% – for example, office space, vehicles, computers, equipment;
- recurring costs – for example, HIV test kits and commodities, printed materials, and office supplies. Donated goods and use of existing equipment may also be included, depending on the goals of the analysis.

Direct non-medical costs

- These include costs incurred by the programme or implementer but not related to direct medical expenses – for example, cost of transportation, food and drinks for waiting clients, reimbursements, financial or non-financial incentives and internal and external quality assurance.

Costs incurred by test recipients

- direct medical costs that are paid by the individual receiving HTS;
- indirect or economic opportunity costs incurred by individuals seeking HTS and/or their accompanying family member or carers – for example, time off work, travel costs and waiting and travel time.

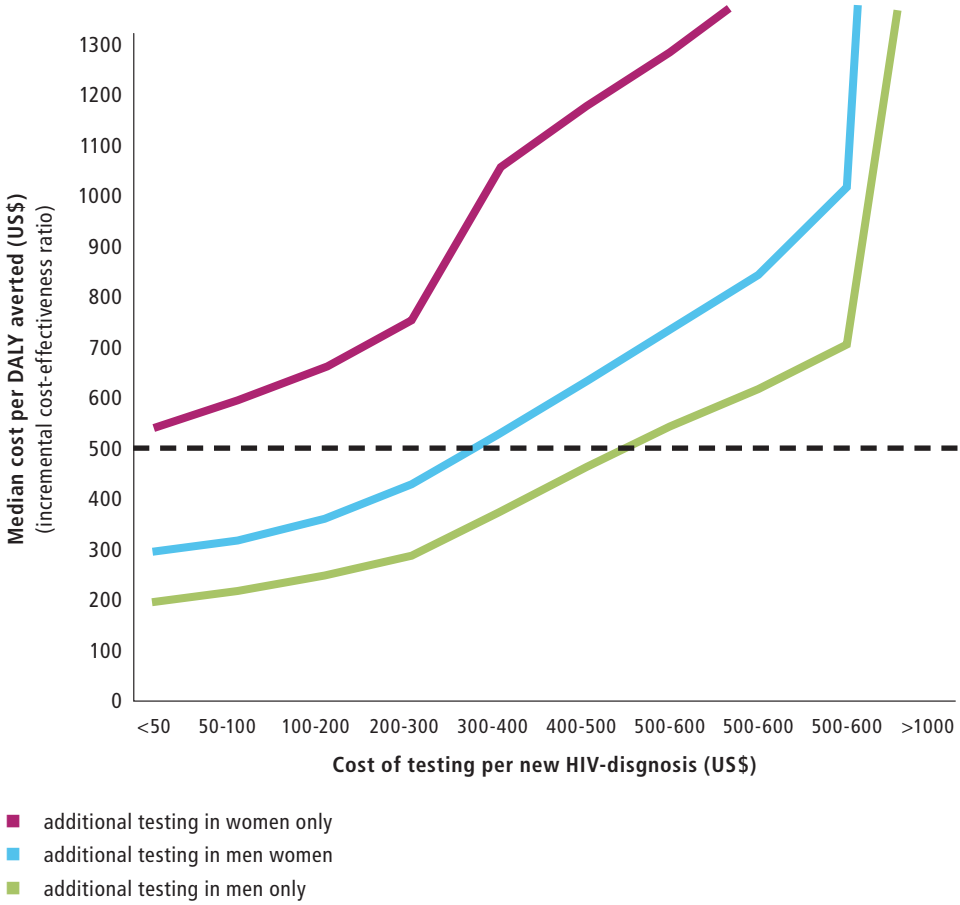
The extent of direct and indirect costs borne by the individual receiving HTS may influence decisions to seek testing and the accessibility of HTS.

Cost categories can be selected to suit the purpose of the analysis, whether it includes only financial costs (actual expenditures on goods and services) or if it includes economic costs (the value of all resources used – for example, donations, volunteered time). Costs also vary based on whether the analysis is limited to the providers' perspective (that is, only costs incurred by the health system) or if they also include the patients' perspective (health system costs plus costs to patient and others, often called opportunity and societal costs).

7.3.2 Cost-effectiveness and budget impact analyses

Considering the extent of costs averted by a given intervention is important. Economic analysis (cost-effectiveness) answers programmatic questions such as whether an intervention should be implemented compared with other available options. Options are usually compared in terms of the incremental cost-effectiveness ratio (in terms of cost per DALY or quality-adjusted life years (QALY) averted)). For example, a single HIV test in pregnancy has been shown to be cost-effective in all epidemic settings because it benefits the mother, prevents paediatric infection and avoids subsequent treatment costs that would have been required for the lifetime of an infected infant *(34).* However, retesting during late pregnancy appears to be cost-effective only in high HIV burden settings *(35).* In southern Africa cost-effectiveness analyses suggest that additional testing, and new approaches such as HIVST, are more likely to be cost-effective if focused – on men, for example *(36, 37)* (Fig. 7.2).

Fig. 7.2. Predicted cost-effectiveness (cost per DALY averted) of testing activities according to the cost per new HIV-positive diagnosis in southern Africa



Source: Phillips, 2019 *(36)*.

Knowing what can be implemented and scaled up with a given budget is important and a common challenge. Budget impact analysis (resource optimization) assesses whether the intervention (even if cost-effective) is affordable within the available budget. Budget impact analysis guides decisions on resource allocation for new and/or existing HTS approaches *(38)*. For example, in South Africa a budget impact analysis of the optimal mix of HIV interventions over a two-year period showed that the current budget was sufficient to scale up HTS within a broader package of social-behavioural change efforts and for infants born to mothers with HIV, but additional HTS for the general population was not affordable *(39)*.

Budget impact analyses generally address duration of a budget cycle or a short period (1–5 years) and are typically presented according to the time intervals used for budgeting (such as annual or quarterly) *(38)*.

There follow some considerations related to costs, cost-effectiveness and budget impact analyses.

- **Cost per person diagnosed HIV-positive** is a good proxy indicator for cost-effectiveness *(36)*. Cost per person diagnosed HIV-positive and also linked to treatment can also be considered, particularly in settings with high levels of retesting among people with HIV who already know their status.
- **The scale of HTS approaches is important to achieving public health impact.** Some HTS approaches that have low cost per person diagnosed HIV-positive may be highly focused and reach a small group of people. Thus, programmes also need to consider the absolute number of people diagnosed HIV-positive with different HTS approaches to assess their value in achieving national targets.
- **HTS approaches with higher costs per person tested may still be valuable** if they achieve a cost per person diagnosed HIV-positive (and linked to treatment) that is comparable to or lower than the costs of other HTS approaches. For example, community-based outreach for key populations, HIVST, partner services and provider-assisted referral can be resource-intensive to implement but are essential to identify infections among people who would not otherwise test *(40-45)*. This logic also applies to HTS approaches that improve equity among underserved populations.
- **Limited resources may mean cost-effective HTS approaches may need to be more intensely focused.** To optimize resources, approaches may need to be focused on specific populations, such as key populations or individuals with indicator conditions or symptoms associated with HIV infection, or on geographic settings or certain types of health facilities.
- **Cost, cost-effectiveness and budget impact analyses** are important parts of an in-depth situational analysis and broader processes of deciding which HTS approaches to scale up and which to discontinue.
- **Changes in cost and overall impact** of different HTS approaches must be evaluated and measured regularly, and programmes should be adjusted accordingly.

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KEY POINTS

- **Programmes should provide affordable and accurate HIV testing services (HTS)** by adhering to the recommended HIV testing strategies and algorithms that use appropriately selected products and achieve an overall positive predictive value of 99% or higher.
- **Updated** In response to changing HIV epidemiology and declining HIV positivity among those being tested, **WHO is encouraging high HIV burden countries, and reminding low HIV burden countries, to use three consecutive reactive test results to make an HIV-positive diagnosis.** By making this shift, high burden countries will be able to ensure accurate HIV diagnoses even as HIV positivity among those being tested (also called national HTS positivity) continues to decline.
- **Treatment-adjusted HIV prevalence** provides an indication of the proportion of people with HIV in the testing population, by excluding those on ART. High-burden countries should consider using national HTS positivity and also consider the treatment-adjusted HIV prevalence to help determine when to begin changing their testing strategy and algorithm.
- **NEW** **Western blotting and line immunoassays should not be used in HIV testing algorithms**. Countries should move away from these assays (tests) and instead select products, such as rapid diagnostic tests (RDTs) and enzyme immunoassays (EIAs), which will facilitate access to and scale-up of HIV testing, treatment and prevention services.
- **Programmes should offer HIV self-testing and test for triage**, using trained lay providers, in health facilities or community settings to reach individuals with HIV who do not know their status.
- **NEW** **Dual HIV/syphilis RDTs can be used as the first test** for pregnant women in antenatal care (ANC). Dual testing is not appropriate for women on ART or women diagnosed and treated for syphilis during pregnancy.
- **Programmes must know how to build and verify a national HIV testing algorithm** and be prepared in case of a product shortage due to stock-out, recall or obsolescence of product.

8. SELECTING DIAGNOSTICS FOR HIV DIAGNOSIS

Box 8.1. NEW and Updated WHO recommendations and guidance

In response to changes in the HIV epidemic, WHO encourages countries to move toward using three consecutive reactive test results to provide an HIV-positive diagnosis.

Western blotting and line immunoassays should not be used within HIV testing strategies/algorithms *(strong recommendation, low quality evidence).*

Dual HIV/syphilis rapid diagnostic tests can be the first test in HIV testing strategies and algorithms in antenatal care settings.

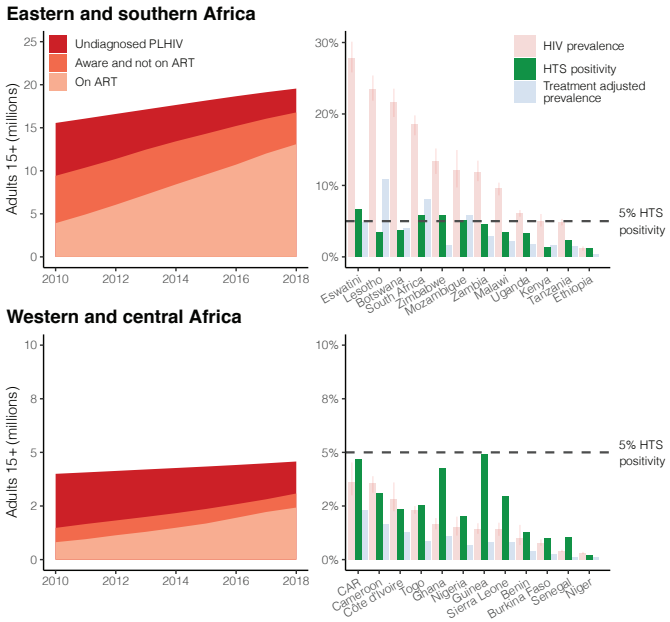
8.1 Introduction

Tremendous progress has been made in the scale-up of the HIV response. Nearly 80% of all people with HIV know their status, and the majority of these people are now receiving treatment and achieving viral suppression *(1).* As a result many countries are reporting declining HIV-related mortality and fewer new infections *(1).*

As HTS and ART scale-up close testing and treatment gaps, fewer people with HIV need HIV testing, diagnosis and linkage to treatment and care. Consequently, national HTS positivity – the proportion of HIV-positive results among those undergoing testing – has also declined. Such trends are most apparent in high HIV burden settings such as eastern and southern Africa (Fig. 8.1).

Despite these achievements, substantial gaps remain. Many of those at highest risk remain unreached. In high HIV burden settings, in eastern and southern Africa, this includes adolescents and young people (ages 15–24 years) and men. Worldwide, key populations – men who have sex with men, people who inject drugs, people in prisons or other closed settings, sex workers and transgender people – are underserved despite being most affected by HIV and at high ongoing risk. Globally more than half of all new HIV infections occur among key populations and their partners *(1).*

Fig. 8.1. Closing the gap in the number of undiagnosed people living with HIV (2010–2018)



Between 2010 and 2018…

…in eastern and southern Africa

- The number of adult PLHIV unaware of their HIV status decreased from 6.1 million to 2.8 million.
- Adult HIV prevalence decreased from 7.1% to 7.0%.
- The proportion of adults with undiagnosed HIV decreased from 2.8% to 1.0%.
- In countries with 20% HIV prevalence and above, in 2018, national HTS positivity was close to or below 5%.
- National HTS positivity was much closer to the treatment-adjusted prevalence (which excludes adults with HIV on ART) than national HIV prevalence.
- Countries where national HTS positivity is lower than the treatment-adjusted prevalence there may be a need to further optimize HTS.

…in western and central Africa

- The number of adult PLHIV unaware of their HIV status decreased from 2.5 million to 1.5 million.
- The prevalence of HIV among adults decreased from 1.6% to 1.5%.
- The proportion of adults with undiagnosed HIV infection decreased from 1.0% to 0.5%.
- National HTS positivity was below 5% in all countries.
- Countries where national HTS positivity exceeded overall HIV prevalence likely reflects highly focused HTS in key populations, priority locations and patients with HIV-related symptoms.

PLHIV: People living with HIV; ART: antiretroviral therapy; HTS: HIV testing services; CAR: Central African Republic.
HTS positivity presented in this figure is based on national programme data reported to 2018 UNAIDS Global AIDS Monitoring. National HTS positivity refers to the number of tests conducted where an HIV-positive result was returned to a person in the calendar year. Treatment-adjusted prevalence refers to the estimated national HIV prevalence, adjusted to exclude people with HIV who are on ART from the numerator and the denominator. Treatment-adjusted prevalence includes: people with HIV who are undiagnosed, people with HIV who know their status but have not initiated treatment, and people with HIV who previously initiated treatment but have disengaged from care.
Source: Estimates shared in personal communication from K Giugere, M Maheu-Giroux, JW Eaton, October 2019; UNAIDS/WHO, 2019; Marsh K, Eaton JW, Mahy M, Sabin K, Autenrieth C, Wanyeki I, Daher J, Ghys PD. Global, regional and country-level 90-90-90 estimates for 2018: assessing progress towards the 2020 target. AIDS. 2019; 33 (Suppl 3): S213. doi: 10.1097/QAD.0000000000002355.

HTS must be planned and implemented to serve these individuals and other underserved populations lest they continue to be left behind. In vitro diagnostics (IVDs), such as rapid diagnostic tests (RDTs), have long been available, and their accuracy and reliability are proven in various settings including resource-constrained facility and community settings.

Efficient and effective diagnosis enables newly identified people with HIV to start antiretroviral therapy (ART) sooner, which has immediate benefits for their health and, importantly, through provider-assisted referral (also called assisted partner notification and index testing), for the health of their partners and the community. Also, evidence shows that people on ART and virally suppressed will not transmit HIV to their sexual partners *(3-5)*. Effective diagnosis also enables those who test HIV-negative to access prevention interventions such as pre-exposure prophylaxis (PrEP) and voluntary medical male circumcision (VMMC) as well as other services according to their needs, for example, family planning/contraceptive services and testing and treatment for sexually transmitted infections (STIs).

Using an RDT, a trained lay provider can establish an HIV diagnosis within a single visit in a health facility or community setting. RDTs are relatively easy to use and to store; thus, access to these tests and their use is widespread. However, in some settings a final HIV-positive diagnosis is not given without additional laboratory testing, such as western blotting. Sending a sample to a laboratory can delay the return of results to a client, can hinder ART initiation and can lead to loss to follow-up *(6)*. To better reach key populations and underserved populations, innovative testing approaches, such as test for triage and self-testing, must also be offered along with standard testing approaches in health facilities. By relying on rapid testing, these approaches can often deliver results on the same day.

Assuring accurate diagnosis. WHO's recommendation to offer treatment to all persons immediately upon HIV diagnosis and to encourage this rapid initiation of antiretroviral therapy (ART) irrespective of immunological status (CD4 count) or clinical stage, has been increasingly adopted *(7-9).* This means efforts must be intensified to ensure that the HIV diagnosis is correct.

People incorrectly diagnosed HIV-negative miss the opportunity to learn their status and start ART. False negative diagnoses may contribute to onward HIV transmission and poorer clinical outcomes due to delayed diagnosis and treatment.

For those incorrectly diagnosed HIV-positive, there is a risk of unnecessary lifelong treatment, as well as important psychosocial, ethical and legal consequences for the individual. False positive diagnoses are difficult to identify, especially after ART has been started. Overall, misdiagnosis can undermine confidence in the health system or the programme, and it constitutes inappropriate use of limited resources (money, staff, test kits, medications, time).

The testing strategy and algorithm used affect the accuracy of the HIV status reported. Attention must be paid to following a standardized testing strategy and to verifying testing algorithms to ensure that discrepant results and misdiagnosis are minimized.

A WHO systematic review and policy review indicated, however, that some programmes do not follow WHO guidance on testing strategies and algorithms *(10, 11).* Departures from the recommendations included: using a single reactive test (one assay) for an HIV-positive diagnosis, using testing strategies designed for high prevalence settings in low prevalence settings, using parallel rather than serial testing strategies, and using the "tie-breaker approach" to rule in HIV-infection (where, after the discrepant result, a reactive Assay 3 (A1+, A2–, A3+), is used to incorrectly make an HIV-positive diagnosis instead of providing an HIV-inconclusive diagnosis) *(10).* The review found the proportion of false HIV-positive diagnoses to be a median of 3.1% (interquartile range (IQR): 0.4–5.2%) and of false HIV-negative diagnoses to be a median of 0.4% (IQR: 0–3.9%) *(10)*.

Table 8.1. Key terms for this chapter

Terminology	Definition
Assay	A synonym of test kit; in the case of HIV, all the components of a test kit used to identify HIV p24 antigen or HIV-1/2 antibodies.
Testing strategy	A sequence of tests conducted on assays to achieve a specific objective, such as screening for infection or diagnosis of infection.
Testing algorithm	When specific products are populated into a testing strategy, it is a testing algorithm. A specific product is defined with a product name, product code(s), a manufacturing site and a regulatory version. The testing algorithm is likely to change depending on which specific products are verified for use together and are procured.
Test for triage	When a trained and well-supported testing provider (possibly a lay provider or community health-care worker) conducts a single HIV RDT, rather than following the entire testing algorithm, and those with HIV-reactive results are referred to health facilities for additional testing to confirm their HIV status.
HTS positivity	The proportion of HIV-positive results among those undergoing HIV testing in a national programme.
Treatment-adjusted prevalence	Treatment-adjusted HIV prevalence provides an indication of the proportion of people with HIV in the testing population by excluding those on ART. Treatment-adjusted HIV prevalence can be calculated by subtracting the number of people (ages 15+) with HIV on ART from the numerator (total population ages 15+ with HIV) and the denominator (total population ages 15+) of national HIV prevalence estimates.
Discrepant test results (sometimes called discordant)	When the test results for two or more assays do not agree. For example, Assay 1 is reactive, but Assay 2 is non-reactive.
Repeat testing	When the same specimen is tested again on the same assay when the initial result is reactive or test results are discordant. The assay is repeated to rule out biological false reactivity. For assays that utilize capillary whole blood, another prick may be needed to collect adequate specimen volume, but it must be in the same testing event.
Retesting	When a second specimen from the same individual is tested again following the same testing algorithm. This is not in the same testing event – for example, retesting 14 days later after an HIV-inconclusive status, retesting every quarter for people taking PrEP or retesting to verify an HIV-positive diagnosis prior to ART initiation.
HIV-inconclusive status	When the testing strategy cannot provide a positive or negative HIV-status. This is different from discrepant test results.
Supplemental testing	Further testing with an additional assay or set of assays to obtain more information to help ascertain HIV status, often used for resolving inconclusive test results.
Confirmatory testing	Use of any assay that definitively confirms an initial reactive test result, providing either an HIV-positive or HIV-negative status. Supplemental testing is sometimes referred to incorrectly as confirmatory testing; there are very few HIV assays that can definitively rule out HIV infection (HIV-negative).

8.2 Where to conduct HIV testing

HIV testing for diagnosis, including testing conducted in the context of surveillance and surveys, can take place at all levels of the health system. Fig. 8.2 depicts how testing services should be organized and shows the different HIV assay formats that should be available at each level of the health system to facilitate HTS.

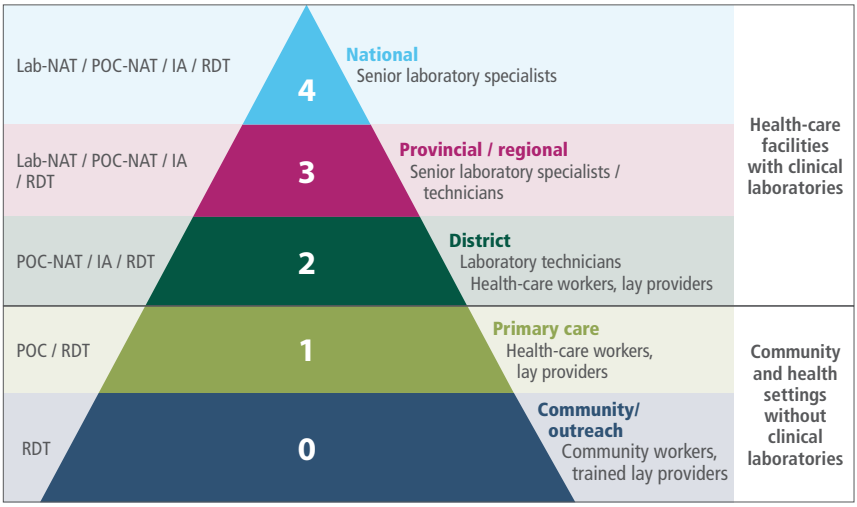
Ideally, HTS should be located and easily accessed at people's first point of contact with the health system, which will usually be at the primary care level (level 1) *(12).* Community-based HTS (level 0), including test for triage and self-testing, provide important opportunities for HIV testing, particularly for reaching members of key populations as well as underserved populations of adolescent girls and young women and men who might not visit health facilities.

The physical infrastructure required for each assay format determines the level of the health system where testing can be conducted using products of that format. Such infrastructure includes reliable electricity and climate-controlled rooms to carry out testing and to store certain test kits, as well as reagent-grade water.

Where to use different assay formats also depends on the availability of staff with the appropriate skills and proficiency. Assays that do not have good thermostability (unlike, RDTs, which can be stored at 4 to 30 °C) and that use specimens requiring more invasive collection (for example, venepuncture rather than capillary/fingerstick whole blood) are unsuitable at levels 1 and 0. How the assay will be used programmatically is as important as the assay's sensitivity and specificity.

See Annex I for description of assay formats for HIV diagnosis.

Fig. 8.2. A tiered testing service, with assay format menu and staff qualifications[1]



IA: enzyme immunoassay; Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; RDT: rapid diagnostic test, including HIV self-testing.

Source: WHO, 2012 *(13).*

1 Fig. 8.2 reflects the WHO Model List of Essential In Vitro Diagnostics, which describes which assays should be offered to provide testing services for common diseases and infections in communities and health facilities without clinical laboratories and in health facilities with clinical laboratories. WHO.

8.3 Serology testing strategy for HIV-1 diagnosis

A testing strategy describes a sequence of tests conducted to achieve a specific objective, such as screening for infection or diagnosis of infection[1] *(14)*. Sensitivity and specificity describe the performance of an assay, but they do not give sufficient information about the clinical value of the test result *(15)*.[2]

Box 8.2. Updated WHO guidance and considerations on HIV testing strategy/algorithm

In response to changes in the HIV epidemic, WHO is encouraging high HIV burden countries, and reminding low HIV burden countries, to use three consecutive reactive test results to make an HIV-positive diagnosis.

Some high HIV burden countries in southern Africa will continue to have national HTS positivity above 5%. These countries may continue to use two consecutive reactive tests to provide an HIV-positive diagnosis.

It will be important for these countries to monitor national HTS positivity and to start transitioning to using three consecutive reactive test results to provide an HIV-positive diagnosis when national HTS positivity starts to fall below 5%.

Clinical value is defined by positive predictive value (PPV), which is the proportion of individuals with positive results who are correctly diagnosed with an HIV-infection, and negative predictive value (NPV), which is the proportion of individuals with negative results who are correctly diagnosed as HIV-negative. Unlike assay sensitivity and specificity, PPV and NPV depend on the level of disease prevalence (HTS positivity) in the population being tested.

At a population level, the percentage of people testing for HIV who receive an HIV-positive diagnosis affects the ability to provide the correct diagnosis. As HTS and ART coverage increase, and fewer people undergoing HIV testing services are HIV-positive, the chances that a reactive test result is false increase (see Box 8.3 as an example). If the level of HTS positivity is low, the PPV will not approach 100%, even if both assay sensitivity and specificity are high.

To achieve accurate results, WHO recommends that countries use an HIV testing strategy/algorithm whereby a combination of RDTs and/or EIAs, used together, achieves at least a 99% positive predictive value (that is, less than one false positive per 100 people diagnosed with HIV). This requirement was the basis of previous WHO recommendations that, to maintain at least a 99% positive predictive value, settings with a national HIV prevalence of 5% or more should use two consecutive reactive tests to make an HIV-positive diagnosis. However, for settings with a national HIV prevalence below 5%, to maintain at least a 99% positive predictive value, WHO recommended the use of three consecutive reactive tests to make an HIV-positive diagnosis.[3]

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1 Selection, access and use of in vitro diagnostics: https://www.who.int/medical_devices/diagnostics/Selection_in-vitro_diagnostics/en/. When specific products are populated into the testing strategy, it becomes a testing algorithm. See Table 8.1 for definitions.

2 See Annex I for definitions used by WHO to calculate sensitivity and specificity.

3 This is based on the assumption that each test (assay) used in the strategy and algorithm has at least 98% specificity.

Box 8.3. Estimates and projections for HIV rapid test kit usage (2000–2025), Malawi, and implications for HIV testing outcomes

In Malawi the total number of adults with HIV has been increasing and is projected to continue to increase through 2025 as people with HIV live longer on ART. At the same time, due to scale-up of HTS and ART, the proportion of people with HIV who are undiagnosed has declined rapidly, from an estimated 78% in 2005 to 14% in 2017, and is projected to continue declining to around 6% in 2025.

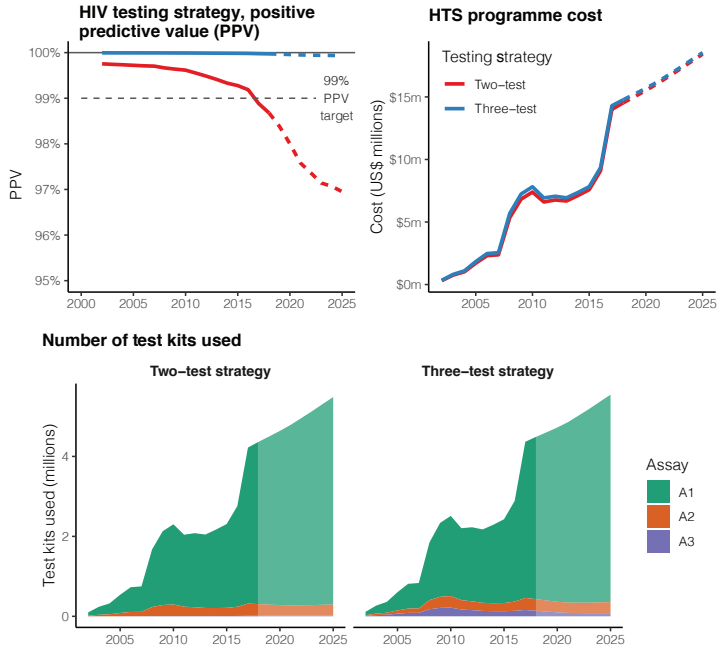
This shift in the HIV epidemic is contributing to rapid declines in the proportion of HIV-positive test results (HTS positivity) and in the percentage of new HIV-positive diagnoses among individuals who undergo HIV testing. Although the annual number of people tested doubled between 2015 and 2017, HTS positivity decreased by 50%, and the number of people with HIV newly diagnosed has continued to decline since 2016. By 2025 national HTS positivity is expected to reach 1.5%, while overall adult HIV prevalence is projected to be 8.4%.

A model-based triangulation of epidemiological estimates and HTS programme data suggests that almost half of the new HIV-positive tests recorded in programme data are people with HIV who know their status but are retesting. Discounting these retesters, who already know their positive status, further reduces the proportion of new HIV-positive diagnoses to 1.7% in 2017 and a projected 0.5% in 2025.

This sharp decline in national HTS positivity in the population being tested in Malawi will reduce the positive predictive value of the current testing strategy. Thus, by 2025, if the testing strategy in Malawi used two consecutive reactive tests each with 98% specificity to provide an HIV-positive diagnosis, the testing algorithm's positive predictive value would be below 97% (even if the tests used performed in the field according to minimum WHO prequalification requirements). In contrast, if three consecutive reactive tests are used to provide an HIV-positive diagnosis, the positive predictive value will be above 99.9%.

If rates of HIV testing stay at current levels, an estimated 120 000 A3 tests would be required to implement the new strategy in 2019, declining to 79 000 in 2025. These quantities are substantially less than the need for more than 4 million A1 tests and 270 000 A2 tests each year. The projected incremental cost of using three consecutive reactive tests to provide an HIV-positive diagnosis (three-test strategy), versus using two consecutive reactive tests to provide an HIV-positive diagnosis (two-test strategy), is less than 2% greater in 2019 and declines to around 0.6% greater in 2025.

Box 8.3. Estimates and projections for HIV rapid test kit usage (2000–2025), Malawi, and implications for HIV testing outcomes, continued



The two-test strategy in this diagram refers to using two consecutive reactive tests to provide an HIV positive diagnosis. The three-test strategy in this diagram refers to using three consecutive reactive tests to provide an HIV-positive diagnosis. The WHO testing strategy is depicted in Fig.8.3 for reference. Estimates of PPV assume 98% specificity for each independent assay (test) in the algorithm, and does not include retesting to verify HIV-positive status. Projections for PPV, costs, and assay usage assume that rates of HIV testing by sex, age, and HIV status remain at 2018 levels through 2025.

The cost difference is small because the primary driver of total HIV testing programme costs is the volume of clients who receive the first test, A1. In contrast, the cost of HIV misdiagnoses is high, as it includes unnecessary treatment costs as well as individual and social costs.

Source: WHO/UNAIDS/Malawi Department of HIV/AIDS, 2019, derived from Maheu-Giroux M et al., 2019 *(16)*.

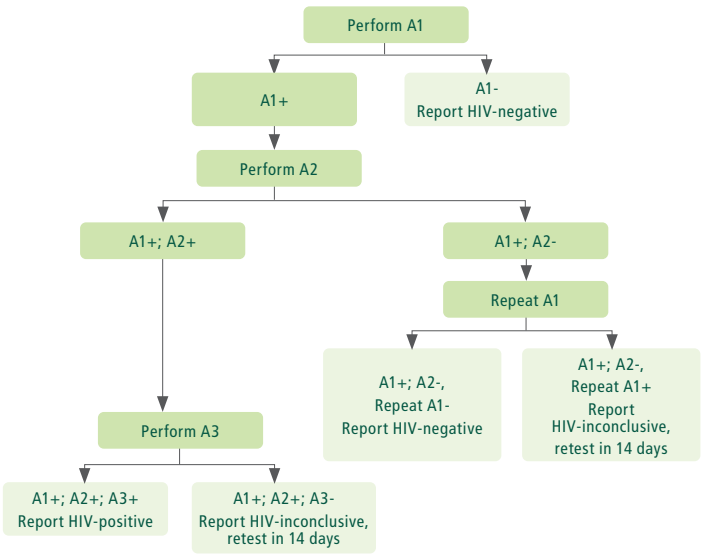
In response to these changes in the global HIV epidemic, particularly declining national HTS positivity and HIV prevalence among those not on treatment (also called treatment-adjusted prevalence) (see Fig. 8.1), WHO is now encouraging high HIV burden countries, and reminding low HIV burden countries, to use three consecutive reactive tests to make an HIV-positive diagnosis. This strategy should now be considered as the WHO standard testing strategy. By making this shift, countries will be able to ensure accurate HIV diagnoses even as national HTS positivity continues to decline *(17, 18)*.

Fig. 8.3 depicts the WHO standard HIV strategy using three consecutive reactive tests to make an HIV-positive diagnosis. This testing strategy applies to all combinations of serology assay formats – for example, RDT or enzyme immunoassay (EIA).

Recency assays, which are used to determine whether someone with HIV was infected in the past year to estimate HIV-incidence, can be used in surveys. While HIV test results (HIV positive, negative or inconclusive) are returned to survey participants, test results from a recency assay are not currently routinely returned to people with an HIV-positive status. Currently, WHO HIV testing strategies and algorithms have not, as yet, considered recency assays in this context.

Several research studies are evaluating the use of recency assays within national HIV testing strategies and algorithms. Findings from these studies on the potential benefits and harms will be critical for determining how these tests could be used in clinical settings.

Fig. 8.3. WHO standard testing strategy for HIV-1 diagnosis (among people ≥18 months of age)



- All individuals are tested on Assay 1 (A1). Anyone with a non-reactive test result (A1–) is reported HIV-negative.
- Individuals who are reactive on Assay 1 (A1+) should then be tested on a separate and distinct Assay 2 (A2).
- Individuals who are reactive on both Assay 1 and Assay 2 (A1+; A2+) should then be tested on a separate and distinct Assay 3 (A3).
  - Report HIV-positive if Assay 3 is reactive (A1+; A2+; A3+)
  - Report HIV-inconclusive if Assay 3 is non-reactive (A1+; A2+; A3–). The individual should be asked to return in 14 days for additional testing.
- Individuals who are reactive on Assay 1 but non-reactive on Assay 2 (A1+; A2–) should be repeated on Assay 1
  - If repeat Assay 1 is non-reactive (A1+; A2–; repeat A1–), the status should be reported as **HIV-negative**;
  - If repeat Assay 1 is reactive (A1+; A2–; repeat A1+), the status should be reported as **HIV-inconclusive**, and the individual asked to return in 14 days for additional testing.

A1: Assay 1 (first test); A2: Assay 2 (second test); A3: Assay 3 (third test).

This testing strategy, including repeat testing, aims to ensure that at least a 99% PPV is maintained and that false-positive misdiagnosis. To achieve at least a 99% PPV, it is critical that:

- **Assay 1** provides the best chance to rule in all HIV-positive individuals and has the **highest sensitivity.** Notably, very high sensitivity will mean the test has lower specificity. For this reason, a degree of false HIV-reactive results on Assay 1 are expected in addition to true HIV-reactive results.
- Assay 2 and Assay 3 must be able to rule out any false HIV-reactive test results. For this reason, both test kits used as **Assay 2 and Assay 3 must have very high specificity – higher than Assay 1.** The relative cost of a testing strategy is driven by the numbers of Assay 1 that are conducted.
- Assay 1 (A1), Assay 2 (A2) and Assay 3 (A3) should be three different HIV assays (products) that share minimal common false reactivity.
- In the event of discrepant test results (A1+; A2–), it is important to repeat Assay 1. Repeating Assay 1 will determine if the individual is repeatedly reactive on the assay that has the highest sensitivity (expecting reduced specificity). Discrepant test results are driven by the specificity of the product chosen as Assay 1: If Assay 1 has 98% specificity, one expects at least two false HIV-reactive results per 100 tests. Individuals who are repeatedly reactive on Assay 1 but cannot be confirmed HIV-positive should be given an HIV-inconclusive status *(19, 20).*
- Unlike with Assay 1, there is no need to repeat Assay 2 after a reactive result, as the product for Assay 2 is chosen for its specificity, and both repeatedly reactive and non-reactive test results on A2 would lead to an HIV-inconclusive status. Similarly, there is no added value to testing individuals with discrepant results (A1+; A2–) on Assay 3, as the result would be HIV-inconclusive, irrespective.
- Where resources permit, other assays, such as assays that detect HIV p24 antigen only or assays that can detect specific types of HIV-1 and HIV-2 antibodies, may be used to resolve atypical diagnoses *(21).*

See Section 8.5 for further details on selecting assays to populate the WHO standard HIV testing strategy.

To provide a correct diagnosis, countries should review and consider products that are WHO prequalified; see https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.

WHO continues to recommend that programmes retest people diagnosed with HIV prior to ART initiation. This retesting to verify an HIV-positive diagnosis is intended to catch human errors such as mislabelling of test results.

Considerations for implementing the WHO standard HIV testing strategy

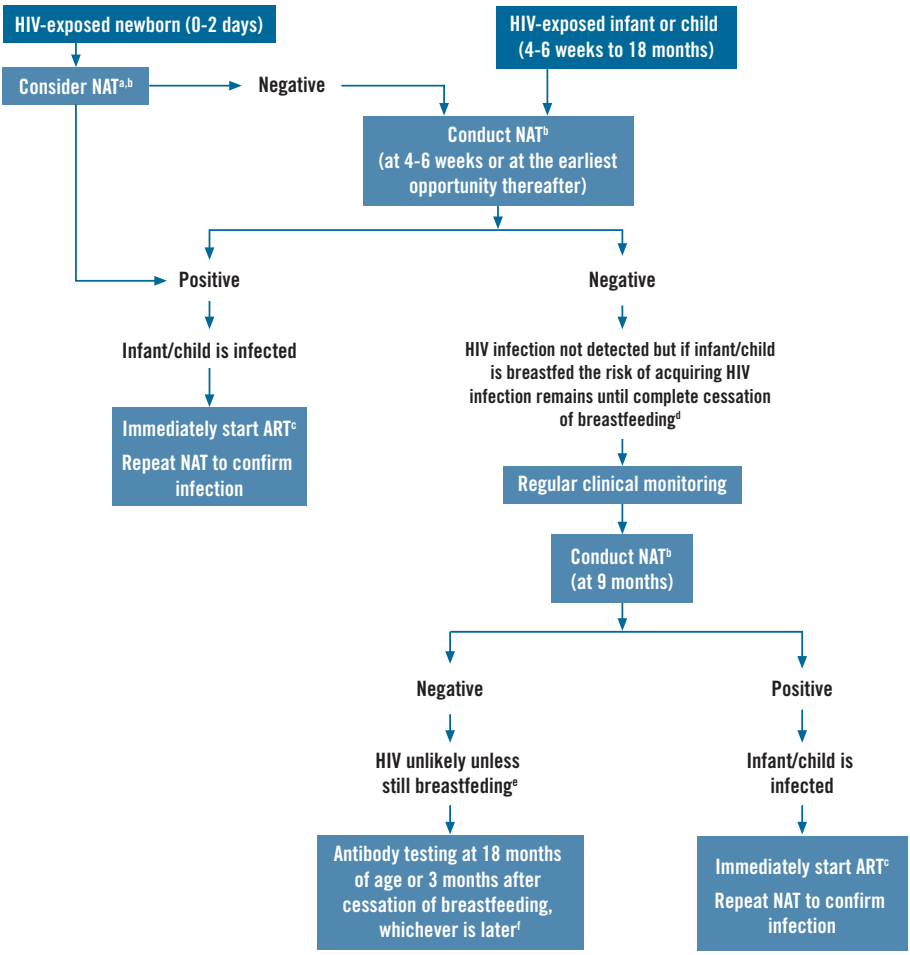
- Programmes with low national HTS positivity and low treatment-adjusted HIV prevalence should prioritize the shift to the WHO standard testing strategy (see Fig. 8.3) to prevent misdiagnoses and unnecessary initiation of lifelong treatment. Some high HIV burden countries in southern Africa will continue to have national HTS positivity above 5%, however (see Fig. 8.1). These countries may continue to use two consecutive reactive test results to provide an HIV-positive diagnosis. It will be important for these countries to monitor national HTS positivity and to start the transition to using three consecutive reactive test results to provide an HIV-positive diagnosis when national HTS positivity starts to fall below 5%.
  Simultaneously using two consecutive reactive test results for some settings or for certain populations or clients and three consecutive reactive test results for others is not advised.
- Efforts to reduce costs and optimize delivery of HTS using the WHO HIV testing strategy are needed and should focus on efficient delivery of the first test in the strategy, since it accounts for by far the largest total cost among the three tests. Scaling up task sharing and utilizing approaches such as HIV self-testing and test for triage may make shifting to the WHO HIV testing strategy more feasible in some settings. In these approaches people often test first at home or in the community, and all those with reactive results are referred to a facility for further testing using the full national testing algorithm.
- Countries changing their national HIV testing strategy and algorithm will need to develop a plan and identify the optimal time for the transition. To assure that all the necessary resources are in place, it will be important to align and coordinate changes in tendering, selection and procurement of new tests (including an A3 test), verification of the testing algorithm, logbook and register updates, training and supportive supervision, and national and site-level policy and guidance.

8.3.1 Serology testing strategy for HIV-1 diagnosis in children 18 months of age or younger

For children 18 months of age or younger (or under 24 months if still breastfeeding), use of serology assays alone is insufficient to rule in HIV infection. This is because serology assays, such as HIV RDTs, may detect maternal antibodies transferred to an infant during pregnancy, birth or breastfeeding. Virological testing, typically using nucleic acid testing (NAT), is recommended to rule in HIV infection in children 18 months of age or younger *(21).* Fig. 8.4 depicts the WHO HIV testing strategy and algorithm for early infant diagnosis.

Details on diagnosing infants and children 18 months of age or younger are available in the WHO *Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV: https://www.who.int/hiv/pub/guidelines/ARV2018update/en/ (22)*.

Fig. 8.4. WHO HIV testing strategy and algorithm for early infant diagnosis



Source: WHO, 2018 *(22)*.

WHO cautions against using NAT technologies to rule out HIV infection in adults and children over 18-months of age where ART coverage is widespread; an undetectable NAT result cannot be reliably interpreted as HIV-negative because people with HIV taking ART properly are expected to become NAT-undetectable *(23, 24)*.

This guidance does not cover testing in the context of clinical trials for HIV cure and vaccinology, however further details can be found in Annex I.

Box 8.4. Limitations on the choice of assays for individuals taking ART

It is not recommended for individuals on ART to retest. However, studies and programmes increasingly report that people with HIV taking ART, disclosed or not, do present for testing *(10, 25)*. When testing someone who is taking ART, the choice of assays is limited due the effect of ART on virus replication and the immune response. All individuals seeking HTS must be made aware of the limitations and the risk of incorrect test results for those on ART. See chapters 3 and 4.

Serology assays. A systematic review commissioned by WHO found that most serology assays are relatively unaffected by ART exposure *(26)*. However, the earlier that ART is initiated, the greater the risk of false-negative serology results. False-negative results are more likely for individuals who initiated ART during acute HIV infection, including adults diagnosed during the early Fiebig[4] stages (I and II) and perinatally infected children who are placed on ART at less than six months of age. For these individuals, any subsequent serology result should be interpreted cautiously. Assays that use oral fluid are more affected than those that use serum/plasma or whole blood, and second generation assays (such as many HIV self-tests) are more affected than third and fourth generation assays. Western blotting is considerably affected by ART, indicating the reduced clinical utility of this assay format in the era of expanded ART access. Western blotting should no longer be used in HIV testing algorithms *(6)*. See section 8.5.7 on this new recommendation.

Virological assays. When taken properly, ART suppresses viral replication to below the limit of detection by NAT assays. People with HIV on ART with suppressed viral load may seek re-testing and are likely to be NAT-undetectable. A NAT-undetectable result does not rule-out HIV infection. Virological assays should not be used to test people taking ART. As individuals may not always disclose prior to testing that they are taking ART, caution should be taken in the use of NAT technologies to rule out HIV infection.

8.3.2 Retesting individuals with an HIV-positive status

As noted, misdiagnosis is difficult to detect after ART is initiated. To ensure that individuals are not incorrectly started on lifelong treatment, WHO recommends that all individuals who are newly diagnosed with HIV be retested to verify their HIV status prior to starting ART *(18)*. Retesting for this purpose is a quality assessment step that aims to rule out random errors related to the test device or lot, testing site or operator. It may also detect any clerical errors, such as transcription errors during result interpretation and reporting, and mix-ups through mislabelling (see section 9.3.9). It is not intended to optimize the PPV of the testing strategy.

Retesting to verify positive status involves collecting and testing of a new specimen from a person newly diagnosed with HIV. Retesting is conducted with the same testing strategy, ideally with the same testing algorithm, but by a different testing provider using different lots of first, second and third assays (A1/A2/A3) at a different testing site. If retesting at a different site is not feasible, at least a different testing provider and a new lot should be used for retesting on the newly collected specimen. Similarly, if

4 Fiebig et al. described a staging system for primary HIV infection based sequential emergence of test reactivity (27).

retesting must take place on the same day to facilitate same-day ART initiation, at least a different testing provider and a new lot should be used for retesting on the newly collected specimen. Ideally, retesting should take place where ART is initiated.

Retesting to verify an HIV-positive status, prior to ART initiation, follows the same testing sequence as shown in Fig. 8.3. Following an HIV-positive diagnosis, individuals should be retested beginning with Assay 1 (A1) prior to starting ART. On retesting:

- **Individuals who are non-reactive on Assay 1 (A1–)** may be HIV-negative. The individual should be referred for additional testing at a higher-level facility using a different testing algorithm (that is, different products).
- **Individuals who are reactive on Assay 1 (A1+)** should then be tested on a separate and distinct Assay 2 (A2). Individuals who are reactive on both Assay 1 and Assay 2 (A1+; A2+) should then be tested on a separate and distinct Assay 3 (A3).
  - **If Assay 3 is reactive (A1+; A2+; A3+)**, the status is verified as HIV-positive, and the person can start ART according to national guidelines.
  - **If Assay 3 is non-reactive (A1+; A2+; A3–)**, the status cannot be verified as HIV-positive and should be reported as HIV-inconclusive. The individual should be asked to return in 14 days for additional testing at a higher-level facility using a different testing algorithm, containing different products.
- **Individuals who are reactive on Assay 1 but non-reactive on Assay 2 (A1+; A2–)** do not need to repeat testing conducted on Assay 1. In these cases the status cannot be verified as HIV-positive and should be reported as HIV-inconclusive. The individual should be asked to return in 14 days for additional testing at a higher-level facility using a different testing algorithm, containing different products.

Retesting, as described above, cannot exclude misdiagnosis caused by a poorly chosen testing algorithm. So, adequate verification of the testing algorithm before widespread roll-out is critical (see section 8.4). Modelling estimates indicate that retesting to identify persons incorrectly classified as HIV-positive is cost-effective and will likely cost less than unnecessary lifelong ART and virological monitoring *(28, 29).*

Chapter 4 discusses key post-test counselling messages on retesting.

8.3.3 Retesting individuals with an HIV-inconclusive status

In a small number of cases, it may not be possible to give a definitive HIV diagnosis on the same day. In these cases the individual will be asked to return in 14 days for retesting. This is not a failure of the assays or of the testing strategy but rather a limitation of any testing, given that no products are 100% sensitive and 100% specific.

Retesting individuals with an HIV-inconclusive status is required to rule in or rule out seroconversion and to rule out the possibility of specimen mix-up or transcription error as well any random errors related to the testing provider or test device. If HIV reactivity evolves or changes from non-reactive to reactive, the individual will be given an HIV-positive diagnosis. If HIV reactivity remains unchanged, individuals will be given an HIV-negative diagnosis.

WHO recommends retesting 14 days after an HIV-inconclusive status using the same testing strategy and testing algorithm:

- If reactivity resolves to either HIV-positive (A1+; A2+; A3+) or HIV-negative (A1–), report accordingly.
- If reactivity remains the same (A1+; A2+; A3– or A1+; A2– / A1+) after 14 days on the same products, the individual should be reported as HIV-negative.[5]

Where possible, retesting of individuals with HIV-inconclusive status must be conducted with the same testing strategy/algorithm and preferably at the same site.

Chapter 4 presents key post-test counselling messages on inconclusive results and HIV-negative results.

8.3.4 Retesting individuals with an HIV-negative status

While most people who test HIV-negative, certain individuals may need annual or more frequent retesting. Chapters 4 and 7 address messages and populations in need of retesting.

8.3.5 Establishing HIV status for PrEP users

To minimize development of HIV resistance, HIV testing is required before starting PrEP to ensure that individuals are HIV-negative. In addition, periodic retesting is recommended for PrEP users to detect breakthrough HIV infection (when a person acquires an HIV infection despite taking PrEP) as early as possible. Breakthrough is very rare but can occur.[6] Most people who acquire HIV while in PrEP programmes, are people who have stopped taking PrEP.

For PrEP initiation. WHO recommends testing using the same strategy and algorithm as for other individuals. Some PrEP clinical trials have employed assays optimized for detection of acute infection at the initial visit for PrEP initiation. More expensive and complex testing strategies are unlikely to provide any greater benefit in settings where NAT assays or fourth generation serology assays are not routinely used for HIV diagnosis. When considering testing in the context of PrEP implementation, programmes must weigh the benefits of introducing a different testing algorithm against the public health benefit of scaling-up access to PrEP.

For periodic retesting while taking PrEP. WHO recommends the same testing strategy and testing algorithm for PrEP users as for others (see Fig. 8.3). Individuals who are taking PrEP properly are at reduced risk of HIV acquisition *(30)*. In any case, the lower the HTS positivity rate, the greater the probability that an HIV-reactive test result is a false-positive. As with testing prior to PrEP initiation, employing a different testing strategy or algorithm may not provide additional benefit for the associated extra costs and complexity.

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5 However, an HIV-inconclusive status may be observed for individuals with clinical signs meeting the WHO criteria for stage III or IV HIV infection because of the decreased HIV antibody response of the impaired immune system.

6 WHO implementation tool for pre-exposure prophylaxis of HIV infection. WHO/HIV/2017.17 https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/.

During periodic retesting, breakthrough HIV infection may be detected (although this is very rare), and it is critical to ensure that the diagnosis is correct before switching from PrEP to ART. Discrepant test results (A1+; A2+; A3– or A1+; A2–) also will be observed. In such cases, the course of action to rule in or rule out HIV infection is as follows:

- Conduct serology testing weekly for four weeks using the same testing strategy and algorithm, as NAT is not expected to be detectable in the presence of PrEP.
  - o If the serology profile does not change, but instead remains A1+; A2+; A3– or A1+; A2–, the PrEP user is HIV-negative, and PrEP can be continued, with quarterly retesting.
  - o If the serology profile does evolve (A1+; A2+; A3+), the PrEP user is HIV-positive. In this circumstance it is critical to ensure that the diagnosis is correct before switching from PrEP to ART. This is done by a different testing provider, preferably at a different testing site, collecting and testing a new specimen and using different lots of A1/A2/A3.

Each case of suspected breakthrough HIV infection will require an individualized decision. If the above course of action is not suitable, PrEP may be discontinued for as much as four weeks, and both serology and virological testing should be performed weekly in the meantime. Four weeks should be sufficient for the virus to re-commence replication, if it is present, and for the antibody response to be induced. In this instance it is critical to strongly recommend other means of HIV prevention, such as condoms.

Box 8.5. Limitations on the choice of assays for quarterly retesting while taking PrEP

When taken properly, any anti-retroviral drug (including ART and PrEP) will suppress viral replication to below the limit of detection in NAT assays. This makes NAT assays unsuitable for periodic testing of PrEP users.

The testing strategy and algorithm in routine use is the most appropriate for quarterly HIV testing for PrEP users.

Source: Fonner, 2019 *(30)*.

8.4 Expanding community-based testing through test for triage and HIV self-testing

As noted, more than half of all new HIV infections globally occur among members of key populations and their sexual partners and other populations that remain underserved *(1)*. Adapting testing services to meet the needs of these communities is critical. Test for triage is an alternative testing strategy that may be particularly useful in community settings, such as mobile outreach. In this strategy a trained and well-supported testing provider (possibly a lay provider or community health-care worker) conducts a single HIV RDT (Assay 0 (A0)) rather than the entire testing strategy and algorithm. WHO recommends delivery of HIV testing by trained lay providers *(18)*. Test for triage may reduce the potential for stigma, as all individuals are tested with the same number of tests, whereas, with the standard testing strategy, further testing identifies those with a reactive result on A1.

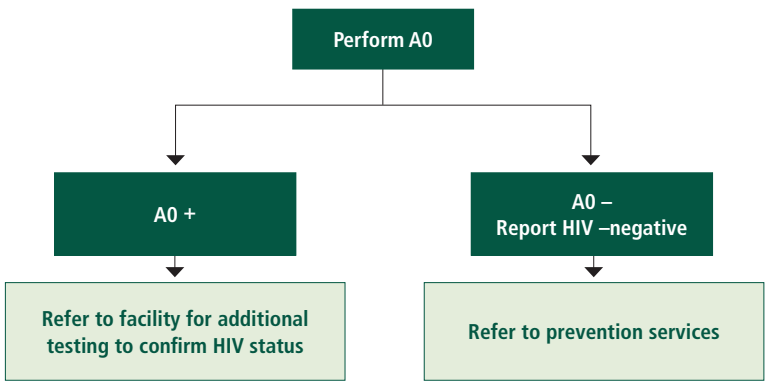
Assay 0 is not intended to replace Assay 1 of the WHO testing strategy for diagnosis. Instead, anyone who has a HIV-reactive test result is promptly linked to a facility where the standard HIV testing algorithm is conducted to provide an HIV diagnosis. As Fig. 8.5 shows, the testing algorithm incorporates Assay 0 at the beginning of the WHO testing strategy for HIV-1 diagnosis shown in Fig. 8.3.

The main advantage of this approach is that test providers need to be trained only on how to conduct one assay (rather than three). Thus, more providers can be trained, and testing can be made more widely available. The test for triage testing strategy might also be useful in HTS venues where it is not feasible to conduct all three tests to provide an HIV-positive diagnosis, as recommended by WHO. It also has advantages for the supply chain, to support decentralization.

Like test for triage, using an RDT for HIV self-testing (HIVST) is considered Assay 0. A reactive self-test result does not constitute HIV diagnosis and always requires additional testing to confirm the HIV status, applying the WHO testing strategy for diagnosis starting at Assay 1 (see Fig. 8.3). See Chapter 5 for more information about service delivery of community-based testing and HIV self-testing.

HIV self-testing and test for triage are not recommended for people with HIV who are taking ART.

Fig. 8.5. Alternative testing strategies: test for triage and HIV self-testing



A0: Assay 0

8.4.1 Testing for other conditions

There are benefits of providing testing services for other diseases or conditions along with HIV testing services. For example, all countries should consider offering key populations testing for both HIV and STIs and, for pregnant women who need testing, for HIV, syphilis and HBsAg[7] (hepatitis B) at least once, preferably in the first trimester. Dual HIV/syphilis RDTs can be used as the first test in antenatal care settings. See chapters 5 and 6 for information on integrated service delivery and considerations for specific population groups.

Box 8.6. Additional resources on testing for other conditions

WHO guideline on syphilis screening and treatment for pregnant women https://apps.who.int/iris/bitstream/handle/10665/259003/9789241550093-eng.pdf

WHO recommendations on antenatal care for a positive pregnancy experience https://apps.who.int/iris/bitstream/handle/10665/250796/9789241549912-eng.pdf

WHO guidelines on hepatitis B and C testing https://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf

WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention https://apps.who.int/iris/bitstream/handle/10665/94830/9789241548694_eng.pdf

8.4.2 Multiplex testing for HIV-1 and other infections

Multiplex testing refers to an assay that can detect more than one analyte. This is most commonly seen in HIV screening assays that combine detection of antibodies to HIV-1 and HIV-2. Assays that combine detection of HIV-1/2 antibodies and HIV antigen are another example.

HIV and syphilis dual detection

The clinical utility of RDTs that detect antibodies to Treponemal pallidum (the cause of syphilis infection) has increased in recent years, particularly for ANC settings, as these assays are easy to perform and, unlike conventional non-Treponemal screening assays, they do not require refrigeration. Treponemal antibodies will be detected when syphilis is both current/active and when syphilis has been treated/resolved because treponemal antibodies persist for some time after successful treatment (depending on the stage of syphilis when treatment was given).

In all settings dual HIV/syphilis RDTs can be offered as the first test in antenatal care to increase testing and treatment coverage. It is important, however, not to use the rapid dual HIV/syphilis test for:

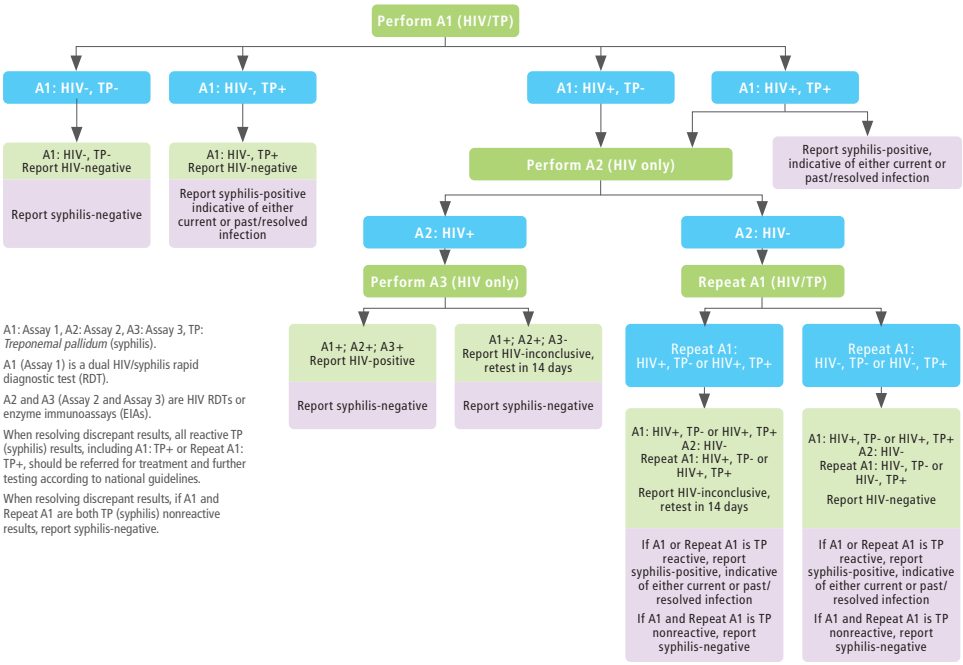
7 Particularly settings with a ≥2% HBsAg seroprevalence in the general population.

- women with HIV taking antiretroviral therapy (ART);
- women already diagnosed with and treated for syphilis during their current pregnancy; and
- retesting for HIV (see chapters 6 and 7).

Countries introducing the dual HIV/syphilis RDT as the first test in ANC will need to revise their HIV testing strategy for pregnant women. Fig. 8.6 presents the testing strategy for dual detection of HIV and Treponemal antibodies. It differs from the WHO-recommended testing strategy for HIV-1 diagnosis (Fig. 8.3) by the type of product that is used as Assay 1.

Countries introducing dual HIV/syphilis RDTs as the first test in ANC will need to verify that the new test works well in combination with the other two HIV tests in the algorithm. Countries should review and consider WHO-prequalified products, which include dual HIV/syphilis RDTs as well as separate HIV and syphilis RDTs. These are listed at https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.

Fig. 8.6. WHO-recommended testing strategy for dual detection of HIV and syphilis infection in ANC settings



HIV and viral hepatitis dual detection

Other common co-infections that can be diagnosed using serology assays are also being considered for multiplex RDTs – for example, HIV and hepatitis C (HCV) as well as a triplex RDT that detects antibodies to HIV, antibodies to HCV and hepatitis B (HBV) surface antigen as a marker of chronic hepatitis B infection.

HIV-1 and HIV-2 discriminatory detection

Some serology assays claim to discriminate between HIV-1 and HIV-2 antibodies as an aid for diagnosis of HIV-2 infection. However, using serology assays to differentiate definitively between dual HIV infection and mono-infection remains challenging.

Dual infection with both HIV-1 and HIV-2 is exceedingly rare, and so dual reactivity observed in a discriminatory HIV-1/HIV-2 assay is more likely caused by serological cross-reactivity than true dual infection. Data suggest that cross-reactivity between HIV-1 and HIV-2 in commercially available assays may be considerable. Data from WHO prequalification performance evaluations indicate rates of anti-HIV-2 specificity among HIV-1 positive individuals of between 3% and 57% *(17)*. Therefore, the potential for incorrect diagnosis of HIV-2 due to cross-reactivity is significant *(31, 32)*.

In settings where HIV-2 is documented, to determine the virus type or to diagnose coinfection, appropriate supplemental testing should be performed, including separate serology assays specific to HIV-1 and to HIV-2 and using virological technologies.

8.5 How to choose HIV assays

Testing strategies should be populated with products to create a testing algorithm based on the following principles:

1. The product used for Assay 1 must provide the best chance to rule in all HIV-positive individuals. Therefore, the product used for Assay 1 must have the highest sensitivity. But, typically, the more sensitive a product, the less specific it is. This means that a degree of false HIV-reactive results are expected in addition to all true HIV-reactive results. Fourth generation assays may be used for Assay 1, but access to supplemental testing is required to maximize their clinical utility – for example, when antigen reactivity is observed in the absence of antibody reactivity, confirmation of antigen by neutralisation is recommended.
2. Products used as Assay 2 and Assay 3 must be able to rule out any false HIV-reactive results. Thus, products used for Assay 2 and Assay 3 must have higher specificity than the product used for Assay 1.

While sensitivity and specificity are critical elements in the selection of products, other factors, such as stability, time to result, number of hands-on precision steps required and ability to run tests as a batch may also influence product choice. A further consideration is that the products selected should not have cross-reactivity (meaning the same false-reactive results) with each other, as this would lead to misdiagnosis. WHO recommends verification of testing algorithms prior to widespread roll-out (see section 8.6).

8.5.1 Choosing Assay 1, Assay 2 and Assay 3 for the WHO testing strategy for HIV-1 diagnosis

1. Select two products that could both be used for Assay 1.
   - Both must have superior sensitivity, of at least 99% (for this information, refer to the manufacturer's instructions for use);
   - Assume that these products could be interchanged with each other but not with Assay 2 or Assay 3.
2. Select three products that could be used for Assay 2 and Assay 3.
   - These must have superior clinical specificity, of at least 99% (refer to the manufacturer's instructions for use);
   - Assume that these products could be interchanged with each other but not with Assay 1.

Regular review of the testing algorithm, every three to five years, will ensure that the products chosen continue to work well together. Products will undergo changes periodically (and need to be validated as part of a testing algorithm), improved and less costly products will be introduced. Publication of studies that verify testing algorithms will benefit programmes that do not have the capacity to conduct such studies themselves.

8.5.2 Choosing Assay 0 for test for triage and self-testing

Because Assay 0 has a different purpose, the product chosen for Assay 0 for test for triage can be the same or different from those chosen for Assay 1, Assay 2 or Assay 3. For self-testing, the product selected will be different, as it is designed for individuals to test themselves.

Test for triage and self-testing drive demand for HIV testing services, whereas the assays in the WHO testing strategy for HIV diagnosis are used to screen for HIV or contribute to diagnosis of HIV. This means that Assay 0 needs to be easy to use and accurate but, as the testing strategy for diagnosis will commence at Assay 1, there is far less concern about cross-reactivity among products. The latest evidence suggests that offering both oral fluid and blood-based HIV self-test kits may be beneficial and acceptable to individuals. Providing options can increase access to and uptake of self-testing (see Chapter 5).

8.5.3 Quality characteristics of IVDs

It is most practical to rely on assessments of quality, safety and performance that have been conducted by WHO through its prequalification process. These assessments have been designed to suit the needs of resource-limited settings. They include particular scrutiny of aspects of critical importance in such settings, including risk management, validation study design, product stability and labelling. WHO's list of prequalified products can be found at: https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.

Another approach is to apply internationally recognized standards, such as those issued by the International Standards Organization, when assessing the product for its compliance with quality, safety and performance requirements. Such an approach requires the national regulatory capacity for conformity assessment of each product.

When the decision has been made to prequalify a product, WHO issues a prequalification public report,[8] and the product becomes eligible for procurement by WHO and other UN agencies. After prequalification, the manufacturer is obliged to conduct post-market surveillance and to notify WHO of any reportable changes to the product or the quality management system, so that these can be assessed to determine whether the product continues to comply with prequalification requirements.

8.5.4 Performance characteristics of IVDs

To support product selection for HIV testing algorithms, Table 8.2 lists suggested minimum performance characteristics. These performance characteristics should form part of the technical specifications for procurement. Manufacturers should be asked to submit data to show that their product meets these requirements.

The WHO prequalification public reports, including the attached instructions for use (IFU) and the performance evaluation summary, are a reliable source of product performance data. An independent performance evaluation for WHO prequalification, which complements the manufacturer's product validation dataset, is an integral part of every prequalification assessment and provides independent data on the product's performance and operational characteristics.

Table 8.2. Performance characteristics for product selection

Performance characteristic	Suggested minimum requirement
Clinical sensitivity	
Assay 1	≥99% for RDTs, 100% for EIAs
Assay 2 and Assay 3	≥99% for RDTs, 100% for EIAs
Clinical specificity	
Assay 1	≥98% for RDTs, ≥98% for EIAs
Assay 2 and Assay 3	≥99% for RDTs, ≥99% for EIAs
Inter-reader variability for visually read assays	
Rate of variability between two or more readers of the same test result	≤5% (faint test lines can increase rate of inter-reader variability)
Invalid rate	
Rate of invalid test devices, if RDT	≤5%
Rate of invalid test runs, if EIA	≤5%

RDT: rapid diagnostic test; EIA: enzyme immunoassay

8 See WHO Prequalification Public Reports at https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.

When a product is well-regulated[9] and there has been a thorough assessment of the manufacturer's performance claims, the likelihood of detecting additional quality or performance issues during a field performance evaluation study will be low. Repeating evaluations in-country of the performance of individual products is not necessary where evidence of regulatory approval or WHO prequalification demonstrates acceptable performance.

Analytical sensitivity for subtype detection may be relevant in certain geographic areas where specific subtypes have been documented. Technical specifications for procurement should include a statement on any subtype detection that is required, and the manufacturer should be asked to submit data to support the claim.

8.5.5 Operational characteristics of IVDs

Product selection should carefully consider operational characteristics. A product may have excellent sensitivity and specificity, but its operational aspects will determine its ease of use and potential for widespread implementation. A product that is difficult to use may be used incorrectly. The choice of products must consider the technical skills of the testing providers at the various testing sites. Operational characteristics to consider include: number of steps requiring precision (for example, phlebotomy, counting of multiple drops, use of precision pipette, timing of steps), ease of reading the results (for example, few faint lines/spots) and ease of interpreting test results (that is, only one test line/spot).

The infrastructure available at testing sites also must be considered. For example, are there any infrastructure requirements that would prohibit use of certain products, such as refrigeration for storage of test kits, refrigeration of reconstituted reagents and controls, temperature-controlled work and storage spaces and electricity with backup uninterrupted power supply. To aid product selection, Table 8.3 lists additional operational characteristics. These operational characteristics should form part of the technical specifications for procurement. The assessment conducted for WHO prequalification are an independent source of these data.

Table 8.3. Operational characteristics for product selection

Operational characteristics	
Are any specimen types excluded?	For example, serum, plasma (including specific anticoagulants), venous whole blood, capillary (fingerstick) whole blood, oral fluid
Detection type	
Analyte detection for second/third generation assays	Combined detection of HIV-1/2 antibodies
	Discriminatory (separate) detection of HIV-1 and HIV-2 antibodies
Analyte detection for fourth-generation assays	Combined detection of HIV-1 p24 antigen and HIV-1/2 antibodies
	Discriminatory (separate) detection of HIV-1 p24 antigen and HIV-1/2 antibodies

9 That is, WHO prequalification or stringent assessment by a founding member of the Global Harmonization Task Force.

Table 8.3. Operational characteristics for product selection, continued

Operational characteristics		
Time to result		
Rapid diagnostic tests (RDTs)	**Minimum reading time** – ranges from "read immediately" to 30 minutes after addition of specimen/buffer	
	Maximum reading time – ranges from 10 minutes to 60 minutes after addition of specimen/buffer	
Enzyme immunoassays (EIAs)	Minimum of 2.5 hours	
Storage/stability		
Transport requirements for test kits (temperature, humidity)	Any excursion ranges accepted during transit? Any specialized shipping requirements?	
In-use stability for specific reagents (temperature, humidity)	Any specific requirements once reagents/pouches are opened? Any specific requirements once the specimen is added to the test? Operating conditions for test procedure.	
Equipment/consumables required but not provided in the test kit		
Does the test kit contain all items required to conduct the assay? If not, can these be obtained from the manufacturer or elsewhere?	For **capillary whole blood:** safety or non-safety lancets, alcohol swabs, cotton wool	For **venous whole blood:** blood collection equipment
	Other general laboratory consumables: gloves, precision pipettes, etc.	
Quality control		
Inclusion of procedural quality control	Control line appears when human specimen is added (that is. qualitative IgG control, likely not to indicate adequate volume of specimen) AND/OR Control line appears when reagents only are added (that is, does not indicate addition of human specimen)	
	With some EIAs, colour control upon addition of specimen and/or certain reagents	
Availability of internal test kit controls	Test kit controls (HIV-positive, HIV-negative) are included in the test kit or are available separately from the manufacturer	
External quality control materials	Compatibility with external quality control materials available from suppliers other than the manufacturer	

8.5.6 Impact of co-infections and their treatment on HIV testing

Additional external factors can affect the interpretation of HIV serology results. It is important to understand the limitations of the products; these are typically described by the manufacturer in the instructions for use. An example of the impact of such an exogenous factor is the higher rates of false HIV-reactivity observed for people co-infected with human African trypanosomiasis, dengue or visceral leishmaniasis *(33-35).* Vaccine-induced sero-reactivity is another factor to be considered in settings where vaccines and other therapies are administered, such as part of trials, to the population that might elicit HIV immune responses. This is because antibodies that are produced in response to immunization may be cross-reactive if similar epitopes (antigens) are used in both the vaccine and the product used for HIV testing. Therefore, any invidual who has participated in a trial for vaccines or other immunological intervention might be false HIV-reactive on current commercially available assays *(36).*

8.5.7 Use of western blotting and line immunoassays NEW

Worldwide, most people are diagnosed with HIV using testing strategies that involve RDTs only. However, in some countries, western blotting and line immunoassays, which are longstanding laboratory-based technologies, are still used as the second or third test in national testing algorithms to confirm HIV infection. This is common in several countries in the European Region and other high-income settings as well as in parts of the South-East Asia, Western Pacific and Eastern Mediterranean regions. In these regions, knowledge of HIV status is generally low, hampering uptake of ART among people with HIV and of prevention services for those at high ongoing risk.

Box 8.7. Definition of western blotting and line immunoassays

A western blot is a first generation serology assay based on viral lysate electrophoresed into antigens/proteins and blotted on a nitrocellulose membrane as the analyte to detect antibodies to HIV-1.

Line immunoassays are similar, but recombinant proteins are used rather than viral lysate, and so these are considered second generation serology assays.

For western blotting/line immunoassays, specimens are collected in a health facility by venepuncture, processed and then sent to a laboratory, where highly skilled staff performs the test. The laboratory then sends the test results to the referring facility, which contacts the client so that they can deliver the result. Compared with RDTs, which provide same-day diagnosis, testing involving western blotting or line immunoassays takes longer to provide the final HIV status to the client. Also, interpretation of the test result and final HIV status with western blotting/line immunoassays can be complex. Indeterminate results are common, leaving affected clients without a definitive diagnosis and the need to return for retesting.

Western blot/line immunoassays also have less sensitivity to acute infection than newer, third and fourth generation serology assays *(37, 38)*. As a result, the median window period is longer when western blot/line immunoassay is used than with other assay formats *(39)*.

HIV testing services delivered with western blotting/line immunoassays will not be able to increase access to and uptake of HIV treatment and prevention services among those in greatest need. The time to conduct western blotting/line immunoassays, interpret the results and return test results to clients is resource-intensive, from both cost and human resources perspectives. These same factors also lead to delayed or no ART initiation, due to loss to follow-up along the testing and treatment pathway. Additionally, HIV diagnosis is delayed for individuals who acquire HIV while taking PrEP *(26, 40)*.

WHO conducted a systematic review to develop new guidance on the use of western blotting in national testing strategies and algorithms. In this guideline update, WHO issues new guidance recommending that western blotting not be used in HIV testing strategies or algorithms in any setting. The following section summarizes the results of the systematic review and the new WHO recommendation (see also Annex C).

Review of the evidence: systematic review on use of western blotting and line immunoassays

The systematic review included 24 studies overall. Nine studies reported on accuracy (sensitivity, specificity and misclassification-related outcomes) *(41-48)* and seven reported on programmatic outcomes *(49-55).* Thirteen studies *(38, 44, 45, 49, 51, 52, 56-58)* also reported on values and preferences (n=9) and costs (n=4), including five that also reported on accuracy or programmatic outcomes. These studies took place primarily in the Americas (n=9, of which 8 were in the USA), and the remainder were in Asia, Africa and Europe. Box 8.8 presents key findings.

Box 8.8. Key findings from the systematic review

Overall, studies included in the review showed that algorithms using western blotting or line immunoassays, compared with those without (that is, using only RDTs and/or EIAs):

- achieved similar accuracy (sensitivity and specificity);
- led to more indeterminate results, requiring more clients to return for retesting 14 days later;
- had longer turnaround time between testing and delivering a final HIV diagnosis;
- increased loss to follow-up and delayed linkage to treatment;
- were costlier and less preferred by clients and providers.

Similar sensitivity and specificity, but more indeterminate results. The evidence reviewed showed that HIV testing algorithms or strategies that used western blotting achieved a sensitivity and specificity similar to those of testing algorithms or strategies that did not use western blotting. A meta-analysis of nine studies *(41-48, 59)* showed slightly better sensitivity and specificity in HIV testing algorithms or strategies that did not use western blotting. A sensitivity analysis excluding three studies *(42-44)* with significant bias resulted in similar findings, slightly favouring HIV testing algorithms or strategies that did not use western blotting. Thus, it was determined that there was likely no difference in sensitivity or specificity. The quality of evidence was low.

HIV testing algorithms or strategies that did not use western blotting reported fewer indeterminate/discrepant results (six false positives, 11 false negatives, zero indeterminate/inconclusive results) than HIV testing algorithms using western blotting (one false positive, seven false negatives, 81 indeterminate/inconclusive results). Nearly half (46%, 37/81) of the indeterminate/inconclusive results were HIV-positive, and the remaining 54% were HIV-negative. Overall, across all six cross-sectional studies reporting on HIV misclassification, 2159 true positive and 99 508 true negative specimens were tested *(43, 44, 46-48, 59).* The quality of evidence was very low.

Longer turnaround time. Programmatic outcomes such as time from determination of HIV status to providing HIV status and time to linkage to treatment or prevention were longer, and loss to follow-up was greater, for testing strategies that included western

blotting or line immunoassays than for those that did not. While there was variation across five reporting studies *(51-55)*, turnaround time was generally shorter when western blotting was not used. Without western blotting: 0.4–8 days (median days) versus with western blotting: 1.1–60 (median days). In other words, clients received their HIV diagnosis between 0.5 and 59.5 days earlier when they were tested with algorithms without western blotting. The quality of evidence was very low.

Increased loss to follow-up and longer time to linkage. Individuals tested with a testing strategy using western blotting had a greater rate of loss to follow-up (36%, 1486/4103) than those tested without western blotting (1.8%, 56/3178). A meta-analysis of three studies showed that loss to follow-up was more likely among those tested with a strategy using western blotting compared with those tested with a testing strategy using western blotting. The quality of evidence was very low.

A meta-analysis of two studies *(49, 50)*, with five comparisons, also showed that a greater proportion of people with HIV were linked to care following HIV testing strategy without western blotting than those tested with a testing strategy using western blotting. The quality of evidence was very low.

Less preferred and costlier. Nine studies *(44-46, 49, 51, 52, 60-62)* reported on patient and provider preferences in Australia, Belgium, China, Malawi and the United States of America. Overall, both providers and patients consistently favoured HIV testing algorithms and strategies that did not include western blotting. HIV testing strategies and algorithms without western blotting were generally preferred because they were fast, easy to perform and easier to use in non-clinical settings. One study reported slightly higher uptake of testing using western blotting or enzyme immunoassays than testing with RDTs (55% versus 45%) *(49).* However, further analysis showed that those who opted for RDTs had the greater risk of HIV acquisition, including men who have sex with men, reported receptive anal sex, sex under the influence of drugs or alcohol, those with a HIV-positive partner in the past or illicit drug use) or more likely to have tested previously.

Four studies *(38, 56-58)*, all in the USA, compared cost and resources use for HIV testing algorithms using western blotting with those that did not use western blotting. One costing study *(58)* collected data from 17 laboratories, measuring median testing cost per specimen tested. This study found that several testing algorithms without western blotting were more affordable both in medium-throughput laboratory settings (without western blotting: fourth generation EIA/RDT US$ 49.89; third generation EIA/RDT US$ 38.21 versus with western blotting: fourth generation EIA/western blotting (WB) US$ 184.30; third generation EIA/WB US$ 172.61) and in high-throughput laboratory settings (without western blotting: fourth generation EIA/RDT US$ 34.53; third generation EIA/RDT US$ 32.62 versus with western blotting: fourth generation EIA/WB US$ 55.58; third generation EIA/WB US$ 53.68).

The study reported that the higher costs of algorithms using western blotting were driven by labour and reagents. Reagents for western blot cost nearly twice as much as RDTs, and labour costs were more than 10 times those for RDTs. The greatest influence on cost per test, however, was how many specimens a laboratory tested. Overall, testing with western blotting cost more than three times testing algorithms without Western blotting.

Two studies in the USA *(38, 56)* assessed the cost-effectiveness of HIV testing with western blotting. Both reported a cost saving when they eliminated the western blot from their testing algorithms. In one study, using RDTs led to reductions in costs because fewer discrepant test results occurred and needed to be resolved. In the other study, cost saving of approximately 15% were obtained by removing the western blot test from the algorithm *(57)*.

Testing without western blot is highly feasible. In many settings clients and providers considered HIV testing strategies and algorithms without western blotting highly feasible because these assays require less infrastructure and can be performed by various types of health workers as well as by trained lay providers and community health workers. Implementing immediate ART and streamlining PrEP implementation, particularly for key populations, may not be feasible with western blotting due to longer times to receive results.

While some countries have made the shift away from western blotting, countries and settings where western blotting is the standard will need support to make the transition to updated testing strategies and algorithms. Reviewing and selecting other assays to take the place of western blotting will require time and resources in the short-term but will achieve greater impact and reduce future costs.

Moving away from western blotting is likely to lead to greater equity and uptake of HIV testing services among people with HIV who do not know their status and those at high ongoing risk who are not reached by existing services.

Based on the current gaps in HIV testing, treatment and care, moving away from western blotting is likely to lead to greater equity and uptake among people with HIV who do not know their status and those at high ongoing risk who are not reached by existing services.

Recommendation

Considering the evidence reviewed and information on acceptability, feasibility, resource use and equity, the Guideline Development Group (GDG) recommended against the use of western blotting in HIV testing strategies and algorithms. This recommendation was based on the overall summary of evidence, which found that testing strategies using western blotting, compared with those using only RDTs and/or EIAs, may take longer for an individual to receive a confirmed HIV-positive status, may contribute to greater loss to follow-up, and results in more HIV-indeterminate results, than testing algorithms and strategies without western blotting. Furthermore, testing with western blotting/line immunoassays costs more and is less acceptable and less preferred by providers and clients.

By consensus, the GDG determined this evidence to be of low quality. After considering all the evidence and the potential public health benefits and risks, the GDG deemed that the harms of using western blotting in testing algorithms strongly outweigh the benefits. Thus, the GDG advised that WHO make a strong recommendation to stop the use of western blotting and line immunoassays in HIV testing strategies and algorithms.

Box 8.9. NEW WHO recommendation

Western blotting and line immunoassays should not be used in HIV testing strategies/algorithms *(strong recommendation, low quality evidence).*

Implementation considerations

- Many HIV RDTs and EIAs can replace western blotting and line immunoassays. The critical task is to verify that the new test selected works well in combination with the other two tests in the algorithm. Most important is to maximize the specificity of the products chosen as the second and third tests in a testing strategy/algorithm. Countries should review and consider WHO-prequalified products listed at https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.
- The move away from western blotting/line immunoassays will facilitate task sharing among health-care providers, as well as community workers, enabling more people in need of HIV testing to be served with fewer resources. Efforts will be needed to support and reorient the role of laboratories, so that they can take on broader roles in supportive supervision and other aspects of quality assurance.
- The transition away from western blotting/line immunoassays will require national policy change and training of staff. These changes should be linked to broader efforts to scale up rapid ART initiation and access to HIV prevention services. Consultation with communities and other stakeholders will be critical.
- Promoting, and providing messages to communities, on the shift to faster, more accurate test results may help to increase demand for HIV testing services, particularly among key populations and populations where the burden of undiagnosed HIV is the greatest.

8.6 Verification of HIV testing algorithms

WHO recommends that HIV testing algorithms be verified prior to decisions on procurement of specific products and before widespread roll-out. When correctly chosen, combinations of RDTs or combinations of EIAs and RDTs can provide reliable results and at low cost *(63).*

8.6.1 Rationale for verification of HIV testing algorithms

A standardized testing strategy and quality-assured products are critical for accurate diagnosis, while poorly chosen testing algorithms can lead to misdiagnosis. Verification of testing algorithms provides objective evidence, before widespread roll-out, that a specific combination of products[10] will accurately diagnose HIV infection. To do this, verification assures that the products selected do not have the same false-reactive results, which would lead to misdiagnosis. When products are less than 100% specific, false HIV-reactive results are expected, but when two or more products are false-

10 An assay is a generic format such as HIV immunochromatographic RDT, whereas a product is defined by the product name, product code, manufacturer's name, regulatory version and manufacturing site.

reactive on the same individual (shared common false-reactivity), then misdiagnosis or delayed diagnosis can occur.

Shared false-reactivity results between different RDTs are not uncommon *(64, 65).* Generally, it occurs when the same antigen preparation is used to produce different products. This is occurring with increasing frequency due to rebranding or re-labelling arrangements among product manufacturers and the fact that there are more suppliers of finished RDTs than of the HIV antigen preparations.

The accuracy of verified HIV testing algorithms should be continuously monitored through post-market surveillance and retesting of newly diagnosed people with HIV before they start ART.

8.6.2 Suggested methodology for verification of testing algorithms

Verifying testing algorithms requires technical expertise and data analysis. Therefore, WHO recommends that a level 4 laboratory or other facility designated by national authorities coordinate the verification study (see Fig 8.7). The study may be carried out in a laboratory setting and/or at the point-of-use (testing site). A national taskforce (or existing technical working group) comprised of diagnostic and programmatic experts should adapt the study protocol, devise a list of candidate products, conduct the verification study and analyse and disseminate the results. To maintain harmonization and standardization, programmes should inform implementing partners about the verification study and seek agreement to act on its outcomes.

The objective of verification is to determine whether products have a high degree of false reactivity in common and are, therefore, not suitable for use in the same testing algorithm. There are three phases for verification prior to widespread roll-out. Because stock-outs and recalls will occur, and products may be removed from the market altogether, it is critical to choose two products for Assay 1 and three products for Assay 2 and Assay 3. If a stock-out requires a switch to a new product that has not be part of the verification study, even temporarily, re-verification of the testing algorithm should be undertaken.

Phase 1: Preparing for the verification study

Step 1: Shortlist products to be considered for the candidate testing algorithms.

It is suggested that no more than six to 10 products be considered for the verification study.

Quality criteria (see section 8.5.3. Quality characteristics of IVDs)
Select products from any of the following lists of quality-assured IVDs and in accordance with national requirements:

- list of nationally registered IVDs
- WHO list of prequalified IVDs
- list of products eligible for procurement by donors/implementing partners.

Performance criteria (see section 8.5.4. Performance characteristics of IVDs)
Any product that is WHO-prequalified is expected to meet certain minimum performance criteria (see Table 8.2). Also, the manufacturer makes a statement about performance in the instructions for use. For WHO-prequalified products, the data claims in the instructions for use have been verified and are reflected in the instructions for use attached to the prequalification public report.

Operational criteria (see section 8.5.5. Operational characteristics of IVDs)
Depending on the testing setting, certain operational aspects may be more important than others.[11]

Step 2: Request test kits.

Obtain a sufficient number of tests from two lots of each product from the manufacturer (or in-country distributor). Test kits should be stored under the conditions stated in the manufacturer's instructions for use. Any additional consumables that are required to perform each of the assays also must be available.

Step 3: Establish the verification panel.[12]

The specimen types that have been validated by the manufacturer are listed in the product's instructions for use. If listed among validated specimen types, serum or plasma are recommended for verification studies of this nature; such specimens can be collected and stored in larger volumes and are more easily handled than other specimens. If so claimed, the HIV-negative panel may include capillary whole blood specimens. However, it may be difficult to collect a sufficient volume of capillary whole blood to test all candidate assays with the requisite number of replicates on two different lots.

The panel specimens must have been adequately characterized for the presence or absence of HIV. That is, the diagnostic accuracy criteria[13] for each specimen have been established. Fig. 8.7 presents an example of characterization of verification specimens.

If the candidate testing algorithm will contain fourth generation IVDs, a fourth generation assay should be used in the characterization of verification panel specimens.

Table 8.4 shows the number of specimens that should be collected for the verification panel and the number of replicates that should be tested on each of the lots.

11 See WHO. Guidance for procurement of in vitro diagnostics and related laboratory items and equipment, second edition. 2017 https://www.who.int/diagnostics_laboratory/publications/procurement/en/.

12 Sources: ISO 15189 Medical laboratories — Requirements for quality and competence. Geneva: International Standards Organization; 2012; and CLSI EP12-A2: User protocol for evaluation of qualitative test performance, second edition. Wayne, Pennsylvania, USA: Clinical and Laboratory Standards Institute; 2008.

13 Diagnostic accuracy criteria are defined by the Clinical and Laboratory Standards Institute (CLSI) as the "best currently available criteria for establishing the presence or absence of the condition, event or characteristic of interest using a single method or combination of methods, including laboratory tests, imaging tests, pathology, and clinical information including follow-up" (CLSI EP12-A2); Wayne, Pennsylvania, USA: Clinical and Laboratory Standards Institute; 2008.

Fig. 8.7. How to characterize specimens of the HIV verification panel

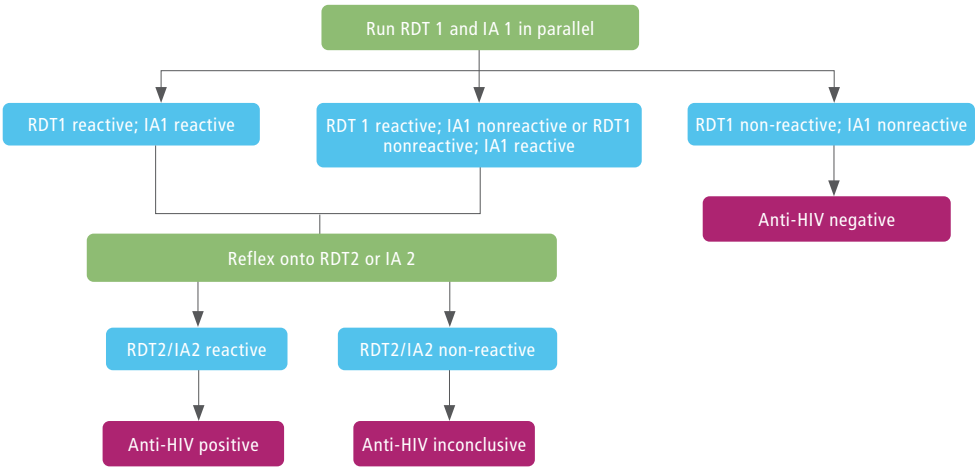


Table 8.4. Verification specimen panel

Type of specimen	Number of specimens	Number of replicates
Negative for HIV-1/2 Ab/Ag	100 clinical specimens	Test duplicates of each specimen on each of 2 different lots.

Specimens may be collected from clinical settings, blood transfusion services or otherwise commercially acquired. The verification panel must be stored at –20 °C before use.

Step 4: Select study site(s).

The verification study may be conducted in any setting (laboratory or point of use), as designated by national authorities.

Step 5: Train study staff.

All test operators should be trained on standard operating procedures (SOPs) for the study, including how to handle specimens, how to perform each assay and how to read and record test results. Training should be documented in training records. Before participating in the study, all test operators should be able to demonstrate proficiency.

Step 6: Implement data quality practices.

Transcription errors are common; accurate record-keeping is crucial. Worksheets should be prepared for each individual run, and one consolidated worksheet should be prepared for overall data analysis. Data entry should be double-checked.

Phase 2: Conducting the verification study

Step 1: Test each product using the verification panel.

Each specimen of the verification panel should be labelled with a specimen identification number that does not reveal the expected result (diagnostic accuracy criteria). Each test operator should be blinded to the expected reference result for each of the specimens. To protect their integrity, aliquots should be removed from storage only when they need to be tested.

Testing should be conducted using only the information provided with the test kit (for example, instructions for use (IFU), labels and other instructional materials). Test operators should be representative of the intended users, and they should work unassisted. If test kit controls are available, whether within the test kit or separately, these should be used in accordance with the manufacturer's instructions for use.

Both lots of each product should be tested on the same verification panel.

Recording results for visually read assays (that is, RDTs)

The test band intensity should be recorded on the following scale, as it is critical to distinguish between weak and strong test lines:

0 non-reactive

1+ weakly reactive

2+moderately reactive

3+ strongly reactive

Step 2: Interpret the results.

Results for visually read assays (such as RDTs)

After the first reader (the testing provider) has read and recorded the result of any visually read assay, a second reader should make a blinded rereading. In addition, the intensity of the test line/band should be recorded so that variability due to faint test lines can be quantified.

- If the two readers interpret the test results the same way, then the status of the specimen is recorded as is.
- If the two readers do not agree, a third reader should adjudicate. The result that has the majority – that is, two of the three readers – should be taken.

If a result cannot be conclusively reached, the result should be recorded as inconclusive, and the specimen should be retested on a new test device from the same lot. These results should be included in the data analysis as a misdiagnosed specimen.

Results for instrument-based assays (such as immunoassays)

Certain immunoassays display an OD/CO ratio that is within the grey zone according to the manufacturer's instructions for use (usually 0.90–1.10). These specimens should be

repeated in duplicate on the same lot. They should be included in the data analysis as a misdiagnosed specimen.

Invalid results

For visually read assays such as RDTs, invalid test results typically occur when the control line does not appear, regardless of whether the test line appears, or when high background colour completely obscures the result window. Other anomalies also should be recorded, such as streaking across the membrane, non-migration of specimen and debris on the membrane.

For instrument-based assays such as immunoassays, chemiluminescence immunoassays and electro-chemiluminescence immunoassays, invalid results or invalid runs occur when the internal and/or external test kit controls (HIV-negative, HIV-positive) are not within the acceptance range specified in the manufacturer's instructions for use.

The rate of invalid test results/runs should be recorded in the data analysis as the proportion of invalid results/runs in the total number of tests/runs performed.

Step 3: Conduct data analysis.

Using the results of the HIV-negative specimens, calculate the rate of common false reactivity between the candidate products. It may not be possible to choose a combination of products that has no shared false-reactive results. If so, choose the combination that has the fewest common false-reactive results.

Using the results of the HIV-Antibody positive specimens, calculate the sensitivity for each candidate products.

Expiry date of study results

The results of the verification study should remain valid for a period of 3–5 years. The verified testing algorithm must be reviewed every 3–5 years to determine if a verification study should be repeated.

Phase 3: Monitoring implementation of the testing algorithms and post-market surveillance

Testing algorithms must be continually monitored for effectiveness, including any adverse events of HIV misdiagnosis.

It is suggested to use new testing algorithms in parallel with the existing testing algorithm for two weeks at high throughput testing sites or four weeks at low throughput testing sites. A discrepancy rate of >1% between new and existing algorithms is noteworthy and requires investigation of the root cause. After this initial familiarization period, the new testing algorithms may be rolled out more widely.

Data should be collected on the rate of HIV-inconclusive status and the rate of invalid test results. No more than 5% is acceptable. Any observations related to test procedure or other operational characteristics that do not appear to meet the manufacturer's claims should be documented and reported according to WHO guidance on post-market surveillance of in vitro diagnostics *(66)*.

The accuracy of algorithms should be monitored through post-market surveillance.

The on-going accuracy of verified HIV testing algorithms should be monitored through post-market surveillance. A *false-negative* HIV status will generally be the result of one product (Assay 1) failing to detect HIV, but it is typically very difficult to detect unless an individual with known HIV-positive status undergoes retesting. (WHO does not recommend retesting for HIV-positive individuals, particularly those taking ART.) A *false-positive* HIV status may be due to one or more of the products in the testing algorithm, typically Assay 2 or Assay 3. WHO recommends retesting before initiation of ART to detect people who have been incorrectly diagnosed as HIV-positive. It may be difficult to determine if one product alone is performing sub-optimally or, rather, the overall testing algorithm is at fault.

Box 8.10. Post-market surveillance and complaints

Any complaints related to the products themselves should be reported to the assay manufacturer and to the national regulatory authority as part of post-market surveillance.

WHO guidance on post-market surveillance of in vitro diagnostics is available at: https://apps.who.int/iris/bitstream/handle/10665/255576/9789241509213-eng.pdf

All WHO information and complaint forms are available online: https://www.who.int/diagnostics_laboratory/procurement/complaints/en/

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QUALITY ASSURANCE FOR HIV TESTING SERVICES

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KEY POINTS

- **Quality management systems are essential** for all aspects of any form of HIV testing services (HTS), ranging from testing in laboratories and health facilities to testing in community-based settings, including rapid diagnostic tests (RDTs) performed by lay providers. Specific quality elements are applicable to HIV self-testing (HIVST).
- **In vitro diagnostics (IVDs) should meet regulatory standards** according to national guidelines, including products used for HIVST. WHO conducts independent prequalification assessment of IVDs, with emphasis on HIV RDTs and other IVDs intended for use at, or near, the point-of-care in resource-limited settings.
- In certain situations HTS providers may refer individuals to another site for additional testing to verify their HIV status. **Consistent, clear, confidential, accurate and timely record-keeping is critical** at both the initial testing site and the referral testing site.

9. QUALITY ASSURANCE FOR HIV TESTING SERVICES

9.1 Considerations for assuring the quality of HIV testing

Ensuring timely, affordable and correct HIV diagnosis is the cornerstone of any HIV programme. It is essential to organize and manage HTS so that all individuals with HIV can be diagnosed and successfully linked to and retained in treatment and care, irrespective of their economic or social status or their geographical location. This is particularly important in the context of "treat all" recommendations for initiation of antiretroviral therapy (ART). Due care must be taken to ensure that individuals who do not have HIV infection are not misdiagnosed as HIV-positive and, thus, initiated on lifelong ART. Individuals with HIV also must not be misdiagnosed as HIV-negative and, therefore, be unable to benefit from treatment and risk onward transmission.

The quality of HTS is suboptimal in some settings, but simple measures can improve quality.

Recent global reports suggest that the quality of HTS is suboptimal in some settings. Misdiagnosis of HIV status – both false-positive and false-negative – has been reported *(1-6)*. A recent systematic review conducted by WHO found a median of 3.1% of individuals were diagnosed false HIV-positive (interquartile range: 0.4–5.2) and a median of 0.4% diagnosed false HIV-negative (interquartile range: 0–3.9) in 68 studies in Africa, the Americas, Asia and Europe *(7)*. Numerous studies have reported use of suboptimal testing strategies that differ from the WHO recommendations, such as using a single RDT result to give an HIV-positive diagnosis, using parallel rather than serial testing strategies and using a tiebreaker testing strategy (where the result of Assay 3 is used to resolve discrepant test results and to rule in HIV infection).

User errors were also frequently reported in studies. These included difficulties with specimen collection, incorrectly performing the test procedure, reading test results too early and incorrectly interpreting test results. Inadequate management and supervision of testing facilities were cited as contributing to stock-outs and the use of damaged or expired RDTs. In some cases sub-optimally trained or untrained staff conducted testing. Staff had poor understanding of testing during the window period and the need for retesting, as well as retesting to verify HIV diagnosis prior to ART initiation. Very few testing sites participated in external quality assessment (EQA) schemes. Poor record-keeping and data collection, as well as transcription errors commonly resulted in poor quality testing. In one study nearly 30% of errors led to incorrect results (8). Some studies reported challenges related to interpretation of weak reactive test lines, which can be interpreted as negative test results.

Any HTS programme, including HIVST, must implement quality management systems, irrespective of where or how testing takes place —community-based services including mobile testing, health facilities or laboratories — and irrespective of who conducts testing — trained laboratory personnel, other health-care workers, lay providers or self-testers. For more information on the core elements of HIVST quality management, see the WHO framework: https://apps.who.int/iris/bitstream/handle/10665/275521/9789241514859-eng.pdf.

A quality management system consists of all the organizational processes put in place to ensure quality. **Quality management** comprises quality assurance, quality control and quality improvement. It focuses on the **quality of the processes** required for effective testing rather than just the **quality of the product** (the IVD) used for testing. Thus, engagement with the people who are part of the testing process is critical, that is, staff responsible for procurement, staff who establish and supervise health facilities, testing providers (including self-test distributors) and clients. For example, was the facility where testing took place safe, welcoming and convenient? Quality management includes customer/client satisfaction as well as occurrence management and process improvement as forms of quality improvement to ensure that testing services consistently meet the needs of the clients. A testing service that uses products of the highest quality and performance, but where test kits are regularly out of stock, or the provider does not know how to correctly use them, or the site is never open at convenient times, is not a high quality testing service.

This chapter covers the quality of HTS. While current international standards are more suited to testing within a laboratory (or other facility) and generally assume dedicated testing staff, the principles of testing quality are applicable to any disease, condition or setting. This guidance adapts the international standards for testing in resource-limited settings, where RDTs and other IVDs at the point-of-care are most commonly used, and staff often have a variety of responsibilities in addition to testing. Quality management aspects, such as record-keeping and documentation, also have major influence on the quality of testing. Quality management for HTS should be implemented irrespective of assay (test) format or testing location. Certain quality management tasks may need to be performed by a supervisor of HTS rather than the provider delivering HTS, but are an integral part of the overall approach to providing a quality service.

Chapter 7 describes WHO's recommended HIV testing strategy and how to verify testing algorithms.

Quality assurance (QA) is defined as "part of quality management focused on providing confidence that quality requirements will be fulfilled" *(9)*. It is a way to manage and plan for maintaining quality by preventing errors and defects in products and services. It tends to be proactive in nature. **Quality control** (QC) verifies that the product meets quality requirements and is a mechanism to identify product defects and to formally reject a defective product. QC is more reactive in nature than QA. It is typically focussed on the actual quality of the product being used. **Quality improvement** (QI) is the process of proposing solutions to improve quality and reliability and, therefore, increase customer satisfaction. The plan/do/check/act cycle is helpful in this regard. WHO guidance on quality improvement is available in the policy brief *Maintaining and improving quality of care within HIV clinical services:* https://www.who.int/hiv/pub/arv/quality-care-hiv-services/en/.

9.2 Assuring quality – what must be done at the national level

There are certain quality management systems that must be addressed at the national level:

1. **National policies, strategic plans, monitoring processes:** how national authorities support quality management systems at testing sites.
2. **Workforce development:** ensuring testing providers are trained and supportively supervised.
3. **Testing strategies and algorithms:** adopting WHO-recommended testing strategy and verifying testing algorithms.
4. **Pre-market assessment:** using WHO's prequalification listing to identify quality IVDs including those for HIVST, strengthening regulatory capacities.
5. **Post-market surveillance:** reporting complaints and participating in EQA schemes.
6. **Procurement and supply chain management:** ensuring uninterrupted supply and appropriate storage of test kits and other items.
7. **Accreditation of testing sites:** ensuring testing sites are supported and are held to a standard of quality.

9.2.1 National policies, strategic plans and monitoring processes

National policies, strategic plans and monitoring processes are critical for planning, budgeting and implementing quality management systems and quality activities. National policies for HIV testing must be updated regularly and linked to other national policies and strategic plans such as those regarding laboratory operations and health and human resources *(10).*

National policies and plans for HIV testing might fall within the remit of the national laboratory strategic plan or be a stand-alone plan for HIV testing; either is acceptable as long as quality objectives are included. National authorities typically task the national reference laboratory to plan, implement and monitor the range of quality activities for HIV testing, or these may be within the remit of the ministry of health. These activities can be decentralized to the provincial or district level, depending on the context and country's needs. The role of the national reference laboratory is to promote the use of standardized logbooks/testing registers, to conduct supportive supervision visits, to organize provision of quality control materials and EQA proficiency testing, and to follow up on corrective actions that might arise from quality activities. See Annex J for more details about how to delegate responsibilities for quality assurance activities.

9.2.2 Workforce development

For health workforce development that supports quality testing, it is critical to plan for standardized and coordinated pre-service and in-service training (with hands-on practicums and competency-based assessments); national policies that support task-sharing for lay providers to conduct testing and issue reports of HIV diagnosis; and staff recruitment and retention strategies, especially for rural and underserved areas.

Training and supportive supervision for any public or private testing site must focus on ensuring the proficiency of HIV testing providers. All testing providers should have adequate competency-based training on the different stages of the testing process. This includes 1) how to maintain testing records in standardized logbooks/testing registers; 2) how to interpret results generated by the testing algorithm as an HIV-status report; 3) understanding the purpose and use of QC materials; and 4) how to participate in EQAs and ensure that appropriate corrective and preventive actions are taken. In-service refresher training is critical to improve knowledge, skills and attitudes and to provide opportunities for support.

Manufacturers of IVDs (or their economic operators, such as suppliers, distributors or agents) must provide in-service training and trouble-shooting when product problems and/or adverse events occur.

Authorities should consider developing national curricula for HIV testing and other aspects of HIV care and treatment that is suitable for a variety of testing settings. Certification of testing providers should be considered, which can act as an incentive to reinforce quality aspects of HIV testing activities.

Box 9.1. Using technology in training of health workforce in Brazil increases coverage of HIV testing

- Increasing access to HIV diagnosis, especially using RDTs, is a key strategy of the Brazilian Ministry of Health to reach the 90–90–90 target by 2020. In 2017, the ministry distributed more than 12 million RDTs, 23 times more than in 2005, when use of RDTs was adopted as a public health policy. It was also necessary to increase the number of health-care workers capable of conducting HIV testing using RDTs. Considering the size of the country, with 5570 cities, and the need for an alternative to on-site trainings, they began to offer a free distance-learning course called TELELAB *(11)*.
- TELELAB provides online courses on diagnosis of STIs with video lessons and instruction manuals. For settings with difficult internet access, TELELAB can be received as a DVD by post. After the course is completed, professionals are awarded a certificate once they pass an exam with a score of 70% or higher.
- Sixty-one percent of providers who receive certification are nurses. In 1943 municipalities that were observed, 10 264 health-care professionals (72% of the total) reside outside the capital, and many of them live and work in remote and rural areas with no access to laboratory services.
- TELELAB ensured greater access to HIV diagnosis as it created the opportunity for health-care professionals, especially nurses, to improve their HIV testing skills. With more professionals qualified to provide HIV testing, it became possible to increase the number of RDTs distributed annually by the ministry of health.
  Building on the initial success, TELELAB will be further expanded countrywide using a mobile phone application.

See website for more information: www.telelab.aids.gov.br

9.2.3 Pre-market assessment

Regulation of IVDs is a critical component of health systems and, as such, directly impacts on the quality of HIV testing. The level of scrutiny applied during the pre-market review depends on the risk classification of the product, the country's needs, the available resources and the implementation of a national framework that governs the regulatory process. Pre-market assessment, according to national regulation and/or legislation, is a necessary step before authorizing the marketing of IVDs such as those for HIV. Pre-market assessment involves controls relative to the product quality, safety and performance. Regulation of IVDs in many countries lacks the legal framework and/or resources. To fill this gap, WHO conducts prequalification assessment of IVDs that are most likely to be used in resource-limited settings, especially those used at or near the point-of-care. WHO independently reviews the quality, safety and performance of these IVDs. WHO encourages national programmes to prioritize WHO prequalified IVDs during their pre-market approval process and when selecting products for their national testing algorithm.

WHO prequalification applies a standardized procedure to determine whether the product meets WHO prequalification requirements. The assessment consists of three components:

1. review of safety and performance as presented in a product dossier compiled by the manufacturer;
2. review of the quality management system through a site inspection;
3. an independent evaluation of performance and operational characteristics.

The WHO publication *Overview of the prequalification of in vitro diagnostics assessment (12)* provides further information. Annex J provides additional details about how WHO prequalification is conducted.

9.2.4 Post-market surveillance

Once a product is found to meet regulatory requirements and is placed on the market, post-market surveillance must be conducted to monitor and detect any quality, safety or performance issues. All stakeholders (end-users, manufacturers/economic operators, regulators and testing laboratories) have a specific role, but post-market surveillance remains the ultimate responsibility of the manufacturer who relies on feedback about their products, primarily through the reporting of complaints.

WHO has issued specific guidance on *post-market surveillance of IVDs. Post-market surveillance of in vitro diagnostics (13)* is available at https://apps.who.int/iris/bitstream/handle/10665/255576/9789241509213-eng.pdf.

Reactive post-market surveillance takes place when an adverse event has already occurred to the individual being tested, the testing provider or other individual in the vicinity. An example is when an individual detects and reports a false-negative test result, such as if they have been diagnosed elsewhere and present themselves for retesting.

Proactive post-market surveillance detects a product problem before it has occurred and associated with an adverse effect to an individual. An example is lot testing of random samples of HIV RDTs from the field or review of scientific literature for similar products.

An **adverse event** can cause direct harm or indirect harm. Direct harm would be a death or serious deterioration in health that occurs or could have occurred. It is more likely that IVDs will result in indirect harm, such as misdiagnosis, delayed diagnosis, absence of treatment or delayed treatment, than direct harm.

Any time a problem with an IVD is detected or an adverse event is reported to the manufacturer, the manufacturer is required to record this in their **complaint system** and launch their procedure for handling complaints. This means reassessing the potential risk related to ongoing use of the IVD. If the manufacturer determines that the risk (to individuals) is unacceptably high and no longer outweighs the benefit to the individual, the manufacturer may take a field safety corrective action to reduce the risk of harm. For example, if one lot of RDTs yields a higher than expected rate of false-negative test results, the manufacturer may conduct a recall to remove the lot from the market.

Typically, end-users of IVDs will be the first to detect an issue with products used in their testing sites. For example, retesting, which is recommended for any newly diagnosed individual before starting ART, presents the opportunity to identify false-positive misdiagnoses. End-users are likely to notice any visual defects or obvious anomalies, especially at sites that follow verified HIV testing algorithms. End-users should report problems and complaints to manufacturers of IVDs and to their economic operators, who have their own obligations to conduct post-market surveillance for the product that they place on the market. Thus, it is critical that end-users are empowered to make complaints using standardized complaint forms (14). National authorities (regulatory authorities and reference laboratories) may also play a role in supporting complaint reporting. See WHO complaint form at: https://www.who.int/diagnostics_laboratory/procurement/111121_user_complaint_form_for_adverse_events_and_product_problems_reporting_english.pdf.

National authorities (regulatory authorities and reference laboratories) may conduct post-market surveillance, as and when their capacity permits, applying a risk-based approach. This means focusing efforts on monitoring specific products that are critical, or where prior reports indicated.

WHO manages a complaint-reporting system for IVDs, with an emphasis on products that are recommended for use by WHO. End-users are encouraged to use the standardized WHO form to report any complaints including false-negative results or an elevated rate of false-positive results and invalid results, as well as obvious visual defects. WHO then oversees the course of the investigation conducted by the IVD manufacturer and any resultant correction and corrective action.

An IVD could be removed from the list of WHO prequalified IVDs if the manufacturer does not address quality issues in a timely and adequate manner.

Annex J provides a detailed description of activities that contribute to post-market surveillance.

Box 9.3. Examples of complaints that might arise from retesting

If HIV-positive and retested before ART initiation and the result is now HIV-negative, report Assay 1, Assay 2 and Assay 3 as a complaint.

If HIV-inconclusive and retested after 14 days and resolves to be HIV-negative, report false reactive Assay 1 and/or Assay 2 as a complaint.

If HIV-inconclusive and retested after 14 days and resolves to be HIV-positive, report false negative Assay 2 as a complaint.

National authorities should consider collaborating with professional EQA providers to build capacity for proficiency testing of their testing services, including to follow up on corrective and preventive actions to address issues identified from quality activities. External quality assessment is an important tool for post-market surveillance and to identify testing sites that are making errors that could lead to HIV misdiagnosis. The objectives of participating in EQA schemes are to:

- evaluate testing competence
- assess performance of individual testing providers
- evaluate the reliability of HIV testing procedures
- ascertain the accuracy of records.

Testing sites should participate as frequently as possible in EQA schemes, but preferably at least once per year. Annex J presents additional details on how to organize EQAs.

9.2.5 Procurement and supply chain management

Procurement and supply chain management of IVDs to support a national HIV testing programme may be arranged differently depending on the setting. In many countries, national authorities will conduct centralized procurement on behalf of testing sites within their mandate. In some settings, implementing partners such as nongovernmental organizations and other donors may provide procurement assistance and may apply their own quality assurance policy for products purchased with their funds.

It is critical that the national procurement policies are written to support procurement of only quality-assured diagnostics, equipment and other required items. This includes using results of testing algorithm verification studies to justify product selection. This is particularly important in countries where many stakeholders conduct procurement activities.

It is essential that **national forecasting and quantification** be coordinated across all implementing partners to ensure that test kits and any other items required to provide HIV testing are available at testing sites. Prevention of **stockouts** that may disrupt, or delay HIV testing is paramount.

Procurers and forwarding agents must ensure that goods are stored and transported according to manufacturer's instructions for use, with attention to conditions such as temperature and humidity, etc.

Box 9.4. WHO guidance for procuring IVDs, including HIV test kits

WHO has issued guidance on how to procure IVDs and other items required for HIV testing: *Guidance for procurement of in vitro diagnostics and related laboratory items and equipment (15).*

English: https://apps.who.int/iris/bitstream/handle/10665/255577/9789241512558-eng.pdf

French: https://apps.who.int/iris/bitstream/handle/10665/259873/9789242512557-fre.pdf

9.2.6 Accreditation of testing sites

Accreditation is a *"recognition of the* [testing site's] *quality and competence"* *(16)*. National or international accreditation bodies assess a testing site to determine if the quality management system is functional and if it complies with the requirements of a given quality standard. The most widely applicable international quality standard is ISO 15189 Medical laboratories, which requires quality and competence. National authorities should consider moving towards accreditation of testing sites within their tiered testing network. Through partnerships, WHO gives guidance on how to move towards accreditation of testing sites.[1]

9.3 Assuring quality – what must be done at the testing site level

The basic principles of quality management systems must apply to all services conducting HIV testing and providing HIV diagnosis. Both facility-based (laboratories and health facilities) and community-based/mobile testing services should assure quality. Site supervisors are responsible for quality activities and thus should be trained on the principles of quality management systems. All testing services must have a quality policy that specifies the following 12 aspects, as described in WHO's Laboratory Quality Stepwise Implementation tool (https://extranet.who.int/lqsi/):

1. **organization**: ensuring quality is at the forefront of any testing service
2. **personnel**: ensuring that competent staff, including lay providers, are employed
3. **equipment**: ensuring appropriate, fully functional equipment, mostly applicable to laboratory-based testing services
4. **purchasing and inventory**: ensuring the purchase and management of quality-assured test kits and consumables
5. **quality control**: ensuring process control of daily testing processes
6. **information management**: creating and managing documents and records, and keeping records confidential and preferably electronic

1 The *WHO guide for Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in the African region* provides further information. (WHO guide for Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in the African region. Brazzaville: World Health Organization Regional Office for Africa; 2015.)

7. **documents and records**: ensuring standard operating procedures are up-to-date and standardized records are kept
8. **occurrence management**: recording and following up on complaints
9. **assessment**: evaluating and following up on results of EQA schemes/proficiency testing and on-site supervision
10. **process improvement**: ensuring effectiveness of preventive and corrective actions that are implemented
11. **client service**: measuring customer satisfaction
12. **facilities and safety**: ensuring safety of staff/clients through proper waste disposal and cleaning/decontamination procedures.

These 12 aspects are described below as they apply to testing services that primarily use RDTs. For HIV self-testing, certain elements of a quality management system approach are not applicable, such as organization, personnel, assessment, process improvement and client service. For conventional laboratory-based testing, these would need to be adapted.

9.3.1 Organization

A common quality policy may be developed for similar types of testing sites. For example, all sites where only RDTs are used, where there is minimal infrastructure and where lay providers conduct testing have similar quality requirements. The policies, processes and procedures should be available as a written manual which is located within a reasonable distance of all staff, including mobile testing staff. Personnel/staff can then use it as a reference.

The standard operating procedure/QA manual should include:

- Name of the QA manager (or champion)
- Description of the testing process flow, from pre-testing to post-testing
- Quality Control Plan that indicates when to run external QC
- Copies of instructions for use for each product as provided by manufacturer
- Procedure instructing how to document and report HIV status to clients
- Procedure for referring specimens or for referring persons for additional testing to confirm their HIV status
- Policy on what to do and how to document when things go wrong during or after testing (for example, invalid test results, failed QC, suspected false HIV-positive or HIV-negative results, adverse client reaction when reporting HIV status)
- Policy on what to do when a false HIV-positive test result occurs. This is important because it may indicate a problem with the testing system including the testing operator
- Policy on protective equipment to be used and how to dispose of sharps or biological waste properly

- If applicable, procedures for referring clients for linkage to care, partner services, post-exposure prophylaxis (PEP), pre-exposure prophylaxis (PrEP), behavioral interventions (as indicated), other services as needed (housing, STI, mental health, substance use).

Testing services should be organized so that they are well-suited to the community they serve and maximize the quality of service and access to testing. This may include adapting opening hours, minimizing waiting time for clients and creating a favourable environment by ensuring the absence of stigma and discrimination.

Quality should not be a one-off activity or an activity that is undertaken by one staff member only. Rather, quality should be an integral part of the continuing roles and responsibilities of every staff member.

How to implement

- Ensure that **policies, processes and procedures** are relevant for the assay formats used as well as for the infrastructure and the skills of available staff.
- Name a staff member to serve as the **quality assurance focal point** in all aspects of the testing site.
- Ensure **professional commitment** to the quality of HIV testing, with regular management reviews of quality data, including turnaround times, rates of invalid results, quality control and EQA data (see component 9).
- Develop an **organogram** that depicts the roles and responsibilities of all personnel.

9.3.2 Personnel

All testing sites must employ enough trained and proficient personnel to conduct all phases of the testing process for the expected site throughput:

- pre-analytical (collecting and processing specimens, recording details of the individual undergoing testing);
- analytical (conducting assay procedure and recording results); and
- post-analytical (interpreting test results and reporting HIV status).

Throughput is the expected number of tests conducted per day, which is a function of the number of individuals tested per day and the expected positivity rate.

The roles and responsibilities of all personnel at the testing site must be defined, including: who collects specimens, who performs testing, who runs QC, who issues reports, who double-checks test results and reports and other data entry tasks, and who conducts cleaning. National regulations will specify which cadres of health workers can perform which functions. All personnel must be adequately qualified and have demonstrated proficiency in performing the tasks within their scope of work.

All personnel should receive both **pre-service** and **in-service training** on HIV testing. Continuing education at testing sites is important to improve and maintain the skills of personnel, particularly for sites with very low throughput of clients or infrequent testing schedules. In addition to continuous education, regular **supportive supervision** and ongoing **mentoring** of all staff are essential.

Ensuring the psychological and physical well-being of HIV testing providers is critical. Good vision is required for reading subjective assays such as RDTs.

How to implement

- Maintain **training checklists** for all staff that documents their ongoing proficiency.
- Encourage annual **bidirectional performance appraisals** to discuss any issues that affect abilities to perform assigned tasks.

9.3.3 Equipment

Wherever testing takes place and whether it is conducted using HIV RDTs or by laboratory-based IVDs, **appropriate and fully functional** equipment is required.

For testing services using primarily RDTs, it is important to have **timing devices**. If temperatures will exceed the manufacturer's recommendations, **refrigerators** are required for storage and to maintain optimal operating temperatures.

For testing services using laboratory-based IVDs, **calibration and maintenance of equipment** is essential for providing accurate testing results.

How to implement

- Ensure areas where test kits are stored and testing is conducted are monitored using a thermometer.
- Maintain an **inventory** of all equipment.
- Ensure that all equipment in the inventory is subject to **preventive and corrective maintenance** on an appropriate cycle, depending on throughput.
- Ensure that **equipment that is not working** is prominently labelled as such and taken out of service.
- Develop **standard operating procedures** for all equipment, for example, instructions on how to turn it on and off, how to clean it and any preventive maintenance or calibration that the operator must undertake.

9.3.4 Purchasing and inventory

Stock-outs of HIV test kits or any essential consumables, such as gloves, lancets, alcohol swabs, specimen transfer devices and waste disposal containers, are a major reason for poor quality and client dissatisfaction. Lack of stock of Assay 1 may lead to use of a less sensitive assay (Assay 2 or Assay 3) instead. The lack of single-use specimen transfer devices will lead to an incorrect specimen volume added and may result in an inaccurate test result.

An adequate system is required at each testing site to **track procurement of test kits, reagents and consumable**s (venous or finger-stick blood collection supplies) – when they are ordered and when received.[2] As stocks are received, it is critical to note expiry

2 Detailed guidance is available in *WHO guidance for procurement of in vitro diagnostics and related laboratory items and equipment, 2nd edition, 2017*. (http://www.who.int/diagnostics_laboratory/procurement/en/).

dates, to store under appropriate conditions and to re-order in advance, before stocks expire or are used up, allowing adequate time for the next delivery to replenish stocks.

How to implement

- Maintain a **list of inventory requirements.**
- Ensure adequate **space to store test kits** (including refrigeration) and record storage temperatures daily.
- **Do not split larger test kits** into smaller quantities, for example, taking a test kit of 100 tests and splitting it into five bundles of 20 tests. Reagents such as multi-use bottles of specimen diluent/buffer and labelling such as the instructions for use cannot be split.
- **Do not interchange components** between test kits, for example, stockpiling buffers or other components for RDTs.

9.3.5 Quality control

Quality control (QC), also known as process control, refers to processes and activities to ensure that **testing procedures** are performed correctly, that **environmental conditions** are suitable and that the assay works as expected. Quality control intends to detect, evaluate and correct errors due to assay failure, environmental conditions or operator performance before test results are reported.

Internal QC refers to processes within the assay that check whether the procedure is working. Appearance of a control line/spot for RDTs is an example. Most RDTs contain a control line/spot that indicates only the flow of liquid. Only a few RDTs contain a control/spot line that indicates that a specimen has been added.

Test kit controls (known as positive and negative controls) may be supplied by the assay manufacturer. They are standard for most assay formats except for RDTs. Few HIV RDTs have accompanying test kit controls, making QC problematic. Any test kit controls should be run according to the manufacturer's instructions.

External QC materials should be used in addition to any internal quality controls or if none is supplied. These are prepared and validated by a QC provider, preferably an experienced and proficient commercial entity, specifically for the product used.

External QC specimens for process control should be run:

- once weekly, preferably at the beginning of the week
- for any new operator (including trained staff who have not conducted testing for some time)
- for each new lot of test kits
- for each new shipment of test kits
- when any environmental conditions (for example, temperature and humidity) fall outside the range recommended by the manufacturer.

When external QC results are different from what is expected, all test results since the last correct QC run are considered invalid ("out-of-control"). When the assay is determined to be out-of-control, all individuals tested during this period should be considered for retesting.

Quality control is a multi-step process with certain checkpoints throughout the testing process.

- Before testing (pre-analytical):
  - o Check that the temperature of the testing area is within the manufacturer's recommendations and record the temperature daily. Testing should not take place if the room temperature is outside the recommended operating temperature range.
  - o Check that stocks of test kits and required consumables are on hand daily.
- While testing (analytical):
  - o Ensure that any QC specimens have been run (for example, test kit controls and/or external QC specimens) and that the results are within pre-established QC acceptance limits.
  - o Ensure that a second reader double-checks all subjectively read assays (see Box 9.5).
- After testing (post-analytical):
  - o Double-check the report of the HIV status to be given to the client.

Box 9.5. Second reader when interpreting test results

Ideally, a **second reader** should make a blinded reading of any visually read assay. The second reader needs to be trained only on how to read the assay, not necessarily on the test procedure itself. If the two readers interpret the test results the same way, the test result can then be interpreted as is. Disagreements between readers for RDTs have been reported ranging from 0 to 1.6% *(17, 18)* and should be resolved with a third reader.

How to implement

- Establish criteria for **specimen acceptance** or rejection and specimen storage, retention, disposal and referral of the specimen to another site for testing.
- Establish criteria for **QC of qualitative and quantitative assays**, with established limits of acceptability.

See Annex J.5 for information about the preparation of quality control specimens for RDTs.

9.3.6 Information management

Information management consists of any **paper-based and/or electronic systems** for recording, storing and retrieving information including records and documents, raw data or emails and text messages that provide testing results or reminders to clients. It is closely linked to documentation and record-keeping.

All testing personnel must work to minimize the risk of transcription errors. Assigning patient/client identification numbers at the level of the health system, and then specimen identification numbers to each subsequent specimen received from the same individual reduces the possibility of mix-ups and errors. It will also protect the confidentiality of people undergoing HIV testing. Linking a series of HIV test results also is needed when retesting to validate HIV-positive diagnosis and for clients with HIV-inconclusive results.

Automated electronic RDT readers that can accommodate one or multiple brands of RDTs are increasingly available and may be useful for providing data for programme management or for planning procurement.

How to implement

- Each client should be assigned a **unique patient identifier code** so that the results of each of that client's subsequent specimens can be tracked.
- Each specimen should be assigned a unique **specimen identifying number**.

9.3.7 Documents and records

Documentation is critical to ensure that the HIV status report goes to the correct person and can be traced back if there are any subsequent questions. Documents are policy, process and procedural records of all aspects of the testing service and its quality management system. These documents should be approved before use, revised when necessary, reviewed at least annually and removed from circulation when obsolete.

Job aids guide test providers' actions and remind them, step-by-step, of a test procedure, how to interpret test results and how to assign HIV status according to the testing strategy. Annex J presents an example of a generic job aid for an HIV RDT. National programmes should assist testing sites in developing site-specific standard operating procedures and job aids for use by testing providers. These help to improve the quality of the report of HIV status given to individuals.

Records are generated from all activities, information or results from performing testing including QC/EQA results, maintenance records, run worksheets, stock inventory records, corrective actions or test result reports. It is critical that these are filled in correctly and securely stored for up to five years. Records must be secured, maintained, and readily retrievable for use when needed for retesting referrals to rule HIV infection in or out and for community-based testing services where results may be verified elsewhere.

The types of records required for a quality system are:

- patient-specific records

- specimen request forms
- laboratory logbook/testing register;[3] the register identifies the individual undergoing testing (patient/client ID, name [optional], date of birth [optional]); the assays used, with lot numbers and expiry dates; the test results for each assay; date of testing; name of operator; and QC results.
- report of HIV status as given to the individual
- copies of referral slip for retesting or other post-test services including prevention services

- site-specific records
  - standard operating procedures
  - quality manual
  - staff training records and other personnel records
  - internal and external audit reports
  - non-conformance and complaint records as well as QC/EQA results, with action taken
  - equipment maintenance records, temperature records, and inventory charts.

How to implement

- Ensure that standard operating procedures exist for all procedures, including specimen collection and processing, testing algorithms and all test procedures, with QC and final reporting (in accordance with a verified testing algorithm).
- Keep equipment maintenance records and temperature records for refrigerators, freezers and the testing room.
- Keep laboratory logbooks/testing registers and forms used to record testing results.

9.3.8 Occurrence management

Occurrence management refers to processes for detecting and documenting non-conformances and then implementing any necessary corrections. A **non-conformance is something that went wrong:** A problem has occurred and needs to be addressed. A non-conformance might be a lack of documented processes/procedures or when documented processes/procedures were not followed.

The following sources of data may be used to check for non-conformances:

- internal audit reports
- supervisory visit reports
- data quality audits
- QC data, including higher than expected rates of invalid results
- results of EQA schemes/proficiency testing

3 For an example of a standardized laboratory logbook/testing register, see *Improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results* (https://www.who.int/hiv/pub/toolkits/handbook-point-of-care-testing/en/).

- a higher than expected rate of discrepant test results for clients returning for retesting (>5%).

How to implement

- Establish a system to continually monitor and detect quality issues or product problems and then to identify the root cause and implement corrective and preventive action.
- See that a complaint form for product issues is in place.
- To identify non-conformance, routinely monitor indicators such as turnaround times for each assay, turnaround time for an overall testing report, rate of discrepant results, rate of invalid results, rate of specimen rejection, rate of test kit stock-outs, rate of supplies stock-outs and frequency of expiration of test kits.

9.3.9 Assessment

Testing services should undertake both internal and external assessments to assure quality. Internal assessment usually takes the form of an **internal audit**, by either a site supervisor or a district health management team that observes testing practices at least annually but preferably every three to six months. For certain tasks an internal audit may be performed by another staff member who does not usually perform the task but is familiar enough with the process to conduct an audit. This is closely related to quality activities such as supportive supervision and ongoing staff mentoring. Assessment in the form of observation of testing procedures is useful to prioritize areas for improvement.

Testing services should participate in EQA where it is made available, as it gives clients confidence that assays are performed accurately, results are reproducible, and errors are detected and corrected. EQA usually takes the form of participation in **EQA schemes** (also called proficiency testing), which should include the follow-up of unacceptable EQA results with appropriate corrective actions.

Retesting is recommended for all individuals newly diagnosed as HIV-positive; retesting should be performed before ART initiation. See Chapter 8 for additional details on how to conduct retesting.

Box 9.6. Use of dried blood spot specimens for EQA not recommended

Rechecking using dried blood spot (DBS) specimens as an EQA mechanism is no longer recommended, especially given the recommendation to retest all seropositive individuals prior to starting ART.

Another form of external assessment is **accreditation** of testing sites (may be referred to as registration or certification) by an external certification body (see section 9.2.6).

How to implement

- All individuals newly diagnosed as HIV-positive should be **retested** before ART initiation.
- All testing sites (facility- and community-based) should participate in **EQA schemes**.
- All testing sites should receive support through **on-site supervision**.
- All testing sites should be **accredited according to national guidelines**.

9.3.10 Process improvement

Testing services need to identify areas requiring improvement, plan and undertake improvements and evaluate their effect. Depending on the improvement suggested, programmes can improve processes at the site level or at the district or national level. Local factors, which may not be predicted at the national level, may define site-level improvements such as changes to opening hours or changes in client flow. Programmes may use data from internal audits, participation in EQA schemes and on-site supportive supervision to improve testing processes.

A **corrective action** is an action taken to address a problem, removing its root cause or reducing or eliminating its recurrence. A **preventive action** is an action taken to avoid a possible problem or reduce the likelihood that it will happen again, usually referring to the issue that was the subject of the correction. Data from QC and EQA activities and process control can guide corrective and preventive actions in the framework process of continual process improvement.

Process management links closely with activities associated with occurrence management.

How to implement

- Site supervisors should **proactively identify opportunities** for improvement and relay these ideas to a higher level of management for broader implementation.

9.3.11 Customer/client service

Programmes need to ensure that clients are satisfied with the testing service. This includes both so-called internal clients, such as doctors, nurses, counsellors and other health-care workers, and external clients, including people undergoing testing, civil society and regulatory agencies. Ensuring client satisfaction means meeting their expectations of quality, and most importantly, delivering **accurate results in a timely manner**.

Health workforce development should address diversity of staff to meet the needs and expectations of the client. Key populations may have specific needs and may respond more positively to services that are delivered in a non-discriminatory or non-stigmatizing manner. Training and sensitization of the health workforce may help to improve inclusion and attitudes towards key populations. Privacy within the testing facility and in record-keeping is critical.

How to implement

- Seek feedback from clients through, for example, periodic exit interviews. Feedback may focus on aspects such as flexibility of opening hours, friendliness of the testing environment and satisfaction with post-test counselling.
- Establish a client suggestion box for anonymous reporting, including complaints and encouragement.

9.3.12 Facilities and safety

It is important that testing facilities are well-designed and maintained. The testing site, including where counselling takes place, where specimens are taken and where the test is performed, should be clean and comfortable with adequate lighting (for visually read assays) and free of potential hazards.

It is imperative to follow the assay manufacturer's recommendation for the ambient temperature of testing areas. Where possible, testing should take place in climate-controlled areas. Also, there must be proper **waste disposal** for biological (infectious and non-infectious), chemical and paper waste and sharps. Water (running or otherwise) and good ventilation must be available to deal with any injuries and for reducing transmission of airborne infections such as tuberculosis.

Facilities must be organized to protect the **confidentiality of clients**, including a separate waiting room for those requiring additional testing. How long an individual client stays in the same waiting room, or how often an individual leaves and returns, may imply a certain test result.

It is critical to guard against harm to any client, HIV testing provider or other person at the testing site. This means that all staff must contribute to maintaining a **safe working environment**, with necessary procedures in place. These procedures include universal precautions (that is, working under the assumption that all specimens are potentially infectious), prevention of and/or response to needle-stick injuries and other occupational exposures, chemical and biological safety, spill containment, waste disposal and use of personal protective equipment.

For HIV testing that takes place outside of a facility, programmes must ensure that providers can conduct the testing without hazard to themselves or to the client. Providers must observe universal precautions and appropriate waste disposal procedures. In addition, providers must make all efforts to protect clients' confidentiality and privacy.

How to implement

- All staff should be trained in biological and chemical safety measures.
- One staff member at each testing site should act as a safety focal point.

9.4 Quality improvement for HIV testing

Quality assurance is not a once-and-done occurrence. Providers and managers of testing must continually monitor and evaluate their programme and improve the quality of services. To maintain a coherent, functioning quality management system that addresses national, subnational, facility and community concerns, all stakeholders must be involved at every level to monitor quality and make improvements. Middle- and low-income countries have applied a range of quality improvement methods in health-care over the past two decades. Deciding which method to use for HTS will depend on the country context, the commitment of policy-makers and programme managers, and the complexity of the problems that need to be addressed.

WHO supports the implementation of high-quality HIV services and provides guidance for selecting measures of high-quality services. Case examples of quality management in HIV services in low- and middle-income countries are cited in the WHO technical brief *Maintaining and improving quality of care within HIV clinical services (19)*.

Box 9.7. Further reading on quality assurance relevant for HIV testing services

- **Laboratory quality management system: handbook**. Geneva: World Health Organization; 2011 (http://www.who.int/ihr/publications/lqms/en/).
- **Laboratory Quality Stepwise Implementation tool**. Geneva: World Health Organization; 2011 (https://www.who.int/ihr/lyon/hls_lqsi/en/).
- **Improving the quality of HIV-related point-of-care testing**: ensuring the reliability and accuracy of test results. Geneva: World Health Organization; 2015. (https://www.who.int/hiv/pub/toolkits/handbook-point-of-care-testing/en/).
- **Handbook for improving HIV testing and counselling services**. Geneva: World Health Organization; 2010 (http://www.who.int/hiv/pub/vct/9789241500463/en/).
- **Guidance for Development of National Laboratory Strategic Plans**. Brazzaville: World Health Organization Regional Office for Africa, US Centers for Disease Control and Prevention, Association of Public Health Laboratories (https://www.finddx.org/wp-content/uploads/2016/03/WHO-CDC-APHL-2010_Guidance-for-Development-of-National-Lab-Strategic-Plans.pdf)
- **Guidance for procurement of in vitro diagnostics and related laboratory items and equipment**. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/255577/9789241512558-eng.pdf)
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GLOSSARY

Acute infection: the period between when an individual becomes infected with HIV and when HIV antibodies can be detected by a serological assay.

Assay (synonym of test kit): in the case of HIV, all the components of a test kit used to identify HIV p24 antigen or HIV-1/2 antibodies.

Analyte: a substance or chemical constituent that is analysed, generally referring to a component of blood or another bodily fluid. In the context of HIV, analytes include HIV p24 antigen and HIV-1/2 antibodies.

Biological surveillance: the collection and use of biological markers to inform surveillance – in this context HIV surveillance systems. This term is replacing the term "serosurveillance" because biological specimens other than serum are increasingly being collected routinely.

Concentrated epidemic: when HIV has spread rapidly in a defined subpopulation (such as men who have sex with men, sex workers, transgender people, people who inject drugs or people in prison or other closed settings) but is not well established in the general population. This type of epidemic suggests that there are active networks of people with high-risk behaviours within the subpopulation. The course of such an epidemic is determined by the extent and nature of the links between subpopulations with a high HIV prevalence and the general population. Numerical proxy: HIV prevalence is consistently over 5% in at least one defined subpopulation but is below 1% in pregnant women attending antenatal clinics.

Confirm: to confirm an initially reactive result, including reactive self-test results, with one or more other assays.

Confirmatory testing: use of any assay that definitively confirms the status either as HIV-positive or HIV-negative. Sometimes supplemental testing is referred to incorrectly as confirmatory testing. There are very few HIV assays that can definitively rule out HIV infection (HIV-negative).

Cross-reactivity: certain false reactivity is due specifically to another pathogen that may have similar properties. For example, cross-reactivity between HIV-1 and HIV-2.

Directly assisted HIV self-testing: when individuals who are self-testing for HIV receive an in-person demonstration from a trained provider or peer before or during HIVST, with instructions on how to perform the self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer-supplied instructions for use and other materials found inside HIVST kits.

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 (provincial, regional, district, subdistrict, primary health-care post and community).

Discrepant test results: when the test results for two or more assays do not agree. For example, Assay 1 is reactive, but Assay 2 is non-reactive.

Early infant diagnosis: testing of infants to determine their HIV status, given that HIV can be acquired in utero (during pregnancy), peripartum (during delivery), postpartum (through breastfeeding) or via parenteral exposure.

Eclipse period: the period between HIV infection and detection of virological markers such as HIV RNA/DNA or HIV p24 antigen.

Enhanced patient referral: when a trained provider uses various support tools to facilitate disclosure and the offer of HTS by HIV-positive clients to their partner(s). These tools may include written information, leaflets and a referral slip or card for the partner(s), use of web-based messaging platforms to inform the partner(s) anonymously, as well as providing HIVST kits to HIV-positive clients to give to their partner(s) to test themselves for HIV. Also see **partner services**.

External quality assessment: inter-laboratory comparison to determine if the HIV testing service can provide correct test results and diagnosis.

False reactivity: the inability for a specimen that was initially reactive to be confirmed when the same specimen is repeated on the same or another assay.

Generalized epidemic: when HIV is firmly established in the general population. Although subpopulations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain the epidemic. Numerical proxy: HIV prevalence is consistently over 1% in pregnant women attending antenatal clinics.

Harm, or social harm: any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt by one person to another, a person to themselves or an institution to a person, occurring before, during or after testing for HIV.

HIV positivity: the percentage of people testing for HIV whose status is determined to be HIV-positive. HIV positivity suggests that HTS are efficiently focussed.

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.

HIV-inconclusive status: when the testing strategy cannot provide a positive or negative HIV-status. This is different from discrepant test results.

HIV testing services: is a term that embraces not only HIV testing itself but also the full range of services that should be provided together with HIV testing, which includes counselling (brief pre-test information and post-test counselling); linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.

HIV status: the final report that is given to the patient; it is the final interpretation of the patient disease state and is based on a collection of testing results generated from one or more assays. HIV status may be reported as HIV-positive, HIV-negative or **HIV-inconclusive**.

HIV test result: the result of a single test on a given assay.

Hotspot: a small area, within a bigger geographic designation, where there is high HIV prevalence or incidence.

Immunoassay: any method for detecting a substance, or antigen, using an antibody that is reactive to it.

Index testing (often also referred to as index case, index patient or index partner HIV testing): a focused HTS approach in which the household, family members (including children) and partners of people diagnosed with HIV are offered HTS. For details, see **provider-assisted referral** and **partner services**.

Indicator condition-guided HIV testing: a focused approach to test people more likely to be infected with HIV who are identified through indicator conditions, such as lymphoma, cervical or anal neoplasia and herpes zoster. These conditions occur more frequently in HIV-infected people than in uninfected people, either because they share a common mode of transmission with HIV or because their occurrence is facilitated by the characteristic immune deficiency associated with HIV infection.

Integration: the co-location and sharing of services and resources across different health service delivery areas. In the context of HIV, this may include the provision of HIV testing, prevention, treatment and care services alongside other health services, such as those focused on tuberculosis (TB), sexually transmitted infections (STIs) or hepatitis B/C, antenatal care (ANC), contraception and other family planning services and screening and care for other conditions, including non-communicable diseases.

In vitro diagnostic medical device (IVD): a medical device, used alone or in combination, intended by the manufacturer for the examination of specimens derived from the human body solely, or principally, to provide information for diagnosis, monitoring or determining compatibility. IVDs include reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status.

Intimate partner violence: behaviour by one person in an intimate relationship that causes physical, psychological or sexual harm to another person in the relationship, including acts of physical violence, sexual violence, emotional or psychological abuse and controlling behaviours.

Key populations: defined groups that, due to specific higher risk behaviours, are at increased risk of HIV irrespective of the epidemic type or local context. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people.

Lay provider: any person who performs functions related to health-care delivery and has been trained to deliver these services but has no formal professional or para-professional certification or tertiary education degree.

Multi-analyte testing: the use of the same platform to test for different analytes with different sets of reagents, typically using more than one specimen. Similar to multiplex testing.

Multiplex testing: testing a single specimen for more than one analyte with one test device – for example, a single test device that detects HIV-1/2 antibodies and antibodies to Treponema pallidum (syphilis).

Negative predictive value: the probability that a person with a negative test result is not infected with HIV, that is, that he or she is truly negative.

Non-reactive test result: a test result that does not show a reaction indicating the presence of analyte, which in the context of HIV refers to HIV-1 p24 antigen or HIV-1/2 antibodies.

Nucleic acid testing (also referred to as molecular technology, for example, polymerase chain reaction (PCR) or nucleic acid sequence-based amplification (NASBA)): This type of testing can detect very small quantities of viral nucleic acid, that is, RNA, DNA or TNA, qualitatively and quantitatively.

Partner services (sometimes referred to as disclosure, contact tracing, index testing or 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(s) HTS. Partner services are provided using **provider-assisted referral** or **patient referral** approaches.

Patient referral: a partner services approach in which HIV-positive clients are encouraged by a trained provider to disclose their status to their sexual and/or drug injecting partners by themselves, and to also suggest HTS to the partner(s), given their potential exposure to HIV infection.

Policy: an institutional statement to guide the action of an institution or a sector in a particular domain.

Positive predictive value: the probability that a person with a positive test result is infected with HIV, that is, that he or she is truly HIV-positive.

Pre-test information: a concise dialogue that provides accurate information to a client, often delivered by a lay provider or a health worker before an HIV test is performed.

Provider-assisted delayed referral (sometimes called contract referral): when an HIV-positive client enters into an agreement with a trained provider to disclose his or her HIV status to sexual and/or drug injecting partners by themselves and to suggest HTS to them *within an agreed time period*. If the partner(s) of the HIV-positive client do not access HIV testing or contact the health-care provider within that period, then the provider will contact the partner(s) directly and offer voluntary HTS.

Provider-assisted referral (previously called assisted partner notification or index testing): when a trained provider assists consenting HIV-positive clients to share their status or to anonymously inform their sexual and/or drug injecting partner(s) of their potential exposure to HIV. The provider then offers voluntary HIV testing to these partners. The provider can contact partners by telephone, e-mail or in-person and offer home-based HTS or invite them to visit a facility.

Provider–patient referral: when a trained provider accompanies and provides support to HIV-positive clients when they disclose their status and the potential exposure to HIV to the client's partner(s). The provider then offers voluntary HTS to the partner(s).

Quality assurance: part of quality management focused on providing confidence among stakeholders that quality requirements will be met.

Quality control (QC): QC verifies that the product meets quality requirements. It is a mechanism to identify product defects and to formally reject a defective product.

Quality improvement (QI): QI is the process of proposing solutions to improve quality and reliability and thus increase customer/user satisfaction. The plan/do/check/act cycle is helpful in this regard.

Quality management system: a system to direct and control an organization with regard to quality. Systematic and process-oriented efforts are essential to meet quality objectives.

Rapid diagnostic test: an in vitro diagnostic medical device of immunochromatographic or immunofiltration format for the detection of HIV-1/2 antibodies and/or HIV p24-1 antigen in the context of HIV.

Reactive test result: a test result that shows a reaction indicating the presence of analyte – in the context of HIV, HIV-1 p24 antigen or HIV-1/2 antibodies.

Repeat testing: a situation in which additional testing is performed for an individual immediately following a first test and during the same testing visit, due to HIV-inconclusive status or discrepant test results. The same assay(s) is used and, where possible, the same specimen.

Retesting: when a second specimen from the same individual is tested again following the same testing algorithm as a quality assurance step. It is not contemporaneous.

Sensitivity: denotes the probability that an HIV assay/algorithm will correctly identify all specimens that contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

Analytical sensitivity: the smallest amount of the analyte (antibodies and/or antigen) that an assay can accurately detect, including detection of different subtypes such as HIV-1 group O.

Diagnostic sensitivity: the percentage of HIV-infected individuals who are identified as HIV-positive by the assay (or testing algorithm).

Seroconversion sensitivity: the ability of any assay to detect HIV infection as the individual undergoes seroconversion, that is, as the HIV-1/2 antibodies increase and evolve from IgM to IgG.

Sentinel surveillance: a type of surveillance that is conducted at selected sites among populations of particular interest or that may provide approximations of prevalence for a larger population, for example, in antenatal clinics.

Seroconversion: when an individual's immune system produces a quantity of HIV-1/2 antibodies sufficient to be detectable on a given HIV serology assay.

Serodiscordant couple: a couple in which one partner is HIV-positive and one partner is HIV-negative.

Serology assay: an assay that detects the presence of antibodies in human specimens. Such assays typically use serum or plasma but also capillary/venous whole blood or oral fluid. For example, **rapid diagnostic tests**, immunoassays and certain supplemental assays are serology assays.

Social network-based HIV testing: 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 HTS. 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.

Specificity: the probability that the assay/algorithm will correctly identify specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

Analytical specificity: the ability of an assay to identify the relevant analyte as distinct from others and, thus, to rule out false reactivity. An understanding of false reactivity, and specifically cross-reactivity, is critical to developing accurate testing algorithms.

"Diagnostic specificity": the percentage of HIV-uninfected individuals who are identified as HIV-negative by the assay (or testing algorithm).

Strategic plan: a document or intended set of actions that translates a policy into planned activities with strategic objectives, generally valid for one year in relation to a budget cycle.

Supplemental testing: further testing with an additional assay or set of assays to obtain more information to help ascertain HIV status.

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

Test for triage: when a trained and well-supported testing provider (possibly a lay provider or community health-care worker) conducts a single HIV RDT, rather than the entire testing algorithm, and those with HIV-reactive result are referred to a health facility for additional testing to confirm HIV-status.

Testing algorithm: when specific products are populated into a testing strategy. A specific product is defined with a product name, product code(s), a manufacturing site and regulatory version. The testing algorithm is likely to change depending on which specific products are verified for use together and are procured.

Testing strategy: a sequence of tests conducted on assays to achieve a specific objective, such as screening for infection or diagnosing infection.

Throughput: the number of specimens per hour per operator that can be tested by an assay; the volume of clients that come through a facility, laboratory or community-based settings.

Unassisted HIV self-testing: when individuals self-test for HIV using only a self-test kit that includes manufacturer-provided instructions for use. As with all self-testing, users may be provided with links or contact details to access additional support, such as telephone hotlines or instructional videos.

Verification: confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Window period: the period between HIV infection and the detection of HIV-1/2 antibodies using serology assays, which marks the end of **seroconversion**.

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