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Contents

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Abbreviations

5 Cs	Consent, Confidentiality, Counselling, provision of Correct test results, and Connection (linkage to prevention, care and treatment services)
AHI	acute HIV infection
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral drug
CAB-LA	long-acting cabotegravir
CDC	Centers for Disease Control and Prevention
DBS	dried blood spot
DSD	differentiated service delivery
DVR	dapivirine vaginal ring
EDL	essential in vitro diagnostics list
EID	early infant diagnosis
EMTCT	elimination of mother-to-child transmission of HIV
EPT	expedited partner therapy
ERG	external review group
EQA	external quality assessment
FB-HIVST	facility-based HIVST
FSCA	field safety corrective action
GAM	UNAIDS Global AIDS Monitoring
GDG	Guideline Development Group
GMRF	Global Model Regulatory Framework
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HCVST	hepatitis C virus self-test
HHS	WHO Department of Global HIV, Hepatitis and STI Programmes
HIVST	HIV self-test
HIV-SST	dual HIV/syphilis self-test
HPV	human papillomavirus
HTS	HIV testing services
IA	immunoassay
IAS	International AIDS Society
IFU	instructions for use
ILO	International Labour Organization
IVD	in vitro diagnostic medical device
LGBTQI	lesbian, gay, bisexual, trans and gender diverse, questioning or intersex
M&E	monitoring and evaluation
MCH	maternal and child health
NAT	nucleic acid testing
NGO	nongovernmental organization
NPV	negative predictive value
NRA	national regulatory authority
PEP	post-exposure prophylaxis
PEPFAR	US President's Emergency Plan for AIDS Relief
PICO	Population, Intervention, Comparator, Outcome
PITC	provider-initiated testing and counselling
PMTCT	prevention of mother-to-child transmission (of HIV)
POC	point of care
PPV	positive predictive value
PrEP	pre-exposure prophylaxis
PT	proficiency testing

QA	quality assurance
QC	quality control
QI	quality improvement
QMS	quality management system(s)
RCT	randomized controlled trial
RDT	rapid diagnostic test
RITA	recent infection testing algorithm
RMNCH	reproductive, maternal, newborn and child health
RTCQI	(HIV) Rapid Test Continuous Quality Improvement
SEAD	Strategic Evaluation Advisory & Development Consulting (Pty) Ltd.
SG	steering group
SMS	short messaging service
SOP	standard operating procedure
SPI-RT	Stepwise Process for Improving the Quality of HIV Rapid Testing
SRH	sexual and reproductive health
SST	syphilis self-test
STI	sexually transmitted infection
TAP	treatment-adjusted prevalence
TB	tuberculosis
TP	treponemal
U=U	Undetectable = Untransmittable
UHC	universal health coverage
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
VCT	voluntary counselling and testing
VL	viral load
VMMC	voluntary medical male circumcision
WHO	World Health Organization

Executive summary

Purpose

These consolidated guidelines on differentiated HIV testing services (HTS) bring together existing and new guidance on testing 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 global HIV targets. Since then, in support of ongoing efforts to achieve the global 95-95-95 targets, guideline updates have added new evidence-based approaches for HTS.

In this guideline WHO features updated recommendations on networking-based testing services, self-testing and a new recommendation against HIV recency testing in routine HTS (see Box 1). This guideline seeks to support 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, post-test services and linkage; service delivery approaches; implementation considerations for priority populations; considerations for optimizing implementation; testing strategies for diagnosis; and considerations for ensuring quality.

Box 1. Summary of new and updated recommendations

Self-testing

NEW: HIV self-testing may be offered as an additional option for testing at facilities *(conditional recommendation, low-certainty evidence).*

NEW: HIV self-testing may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation *(conditional recommendation, low-certainty evidence).*

NEW: Syphilis self-testing is suggested as an additional approach to syphilis testing services *(conditional recommendation, low-certainty evidence).*

Network-based testing services

NEW: STI partner services should be offered to people with STIs as part of a range of options based on their needs and preferences and within a comprehensive package of voluntary STI testing, care and prevention *(strong recommendation, low-certainty evidence).*

UPDATED: Social network testing services may be offered as an additional HIV testing approach as part of a comprehensive package of care and prevention *(conditional recommendation, low-certainty evidence).*

HIV testing strategies

NEW: HIV recency testing is not recommended as part of routine HIV testing services *(conditional recommendation, low-certainty evidence).*

These guidelines discuss HTS implementation, including when integrated with other areas, for the following groups:

- key populations
- general population
- men
- pregnant and postpartum women
- infants and children
- couples and partners
- adolescents (10–19 years old) and young people (15–24 years old)
- other vulnerable populations.

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.

Key messages on HIV testing services

Cross-cutting messages

- Virtual interventions have improved access to HIV testing, treatment and prevention services and should be implemented in all settings as feasible, particularly using online distribution of self-test kits, telehealth consultations and counselling, and outreach through social media platforms or through social influencers.
- It is critical that pre-test, post-test and ongoing treatment and prevention services be used as opportunities to explain the benefits of early ART, emphasizing that "undetectable=untransmittable" (U=U); U=U means that people with HIV who have an undetectable viral load and continue taking medication as prescribed have zero risk of transmitting HIV to their sexual partner(s).
- Confidentiality is essential, particularly when offering testing as part of network-based testing services and virtual service delivery, especially in terms of security of data and devices used by providers.

Chapter 3. Mobilizing demand and implementing effective pre-test services, information and messaging

- Demand creation needs to focus on those most likely to benefit, thus promoting efficient and effective HTS and avoiding further increases in cost per person diagnosed with HIV.
- Pre-test counselling is often not needed or recommended. Instead, information about testing and linkage, including its benefits for those seeking treatment, can and should be provided in many other ways, including through virtual platforms.

Chapter 4. Post-test services and linkage

- Post-test services must include linkage to treatment (including "welcoming back" services for people who have dropped out of care) and appropriate prevention options for those testing HIV-negative, including post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP).
- Post-test counselling messages need to be tailored to specific populations and their situations.

- For those testing HIV-positive, messages should focus on achieving viral suppression with ART, including messages about the prevention benefits of being on ART (U=U), and network-based testing services.
- For those testing HIV-negative, post-test services should focus on identifying those at ongoing risk to link them to appropriate prevention services.
- The package of post-test services should be comprehensive, with tools to facilitate linkage to treatment, prevention and other relevant services. Post-test counselling alone does not improve linkage or lead to sustained behaviour change.

Chapter 5. HTS service delivery approaches

- Network-based testing approaches comprise a range of service delivery modalities that broaden the reach of testing services by supporting individuals to disclose to, refer for testing, and/or distribute self-tests to partners, families, and other members of their social networks. Such testing strategies may involve people with HIV, TB, STIs and/or viral hepatitis, as well as testing for their sexual and/or injecting partners, family members including children and other people in the home, and social contacts. Integration across conditions should be considered based on epidemiology and feasibility.
- Self-testing is empowering, acceptable and a low-cost way of increasing access to testing for people who have not tested before or who could benefit from regular opportunities to test. Self-testing is an important tool for supporting PEP and PrEP delivery. It can be delivered in health facilities and communities, offered to partners and social contacts and made available through virtual platforms. It can be also performed with HIV/syphilis dual self-tests as well.

Chapter 6. Priority populations

- Different testing approaches are available for different populations. Men and key populations are often less likely to access testing, and critical gaps for testing children, adolescents and pregnant women remain. Chapter 6 provides detailed information on how to reach and deliver acceptable and effective HTS for a range of priority populations.

Chapter 7. Strategic planning

- HTS should prioritize reaching the largest number of people with HIV who remain undiagnosed and reaching population groups with substantial risk who may benefit from prevention options such as PrEP, PEP, harm reduction or voluntary medical male circumcision (VMMC).
- HTS can be optimized through situational analysis that identifies areas of existing HTS that require modification, for example, by highlighting gaps in service delivery for specific populations and geographies.
- HTS can be optimized by prioritizing certain HTS approaches based on local epidemiology and focusing testing on specific health services, priority populations and geographic settings.

Chapter 8. Selecting diagnostics

- Programmes should provide affordable and accurate HTS, adhere to the recommended serial three-test HIV testing strategy, provide retesting before ART initiation and use appropriately selected products to achieve an overall positive predictive value (PPV) of 99% or higher.
- When results are inconclusive, retesting after two weeks is recommended.
- Dual HIV/syphilis rapid diagnostic tests (RDTs) and self-tests can be used. They are most relevant for key populations and pregnant women and their male partners.
- HIV recency testing is not recommended as part of routine HIV testing services.

Chapter 9. Quality assurance

- Quality management systems are essential for any form of HTS, including for RDTs performed by lay providers and HIVST programmes. Ensuring the quality of HTS is critical to prevent misdiagnosis, which has serious consequences for individuals and public health.
- All HIV tests must meet regulatory standards according to national legal provisions and must be quality-assured and appropriate for their intended setting of use. WHO conducts independent prequalification assessment of HIV RDTs, including dual HIV/syphilis tests and self-tests, to support procurers', manufacturers', providers' and clients' access to quality-assured products.

Guideline development methodology

In response to the changing needs of Member States and the availability of new evidence, the WHO Department of Global HIV, Hepatitis and STIs (HHS) Programmes updated existing HTS guidance. The process involved a WHO Guideline Steering Group (SG), an independent Guideline Development Group (GDG) of regionally representative external experts, consisting of academics, researchers, programme managers, implementers and representatives of community networks and organizations and an external peer review group (ERG).

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 HHS Programmes 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.

Based on the evidence reviewed and presented, the GDG made new recommendations: 1) for expanded use of self-testing to support PrEP and within facility-based services and 2) against routine HIV recency testing in HIV testing services. The GDG also updated recommendations on network-based testing services and offered guidance and considerations on caregivers testing children. Related WHO testing guidance was also integrated where deemed necessary as part of integrated service delivery priorities, including syphilis self-testing and STI partner services. At the end of this process, the ERG, UN agency reviewers and WHO HHS staff, other WHO departments and WHO regional offices reviewed and provided further input into these guidelines.

About the recommendations

The new recommendations are in line with, and build on, existing WHO recommendations. They emphasize the importance of expanded access to self-testing and network-based testing services.

Implications for programming

Closing the HIV testing gap and diagnosing 95% of all people with HIV and linking them to treatment and care is critical to the success of the global HIV response. Reducing HIV infections by 90% will also take increased testing and linkage to prevention services among those with high ongoing risk.

These guidelines seek to support countries to provide a strategic mix of HTS options that reach people with HIV who do not know their status and people at high risk who need HIV prevention interventions, including HTS.

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.

These guidelines highlight the need to promote integrated testing services across conditions and the utilization of tools such as the dual HIV/syphilis RDTs and self-tests. They continue to emphasize the importance of providing quality HTS with a focus on quality assurance (QA)/quality improvement (QI) initiatives, using the WHO three-test strategy and retesting all people before ART initiation to avoid misdiagnoses, which have serious individual and public health consequences.

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 5 Cs 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 and to involve communities in designing, delivering and monitoring HTS to make sure services are safe, acceptable, effective and equitable.

Table 1 summarizes all current WHO guidance on HTS.

Table 1. Summary of WHO recommendations, good practice statements and updated guidance on HIV testing services

Approach and references	Recommendations and good practice statements
Mobilization and pre-test services	
Demand creation for HIV testing services WHO (2019). Consolidated guidelines on HIV testing services.	**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, face-to-face or virtual) • 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 • 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 incentives 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, reduce barriers and disincentives, such as patient costs associated with accessing health services more broadly.

Approach and references	Recommendations and good practice statements
Service delivery approaches	
Facility-based HTS WHO (2019). Consolidated guidelines on HIV testing services.	**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.
Community-based HTS WHO (2019). Consolidated guidelines on HIV testing services.	**High HIV burden settings** WHO recommends community-based HIV testing services, with linkage to prevention, care and treatment services, particularly for key populations, in addition to routinely offering facility-based testing *(strong recommendation, low-certainty evidence)*. **Low HIV burden settings** WHO recommends community-based HIV testing services, with linkage to prevention, care and treatment, for key populations in addition to facility-based testing *(strong recommendation, low-certainty evidence)*.
Self-testing WHO (2024). Consolidated guidelines on differentiated HIV testing services. WHO (2024). Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services WHO (2021). Recommendations and guidance on hepatitis C virus self-testing WHO (2019). Consolidated guidelines on HIV testing services	**NEW recommendation:** Syphilis self-testing (SST) is suggested as an additional approach to syphilis testing services *(conditional recommendation, low-certainty evidence)*. • **Integration:** SST, as with all testing approaches, should be offered within a broader programme and package of services, which includes ensuring access and linkage to further testing (where available) and immediate treatment initiation. Opportunities to integrate SST into and/or to expand existing services should be a priority. • **Quality-assured products:** SST may include products such as dual HIV/syphilis self-tests, treponemal self-tests and dual treponemal/non-treponemal self-tests. As with all testing approaches, SST should be conducted using quality-assured products. • **Epidemiology and context:** Policymakers and implementers need to have a clear understanding that SST can be reactive with any current or prior infection by any treponematosis (e.g., syphilis, yaws, bejel or pinta) when determining how and where to deliver self-testing to specific populations and in certain geographies. • **Clear messages:** Self-testers need to be provided with clear guidance about when they should test themselves, how to interpret their self-test results and, if needed, where to go for further testing and treatment. These further services are particularly critical when single treponemal self-tests are used that cannot differentiate previously treated infections from current infections. In endemic areas, it is critical to clarify that reactive serologic tests cannot differentiate between syphilis and other treponematosis (e.g., yaws). Self-testers may also need support tools to ensure they know how to self-test, and this can include instructions for use, videos, in-person demonstrations and support from peers or community health workers. Information about testing with a partner should also be provided, when appropriate, to encourage use of partner services. Self-testing for hepatitis C virus (HCVST) should be offered as an approach to HIV testing services *(strong recommendation, moderate-certainty evidence)*. HIVST should be offered as an approach to HIV testing services *(strong recommendation, moderate-certainty evidence)*.

Approach and references	Recommendations and good practice statements
Self-testing (cont.)	**NEW recommendation:** HIVST may be offered as an additional option for testing at facilities *(conditional recommendation, low-certainty evidence)*. • HIVST does not replace provider-administered testing. Individuals with a reactive self-test result should receive further testing from a trained provider using the full national testing algorithm. • HIVST can replace risk screening tools* to optimize testing among those presenting at health facilities. **NEW recommendation:** HIVST may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation *(conditional recommendation, low-certainty evidence)*. • HIVST may be an important tool to reach underserved populations with PrEP. • HIVST is an option to support PrEP delivery; its use should be driven by client needs and preferences. • There is a range of PrEP options available for which HIVST use could be considered, including oral PrEP and the dapivirine vaginal ring (DVR). HIVST can also be considered as part of post-exposure prophylaxis (PEP) implementation. Further research is needed on the role of HIVST in the use of long-acting injectable prevention options, such as cabotegravir (CAB-LA). * Risk-screening tools, provider- or self-administered, typically comprise questions designed to identify individuals with elevated HIV risk factors, such as their practices, symptoms or other characteristics. Tools are generally used to prompt testing among those who would otherwise not be offered testing (screening in) or to stop testing people who would otherwise be offered testing (screening out). WHO does not recommend the use of screening-out tools.
Network-based testing services WHO (2024). Consolidated guidelines on differentiated HIV testing services. WHO (2024). Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services. WHO (2019). Consolidated guidelines on HIV testing services.	**UPDATED recommendation:** Network-based testing is recommended including the use of social network testing *(conditional recommendation, low-certainty evidence)*, family and household testing services and partner services *(strong recommendation, moderate-certainty evidence)*. **NEW recommendation:** STI partner services should be offered to people with STIs as part of a range of options based on their needs and preferences and within a comprehensive package of voluntary STI testing, care and prevention *(strong recommendation, low-certainty evidence)*. • **Human rights:** STI partner services must always be voluntary and never mandatory. Coercive or forced testing is never warranted. All consenting patients should have their privacy protected and personal information should be kept confidential. • **Important to offer options:** There are a range of STI partner services that should be offered based on patient preferences, feasibility and resources available. Partner services include several options, such as patient referral, enhanced patient referral, delayed provider referral, provider-patient referral, and provider-assisted referral and social network approaches. Approaches with provider support are particularly effective and can be prioritized or encouraged where feasible. Expedited partner therapy (EPT) could also be considered as part of partner services for some curable STIs, such as chlamydia or gonorrhoea. • **Linkage:** Linkage to STI management services for sexual partners is an essential component of STI services. • **Integration:** STI partner services should be based within a broader programme and package of services. It is important to build on existing services (e.g., sexual and reproductive health services and family planning services), and integrated delivery across disease areas (e.g., HIV and viral hepatitis).

Approach and references	Recommendations and good practice statements
Lay provider HIV testing WHO (2019). Consolidated guidelines on HIV testing services.	Lay providers who are trained and supervised can independently conduct safe and effective HIV testing using RDTs *(strong recommendation, moderate-certainty evidence)*.
Retesting	
Retesting WHO (2019). Consolidated guidelines on HIV testing services.	**Key populations** should be tested at least annually and more frequently based on risk and cost analysis, such as biannually or quarterly. **Individuals with STIs, TB or viral hepatitis**, and presenting related infections, signs, symptoms or other indicator conditions, should be tested for HIV regardless of testing history. **Pregnant women** in high HIV burden settings or from key populations should be retested in the third trimester/labour and delivery. If this visit is missed, catch-up testing in needed. Dual HIV/syphilis RDTs can be used for retesting where affordable and pragmatic. **Sexually active individuals** in high HIV burden settings should be tested at least annually depending on risk. **Individuals with reporting a recent HIV exposure** should be tested and also offered PEP and PrEP. Retesting in 14 days is advised to provide a diagnosis to someone with an inconclusive status and can be considered to resolve cases of suspected acute infection. **Individuals taking PrEP** should be encouraged to test or self-test every 2–3 months depending on the type of PrEP being used (oral, vaginal ring or injectable). **Individuals with HIV not taking ART** may benefit from welcome back services and can utilize testing services to re-engage in care. **Verification of HIV diagnosis** is recommended for all people newly diagnosed with HIV as a quality assurance measure prior to initiating life-long treatment.

Approach and references	Recommendations and good practice statements
HIV diagnosis and testing strategies	
HIV diagnosis and testing strategies WHO (2024). Consolidated guidelines on differentiated HIV testing services. WHO (2022). Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. WHO/UNAIDS (2022). Using recency assays for HIV surveillance – 2022 technical guidance WHO (2019). Consolidated guidelines on HIV testing services.	**HIV testing strategy/algorithm** WHO recommends that all HIV testing algorithms achieve at least 99% PPV and use a combination of tests with ≥99% sensitivity and ≥98% specificity. WHO recommends countries use three consecutive reactive tests to provide an HIV-positive diagnosis. Western blotting and non-line immunoassays should not be used in national HIV testing strategies and algorithms *(strong recommendation, low-certainty evidence)*. **NEW recommendation:** HIV recency testing is not recommended as part of routine HIV testing services *(conditional recommendation, low-certainty evidence)*. • This recommendation applies to excluding recency testing from routine HIV testing services. HIV testing services are defined as a package of services including 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. • Recency assays have been used to estimate HIV incidence in representative cross-sectional surveys and in epidemiological studies, which can facilitate more strategic targeting of testing and prevention interventions, optimize allocation of resources and measure progress in the HIV response. WHO and UNAIDS have issued guidance on this use of recency assays for HIV surveillance. **Pregnant women and key populations** Dual HIV/syphilis RDTs can be the first test in HIV testing strategies and algorithms in ANC settings and for key populations.
Post-test services and linkage	
Post-test services and linkage WHO (2021). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach.	Rapid ART initiation should be offered to all people with HIV following a confirmed HIV diagnosis and clinical assessment *(strong recommendation, high-certainty evidence for adults and adolescents; low-certainty 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) staff training to provide multiple services and (v) streamlined and co-located services *(moderate-certainty evidence)*; • peer support and navigation approaches for linkage *(moderate-certainty evidence)*; • quality improvement approaches using data to improve linkage *(low-certainty evidence)*. **Good practice statements:** ART initiation should follow the overarching principles of providing person-centred care. Person-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 individuals and families to play an active role in their own care through informed decision-making. People should be encouraged to start ART as quickly as possible, including the offer of same-day initiation where there is no clinical contraindication.

Approach and references	Recommendations and good practice statements
Priority populations	
Key populations WHO (2022). Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. WHO (2021). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. WHO (2019). Consolidated guidelines on HIV testing services.	HIV testing services should be routinely offered to all key populations both in the community and in facility-based settings. Dual HIV/syphilis testing can be used for key populations. 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-certainty evidence)*.
Adolescents and young people WHO (2021). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. WHO (2019). Consolidated guidelines on HIV testing services.	HIV testing services, with linkages to prevention, treatment and care, are recommended for adolescents from key populations *(strong recommendation, very low-certainty 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-certainty 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-certainty evidence)*. **Low HIV burden settings** HTS, with linkage to prevention, treatment and care, should be accessible to adolescents in low-burden settings *(conditional recommendation, very low-quality evidence)*. This is particularly important for young members of key populations. 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-certainty evidence)*. Additionally, adolescent girls (ages 9–14 years) should be offered human papillomavirus (HPV) vaccination as per national guidance *(strong recommendation, moderate-certainty 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 wellbeing (with consideration for different levels of maturity and understanding).

Approach and references	Recommendations and good practice statements
Pregnant and postpartum women WHO (2019). Consolidated guidelines on HIV testing services.	**All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)* at least once and as early as possible, ideally at the first antenatal care visit** *(syphilis: strong recommendation, moderate-certainty evidence; HBsAg*: strong recommendation, low-certainty evidence).* **Particularly in settings with a ≥2% HBsAg seroprevalence in the general population.* **Pregnant women** in high HIV burden settings or from key populations should be retested in the third trimester/labour and delivery. If this visit is missed, catch-up testing in needed. Dual HIV/syphilis rapid diagnostic tests (RDTs) can be considered as the first test in ANC and for maternal retesting where affordable and pragmatic. Dual HIV/syphilis RDTs can be used for retesting where affordable and pragmatic.
Infants and children WHO (2024). Consolidated guidelines on differentiated HIV testing services. WHO (2021). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach.	**All settings** All HIV-exposed infants should have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter *(strong recommendation, high-certainty evidence).* HIV virological testing should be used to diagnose HIV infection in children below 18 months of age *(strong recommendation, high-certainty evidence).* Point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age *(strong recommendation, high-certainty 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-certainty evidence).* Infants with an initial positive virological test result should be initiated on ART without delay, while at the same time a second specimen is collected to confirm the initial positive virological test result. Immediate initiation of ART saves lives and should not be delayed while waiting for the results of the confirmatory test *(strong recommendation, high-certainty evidence).* An indeterminate range of viral copy equivalents should be used to improve the accuracy of all nucleic acid-based infant diagnosis assays *(strong recommendation, moderate-certainty evidence).* Rapid diagnostic tests for HIV serology can be used to assess HIV exposure among infants younger than four months of age. HIV exposure status among infants and children 4 to 18 months of age should, therefore, be ascertained by undertaking HIV serological testing in the mother *(conditional recommendation, low-certainty 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-certainty evidence).* Caregiver-assisted testing using HIVST kits for children 18 months and older is not currently recommended. **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-certainty 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-certainty evidence).*

Approach and references	Recommendations and good practice statements
Infants and children (cont.)	**Network-based testing is recommended including the biological children of people with HIV**, including within social network testing (conditional, low-certainty evidence), family and household testing services and partner services *(strong recommendation, moderate-certainty evidence).* 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.
Couples and partners WHO (2024). Consolidated guidelines on differentiated HIV testing services. WHO (2024). Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services. WHO (2021). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. WHO (2019). Consolidated guidelines on HIV testing services. WHO (2013). Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines.	**UPDATED recommendation:** Network-based testing is recommended for couples and partners of people with HIV and those with ongoing risks including the use of social network testing *(conditional, low-certainty evidence)*, family and household testing services and partner services *(strong recommendation, moderate-certainty evidence).* **NEW recommendation:** STI partner services should be offered to people with STIs as part of a range of options based on their needs and preferences and within a comprehensive package of voluntary STI testing, care and prevention *(strong recommendation, low-certainty evidence).* • **Human rights:** STI partner services must always be voluntary and never mandatory. Coercive or forced testing is never warranted. All consenting patients should have their privacy protected and personal information should be kept confidential. • **Important to offer options:** There are a range of STI partner services that should be offered based on patient preferences, feasibility and resources available. Partner services include several options, such as patient referral, enhanced patient referral, delayed provider referral, provider-patient referral, and provider-assisted referral and social network approaches. Approaches with provider support are particularly effective and can be prioritized or encouraged where feasible. EPT could also be considered as part of partner services for some curable STIs, such as chlamydia or gonorrhoea. • **Linkage:** Linkage to STI management services for sexual partners is an essential component of STI services. • **Integration:** STI partner services should be based within a broader programme and package of services. It is important to build on existing services (e.g., sexual and reproductive health services and family planning services), and integrated delivery across disease areas (e.g., HIV and viral hepatitis). 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, at 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 setting 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).*

Chapter 1
Introduction

Chapter contents

1.1 Progress and challenges

People's knowledge of their own and their partners' HIV status is essential to an effective HIV response. The goals of providing HIV testing services (HTS) are to promptly deliver a correct diagnosis and to facilitate access to and uptake of HIV prevention, treatment and care. These services can include, for treatment, antiretroviral therapy (ART) and, for prevention, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), voluntary medical male circumcision (VMMC), prevention of mother-to-child transmission (PMTCT), condoms, contraception and harm reduction services for people who inject drugs *(1-3)*.

Globally, substantial scale-up of HTS continues. In 2005 it was estimated that only 12% of people who wanted to test for HIV were able to do so *(4)*. In contrast, by the end of 2022, nearly 20 years later, an estimated 86% of people with HIV knew their status. In high-burden settings, progress toward global goals to achieve and maintain low incidence is strong *(5)*. In 2023, Botswana, Eswatini, Rwanda, United Republic of Tanzania and Zimbabwe reached the "95-95-95" targets: 95% of the people living with HIV know their HIV status, 95% of the people who know their status are on ART, and 95% of people on treatment are virally suppressed *(5)*, compared to 10% in 2005 *(4)*. As countries reach 95-95-95 targets, it is important for HIV programmes to support those who tested HIV-negative to stay negative by strategically identifying those with ongoing HIV infection risk by populations, locations and specific settings. Programmes should also interrupt HIV transmission through early initiation of ART and support for achievement of an undetectable viral load for those that have been diagnosed with HIV *(6)*.

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

Despite these achievements, a substantial testing gap remains, especially for key populations, adult men, partners of people living with HIV (PLHIV), adolescents and children. HTS is often not sufficiently focused on these groups and those who remain at high and ongoing risk *(5)*. Priority populations are those that: (i) are most affected by HIV and at high ongoing HIV risk; (ii) are critical to achieving and sustaining low HIV incidence; and/or (iii) have specific individual or structural HIV-related vulnerabilities *(2)*. Countries can further refine their response by using their data to improve the understanding of patterns of HIV transmission in specific groups and/or locations, which will assist in focusing HIV prevention strategies on those groups or locations which will benefit the most or would yield the highest impact *(1)*.

It is increasingly important for countries and existing HIV programmes to support integration of HTS into other health services. Not only is integration often cost-effective, but it is a critical way to provide effective client-centered services *(7)*. Tools such as dual HIV/syphilis rapid diagnostic tests and self-tests offer unique opportunities for integration of services *(8)*, as well as network-based testing approaches, which include a range of services such as partner services, family and household testing services and social network testing services *(3, 9-11)*. Integration priorities will vary by epidemiology but may include TB, STIs, viral hepatitis as well as non-communicable diseases.

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. However, gaps remain in linkage to and retention in care, particularly for key populations, men, young people, children and people with HIV who had been previously diagnosed but had not initiated ART or who had started treatment but had disengaged or been lost to follow-up.

1.1.1 Preventing misdiagnosis

With the scale-up of HTS and increased ART coverage, there are fewer people with HIV who do not know their status, and the percentage of HIV-positive results amongst those who test for HIV declines over time. At population level, the number of people who test for HIV and get a positive result affects the probability of getting a correct diagnosis *(12)*. It is important to ensure that all clients who test for HIV receive correct diagnoses. Reports suggest that misdiagnosis of HIV status is occurring in resource-limited settings, often due to the use of suboptimal testing algorithms and out-of-date testing strategies *(13, 14)*. As a result of changing epidemiology and declining HIV positivity in testing

programmes, WHO recommends all countries to use a standard three-test strategy to ensure a PPV of at least 99%, minimizing false-positive misdiagnosis *(1, 12)*.

Recent mathematical modelling has shown that the WHO-recommended HIV testing strategy, along with quality assurance (QA) measures such as retesting to verify a positive diagnosis prior to ART initiation, is cost-effective as it prevents misdiagnosis and unnecessary initiation of costly lifelong treatment *(15-17)*.

Beyond the 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 the test or interpreting the test result, and poor documentation and record-keeping. Lack of provider training, supportive supervision or standard operating procedures can aggravate these problems. Thus, quality management systems (QMS) are important and should be expanded in parallel with scale-up of HTS.

1.1.2 Limited access to HTS by key populations

HIV disproportionately affects key populations – men who have sex with men, people who inject drugs, sex workers, transgender people, people in prisons and other closed settings, and their sexual and injecting partners. People from key populations comprise up to half of the 1.7 million new HIV infections every year *(18)*. 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 *(2-6)*.

Barriers to HTS uptake include HIV-related stigma and discrimination, criminalization and punitive laws and practices *(2)*. Indeed, HIV testing is sometimes misused in punitive or coercive ways against key populations, especially where their practices are criminalized *(2)*. In many countries inadequate coverage and the low quality of HIV services for key populations, including HTS, can undermine the national response to HIV *(19)*.

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

1.1.3 Men continue to lag behind

Globally, men with HIV are less likely than women to know their status, to be on treatment and to be virally suppressed *(5, 20)*. In 2022 an estimated 72% of all adult men with HIV (ages 15 years and older) had access to ART compared with 82% of women of the same age *(5, 18)*. Such gaps are greatest in sub-Saharan Africa, where population-based surveys consistently show similar findings *(5, 20-25)*. Consequently, in many settings HIV-related morbidity and mortality rates are higher among men than women *(21)*.

Recent data from Uganda show that there are 1.5–2-fold higher suppression rates in HIV-positive women than men. Such findings make clear that increasing access to testing and linkage to ART for men is important for their own health and critical for reducing new infections in women *(26)*. Men from key populations bear significant HIV burden, and many living with HIV are undiagnosed *(2, 27)*.

There are multiple reasons for men's lower uptake of health services than women's, which leads to poorer health outcomes among men *(20)*. Men can and do access health services and programmes, but health services in many settings are not structured to serve them *(28)*. Many HIV programmes have effectively integrated HIV testing and related services into ANC *(29)* but not consistently into other clinical services relevant to men *(30, 31)*. This results in fewer opportunities to reach men and contributes to perceptions that health services are not friendly to men and are primarily for women and children *(32-36)*. Other barriers include fear, stigma and direct and opportunity costs of accessing services *(32-36)*.

1.1.4 Adolescents and young people, too, are underserved

Adolescents and young people also are at significant risk of HIV infection in high HIV burden settings in eastern and southern Africa, where an estimated nearly 90% of HIV-positive adolescents (ages 10–19 years) live *(21, 37)*. 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 *(21, 38)*.

Coverage and uptake of testing remain poor for adolescent girls and boys. In 2022 only 25% of adolescent girls and 17% of adolescent boys (ages 15–19 years) had been tested for HIV in the previous 12 months and received the result of the last test *(37)*. Population-based surveys in Malawi, the United Republic of Tanzania, Uganda and Zambia suggest that roughly half of young people (ages 15–24 years) with HIV were aware of their status, and only 37–46% of those who were aware of their status were on treatment *(25)*. However, recent data shows HIV incidence is shifting from adolescent girls to women ages 25–34 years in many high-burden settings *(26)*.

Poor access and uptake of HTS services are often due to the actual or perceived poor quality of services as well as restrictive laws and policies – for example, age-of-consent laws for testing and self-testing, as well as treatment and prevention – that hinder adolescents from accessing services *(39, 40)*. Greater efforts are particularly needed to improve access for adolescents where HIV incidence remains high, in sub-Saharan Africa among young women and girls and among young members of key populations in all settings.

1.1.5 Services for pregnant and breastfeeding women can be expanded and integrated

Globally, there are an estimated 1.3 million pregnant women with HIV *(41)*, more than one million pregnant women with active syphilis infection and 65 million women of childbearing age with a chronic hepatitis B virus (HBV) infection *(21, 42, 43)*.

For pregnant women early testing and services for HIV, syphilis and HBV lead to the best health outcomes and reduces transmission.

Elimination of mother-to-child transmission (EMTCT) of HIV, syphilis and HBV is a global health priority *(44)*. Efforts to support EMTCT require broader integration of testing services among other priority populations such as partners and key populations. ART is most effective in preventing HIV transmission from mothers to infants when started before or early in pregnancy, however early testing and linkage is critical. Globally, syphilis and HBV testing coverage in pregnant women is considerably lower than for HIV *(45)*. This leads every year to adverse birth outcomes and congenital infections requiring treatment *(21)*.

HTS should be routinely offered as early as possible during pregnancy *(29)*. At the same time, 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 *(46)*. Maternal HIV retesting in the third trimester of pregnancy and during breastfeeding is only recommended for all women in high HIV burden settings *(1, 47)*. In low HIV burden settings, maternal retesting in the 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 *(1, 47)*. 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 on women with high ongoing risk *(1, 47)*.

1.1.6 Children and infants are still missed

HIV testing coverage among children is often low. Despite reports of high positivity among children tested in clinical settings in countries with a high HIV burden *(48-51)*, facility-based HIV testing is still rarely offered routinely for children in tuberculosis (TB) and malnutrition clinics *(52, 53)*. Although HIV testing coverage through PMTCT programmes has improved considerably over the past decade, rates of early infant diagnosis (EID) remain far from optimal. In 2019 only 60% of infants received an HIV nucleic acid test (NAT) within the first two months of age *(54)*.

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

While EID coverage has risen in eastern and southern Africa to 83% [69–98%], it remains very low in western and central Africa at 23% [19–29%] *(5)*. For infants who are tested, delays in obtaining results and further losses in the treatment cascade still occur, resulting in less than one third of perinatally infected infants linked to services and initiated on ART in a timely manner *(55)*. Evidence showed that children

accounted for 13% of AIDS-related deaths in 2022, even though they comprise only about 4% of PLHIV *(5)*. Network-based testing services, which include family and household testing to reach the children of people with HIV are often poorly implemented and have suboptimal coverage *(56)*.

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, inconvenient service hours and long waiting times at health facilities *(52, 53)*.

1.1.7 Retesting among PLHIV may be common in some settings

Increased access to HTS and ART may be contributing to retesting among people with HIV who already know their status, including those on treatment *(13, 57-59)*. A systematic review reported retesting rates ranging from 13.2% to 68.1% among people with HIV who already knew their status *(60)*.

Motivations for retesting vary among people who know already their HIV-positive status, including those on treatment and those who have disengaged from care. 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 *(60)*. Retesting for people on ART is not recommended, as it may provide incorrect results. Therefore, people on ART who seek retesting should discuss this with their provider.

For some people who know their HIV status but have not initiated or have 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 *(61)*. Testing providers should welcome back these clients and be supportive rather than judgmental of those who have dropped out of care.

1.2 Rationale

These guidelines provide new and updated recommendations on self-testing, network-based testing services and HIV recency testing. They also seek to address gaps that countries have identified in the 2019 WHO Consolidated guidelines on HIV testing services *(1)*.

Countries and other end-users of HTS guidelines have indicated that this new guidance will enable them to make decisions about introducing and scaling up new HTS approaches, as well as increasing the effectiveness and efficiency of HTS programmes as part of national and global efforts to achieve and maintain low HIV incidence.

1.3 Goal and objectives

The primary goal of these guidelines is to update the existing consolidated guidelines on HTS *(1)* and to better support countries and national programmes to achieve national and global goals to achieve and sustain low HIV incidence by 2030 *(62, 63)*.

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 and linkage approaches across facilities, communities, as well using network-based testing and self-testing;
- support integration of testing services, such as maximising opportunities for multi-disease testing and scaling up the use of HIV/syphilis dual testing as the first test in ANC and for key populations;
- support programmes to implement quality HTS using WHO-recommended testing strategies;
- provide guidance on how programmes can strategically plan and effectively rationalize resource use; and
- reinforce greater national and global commitment to implement effective and efficient HTS as a key element of the national and global HIV response.

1.4 Scope of the guidelines

These guidelines outline a public health approach to strengthening and expanding HTS. They present and discuss key updates to 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.

In addition to updating the 2019 guidelines, these guidelines also update the 2015 *Consolidated guidelines on HIV testing services (64)* and the 2016 supplemental guidance on HIV self-testing and assisted partner notification services *(65)*. The 2019 guidelines are available in full and as abridged policy briefs.

The background documents supporting these guidelines and new recommendations appear in the annexes and on the WHO website.

New guidance on STIs that is included in this document is also available in the *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services*

Not addressed in these guidelines are detailed guidance on testing for long-acting injectable prevention options, additional multiplex assays, such as those to support detection of HIV, HBV and syphilis; and molecular testing in testing algorithms. These will be addressed in future guideline updates planned by WHO.

1.5 Intended audience

These guidelines are intended for use by national HIV programme managers, particularly in ministries of health, who are responsible for the national health sector's response to HIV, including HTS, as well as prevention, care and treatment services in Member States. These guidelines also will assist national and subnational programme managers responsible for the provision of HTS and a range of other integrated services such as 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 organizations and community-based organizations. They also can serve donors as the normative guidance to support effective funding, planning and implementation of HTS.

1.6 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 rates of testing uptake or to meet HIV testing targets, but also to provide, for all people in need, access to appropriate, quality HTS with effective linkage to prevention, 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. HIV testing for prevention supports HIV-negative people to stay negative, and is offered in various programmes such as ANC, VMMC, PrEP and PEP.

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) *(1)* (see Box 1.1).

Box 1.1. 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. Partner services 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. Quality assurance (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 be 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 quality testing services, and QA mechanisms should ensure that people receive correct diagnoses. QA may include both internal and external measures, supported by the national reference laboratory. All countries should adopt the WHO standard three-test strategy for HIV diagnosis. 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 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. Testing providers may also need to support individuals with HIV to re-link or re-engage in care.

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Chapter 2
Methodology

Chapter contents

2.1 Overview

These guidelines were developed to provide guidance on implementing effective and efficient HIV testing services (HTS) and in response to Member States' requests to update the WHO guidance on HIV testing services (HTS) *(1, 2)*. All current WHO recommendations that pertain to HTS are included.

The WHO Department of Global HIV, Hepatitis and STI Programmes (HHS) led the development of these guidelines in accordance with the *WHO handbook for guideline development (3)*.

2.2 Establishing the groups to develop the guidelines

The HHS 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:

1. **WHO Guideline Steering Group (SG).** The WHO HHS Testing, Prevention and Populations Unit led this group and served as the WHO secretariat. Participants included WHO staff from other units in HHS, the Department of Essential Medicines and Health Products, the Department of Sexual and Reproductive Health and Research and the Global Tuberculosis Programme. This group also included technical staff from all WHO regional offices. WHO country offices and other United Nations (UN) agencies and partner organizations also contributed.
2. **Guideline Development Group (GDG).** This group consisted of 25 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 was then 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 guidelines document.
3. **External Review Group (ERG).** This group was selected in consultation with the WHO SG and GDG to assure geographic and gender balance. It comprised 83 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 members of key populations, people living with HIV (PLHIV) 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.

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 2019 *Consolidated guidelines on HIV testing services (1)* and 2016 *Guidelines on HIV self-testing and assisted partner notification (2)*. Following initial mapping, in 2022 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. Through this process three critical gaps requiring normative guidance were identified:

1. Expanded use of self-testing, particularly in facilities, within PrEP programmes and as part of caregiver-assisted testing of children 18 months and older
2. Expanded use of network-based testing services for all populations
3. General use of recency assays within routinely offered HIV testing services.

Opportunities to integrate and cross-reference additional WHO guidance were also highlighted and included:

1. Self-testing and self-care across disease areas
2. Network-based testing services across disease areas.

Efforts to integrate and cross-reference guidance developed during a similar time period included the: *Guideline on self-care interventions for health and well-being*, *Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection*, *Updated recommendations on treatment of adolescents and children with chronic HCV infection, and HCV simplified service delivery and diagnostics* and *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services* were also prioritized.

2.4 Review of the evidence

These guidelines present existing recommendations, updated recommendations on self-testing and network-based testing services and a recommendation against the use of recency assays as part of HIV testing services.

The GDG and SG recommended commissioning five systematic reviews and one modelling study to inform normative guidance and recommendations to address the gaps identified.

Cross-cutting WHO guidance was also integrated where relevant, such as recommendations developed and approved through the *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services*.

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.

2.5 Development of recommendations

The WHO SG and GDG developed five PICO questions to inform the development of guidance. Protocols and reviews were assessed and reviewed by Nandi Siegfried, the appointed independent methodologist, as well as by the GDG, SG and WHO secretariat. 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)*. Table 2.1 provides details.

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

Table 2.1. GRADE systematic review and PICO question summary

	HIV self-testing in clinical settings	HIV self-testing for PrEP	Social network-based approaches	Caregiver-assisted testing with HIVST	Recency assay in testing services
Search dates	Searched up to 1 February 2022	Searched up to 25 August 2022	Searched between 1 January 2010 and 22 July 2022	Searched up to 5 February 2022	Searched up to 31 December 2022
Question	*Should HIVST be offered as an additional testing option in health facilities?*	*Should HIVST be used to support PrEP delivery?*	*Should social network-based testing approaches be used as an additional option for all populations and their contacts?*	*Should caregiver-assisted testing with HIVST kits be offered as an additional HIV testing approach for children 18 months or older?*	*Should recency testing be used in HIV testing services?*
Population	Populations receiving HIV testing	Individuals at risk of HIV acquisition who could benefit from PrEP use	All populations receiving testing and their social, sexual and drug-using/sharing contacts	Children 18 months and older receiving HIV testing	Populations receiving HIV testing services
Intervention	HIV testing services that include facility-based HIVST	PrEP service delivery that includes HIVST	HIV testing services that include social network testing approaches	HIV testing services that include caregiver-assisted testing with HIVST kits	HIV testing services that include recency testing
Comparator	Standard facility-based HIV testing services, without HIVST	Standard HIV testing services for PrEP, without HIVST	Any other HIV testing service, or no intervention	Any other child HIV testing services, or no intervention	HIV testing services that do not include recency testing
Critical outcomes	• uptake of HIV testing • acceptability • feasibility • HIV positivity • linkage to prevention and care services • social harm.	• PrEP initiation • PrEP continuation • HIV testing • HIV incidence • HIVST performance • drug resistance • sexual risk behaviours • HIV positivity • social harms • PrEP offer.	• acceptability • uptake of social network-based approaches • uptake of HIV testing among contacts of test promoters • number of first-time testers identified/ reached through social network-based approaches • HIV positivity • baseline CD4 count or viral load among people diagnosed with HIV • linkage to prevention and care services if HIV-negative • linkage to clinical assessment or ART after testing HIV-positive • social harm.	• HIV testing uptake • acceptability • feasibility • HIV positivity • linkage to prevention and care services • social harm.	• recency assay performance (sensitivity, specificity, concordance) • uptake of partner services • proportion of recent infections among all those tested (in contacts of seeds) • social harm or intimate partner violence (of client or partner/s) related to or following HIV recency testing • proportion of new HIV diagnoses among all those tested.

2.6 Evidence assessment

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

2.6.1 Interpreting the certainty 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 certainty of evidence as the extent to which one can be confident that the reported estimates of desirable or undesirable effects are close to the actual effects *(4)*. The GRADE approach specifies four levels of certainty of evidence (Table 2.2).

Table 2.2. Interpretation of the four GRADE levels of evidence

Certainty 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. The values and preferences of users, feasibility and costs, acceptability, human rights and equity, and consideration of potential benefits and harm, contribute to determining the strength of a recommendation.

Within WHO guidance, 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. Further research may also be needed to address uncertainties.

2.7 Developing the recommendations

During 2022–2023 WHO convened two virtual guideline development meetings and 12 WHO SG meetings.

During these meetings participants considered the evidence for formulating new recommendations and reviewed all relevant sections of the consolidated guidelines. 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 them.

The GDG reached consensus on the direction of four recommendations, covering self-testing, network-based testing and recency testing. The GDG were unanimous on the strength of recommendations on self-testing and social network testing (in favour). For recency testing, a vote was taken, and the majority voted for a conditional recommendation against the programmatic use of recency testing. Four members requested that it be noted that they favoured a strong recommendation against. The GDG unanimously agreed not to make a recommendation on caregiver-assisted testing using self-test kits for children.

2.8 Producing the guidelines

Following the GDG virtual consultations, 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.

2.9 Plans for dissemination

The guidelines will be disseminated through a coordinated effort across three levels of the organization and together with key stakeholders.

WHO will also assist Member States to adapt the guidelines to their national contexts.

2.10 Updating

WHO will continue to monitor the uptake and implementation of WHO guidelines through the Global AIDS Monitoring (GAM) survey *(5)*, policy reviews and country and partner dialogues.

The HHS Department will review this guidance and consider potential updates as needed based on the emergence of important new evidence.

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Chapter 3

Mobilizing demand for HIV testing services and pre-test information

Chapter contents

Key messages

- Demand creation can be used to **maximize efficiency** through effective HTS promotion, targeting specific subpopulations. It is important to **identify effective demand creation strategies** for HIV testing and de-prioritize those that are less effective.
- **Effectively mobilizing people with undiagnosed HIV infection and ongoing HIV risk** to access HIV testing, prevention and treatment services is important for achieving global goals.
- Important demand generation strategies span policies which are part of creating an enabling environment for service delivery, utilizing platforms such as peer-based and virtual-based interventions, and investing in evidence-based demand creation approaches.
- It is critical that demand creation efforts include 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 sexual partners – Undetectable = Untransmittable (U=U).[1]
- **An enabling environment** that removes barriers such as stigma, discrimination and criminalization and addresses 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.
- **Evidence-based approaches to demand creation** include peer-led activities and use of virtual interventions and digital platforms; advertisement of specific HTS delivery modalities such as community-based testing; messages encouraging testing during couples-oriented counselling; messages related to risk reduction; and motivational messages.

[1] U=U means that people with HIV who have an undetectable viral load and continue taking medication as prescribed have zero risk of transmitting HIV to their sexual partners.

3.1 Introduction

As more countries reach the 95-95-95 targets, the population of people living with HIV (PLHIV) who remain undiagnosed become systematically different from those previously tested, and some of the demand creation activities used previously to encourage testing are now less effective. It is important therefore to tailor messages for subpopulations unreached or underserved by existing approaches *(1)*. Box 3.1 highlights core approaches and strategies for demand creation.

Box 3.1. Core approaches and strategies for demand creation

Enabling environment

- protecting confidentiality
- preventing social harm, stigma, discrimination, and criminalization
- empowering communities
- ensuring appropriate age-of-consent policies
- offering virtual self-care options for HTS services.

Mobilization platforms for creating demand

- peer-delivered, participatory and community-led approaches, such as using peer educators, community groups and faith-based programmes
- technology and internet driven solutions, mobile phone-based and social media platforms, dating apps, telehealth platforms or models and other digital media channels.

Mobilization strategies for creating demand

- online targeted advertisements, adaptive social media promotions, involvement of social media influencers, online peer outreach and messaging related to access to HTS services
- educational messages through, for example, drama, sports-based and faith-centred activities
- counselling strategies (for example, motivational messages such as "U=U"
- couples-oriented counselling and partner services (including social network-based approaches).

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 than average *(2)*. Few people may know where or how to obtain HIV testing outside of facilities, such as ordering a self-test online or how to access community-based services *(3)*. Messages about how ART can prevent HIV transmission, known as U=U, are also not widely communicated, even though they may help increase uptake of testing and onward services *(1)*.

Efforts to increase HIV testing are needed among those at risk of acquiring HIV infection and those with HIV who do not know their status. In addition to creating an enabling testing environment, person-centred demand creation tools and interventions may be the only way to reach people who are hesitant or unable to access testing, as well as people who may be uninformed about testing and the latest advances in treatment and prevention.

U=U, Undetectable is Untransmittable

It is important to include messages about the benefits of taking ART for preventing transmission to partners.

People with HIV who have attained an undetectable viral load and continue taking ART as prescribed have zero risk of transmitting HIV to their sexual partner(s).

Source: WHO 2023 *(4)*.

3.2 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 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 *(5)*.

Policies and laws are also needed to implement effective HTS approaches, including testing by lay providers (policies enabling task sharing), network-based testing services (policies addressing confidentiality), access to self-testing (policies addressing use of medical devices) and use of virtual interventions and telehealth (policies to allow self-care options and home delivery of commodities and services). Emphasis on self-care options can help overcome barriers associated with conventional services, such as stigma, discrimination and confidentiality concerns. By enabling individuals to test in the privacy of their own homes or to collect their own specimens, self-care options can encourage those who may be hesitant to access testing services for these reasons *(6)*.

Laws and policies that support human rights and foster access to and uptake of services are crucial to public health impact.

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) *(5)*. Box 3.2 summarizes WHO guidance for creating an enabling environment for HTS.

Box 3.2. WHO guidance for creating an enabling environment for HIV testing services

Consent and confidentiality

- Initiatives to enforce privacy protection and to institute policy, laws and norms that prevent discrimination and promote tolerance and acceptance of people living with HIV can help create environments where disclosure of HIV status is easier *(strong recommendation, low-certainty evidence)*.
- HIV testing must be voluntary and not mandatory and be offered without coercion. People offered testing must give informed verbal consent and be made aware of their right to refuse testing.
- Countries are encouraged to examine their age-of-consent policies and consider reducing age-related barriers to HIV services and to empower providers to act in the best interests 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 within 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, or ensure that someone else (within their health care setting or in another location 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).*
- Health and other support services should be provided in a timely way to people with HIV and to key and vulnerable populations. People experiencing sexual violence should have prompt access to comprehensive services, including post-rape care, and violence should be monitored and reported and should be addressed in partnership with affected communities, as well as in prisons and other closed settings.
- 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, bisexual, trans and gender diverse, 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.

Source: WHO 2013 *(7)*, WHO 2016 *(8)*, WHO 2019 *(5)*, WHO 2016 *(9)*, WHO 2019 *(10)*, WHO 2019 *(11)*, WHO 2022 *(12)*.

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 and obtain services based on their needs and preferences *(12)*.

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 testing. Testing should not be a condition for obtaining other benefits and refusing testing should not be a reason for withholding other benefits *(5, 9, 13)*.
- **Protecting confidentiality.** Lack of confidentiality discourages people from testing for HIV *(5)*. Programmes and facilities where HTS are delivered need site-level policies and standard operating procedures (SOPs) that protect clients' privacy and confidentiality. Safety and security policies are also required where HTS services are offered and delivered virtually, using digital technology, phone devices, telehealth and other virtual interventions. Within a facility, all staff members have a role in providing a *safe, friendly and welcoming* environment. Provider training to reduce stigma and discrimination at service delivery can be helpful. To prevent violence, training and educating law enforcement agents can also be effective *(7, 14)*. Additional provider training on identifying intimate partner violence or abuse, as well as and how to provide effective referrals for available services, should also be considered *(7)*.
- **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.

3.3 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 access HIV testing services. These strategies can be implemented using peer-based or community-led approaches as well as virtually (such as social media posts, chatbots, GIFs, videos and short messaging service [SMS]).

Demand creation and mobilization efforts should consider adopting approaches which can reach those most affected by HIV and with lowest testing uptake and knowledge of status, such as key populations, adolescents and young people, men in east and southern Africa, and other vulnerable groups. Strategies need to be tailored to suit the intended audiences, considering such issues as who delivers demand creation messages (for example, outreach workers, health workers, peer mentors, partners, popular or social media influencers or other public figures), media (for example, face-to-face, social media, theatre, radio, posters, SMS and chatbots *(15)*, format (for example, drama, influencers' 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 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 HTS alone may not be as effective as efforts focused 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 *(16)*.

However, in the current era this more generalized approach may not have the impact on uptake of testing that focused efforts could 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.

Mobilization strategies need to focus on reaching those with HIV who do not know their status and those at high ongoing risk.

Clear signage, posters, videos, social media posts, appointment booking websites, brochures and other materials in local languages are important to inform prospective clients about testing services and direct

them to services. Such information is crucial regardless of where testing services are delivered, whether in health facilities, in the community, through virtual interventions or through outlets distributing self-tests. In settings where HIV testing is routinely offered, such as antenatal care, 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 guidance has highlighted effective demand creation approaches which should be prioritized *(1, 17)* (see Box 3.3).

Box 3.3. 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 those with 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, social media platforms, dating apps.

Approaches that have showed evidence of increasing demand include:

- advertisement of specific HTS service delivery modalities and linkage of services
- brief key messages and counselling by providers (less than 15 minutes, face-to-face or virtual)
- 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 (UHC);
- 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.

Source: WHO 2019 *(5)*

3.4 Implementation considerations for demand creation interventions

The following implementation considerations should be prioritized for guiding decisions on demand creation interventions. Considerations below detail broader efforts on demand creation, and optimizing delivery of messages prior to testing.

- 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 may be reluctant to respond to demand creation interventions and avoid services, especially key populations.
- 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 focus on those most likely to benefit to promote efficient and effective HTS and to avoid substantially increasing the cost per person diagnosed with HIV.
- Partner/couples-oriented counselling are beneficial within broader interventions, and they should be considered and implemented to support scale-up of partner services and social network-based approaches, which WHO recommends as high-impact approaches.
- It is critical that demand creation efforts include informational and counselling messages explaining the benefits of early ART and that people with HIV who achieve and maintain an undetectable viral load cannot transmit HIV sexually to their partners (U=U).
- Demand creation approaches for HIV testing are highly relevant for other disease areas, particularly TB, STIs, HBV and HCV and for 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.
- Close attention and monitoring are needed to ensure that demand creation is increasing programme efficiency and effectiveness by focusing on 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.
- Virtual platforms and interventions should be considered where feasible and helpful *(18)*. Examples include video-based messages and counselling, medical consultation over video call, social media posts, advertisements and engagement with influencers. Virtual platforms are especially useful where HTS coverage is sub-optimal and with populations who may spend a lot of time online and 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, which are inexpensive for users and can be tailored to specific audiences, may be important for introducing, scaling up and focusing demand creation efforts.

Box 3.4. Case example: Demand generation using virtual platforms for HIV self-testing – India

Through the Unitaid-funded STAR initiative, PATH, with partners, sought to demonstrate the feasibility and acceptability of HIVST among key population and other individuals with substantial HIV-related risk to inform an HIVST policy in India. The project implemented a virtual model of HIVST service delivery, which distributed 645 HIVST kits.

Phase 1: Demand generation using Facebook, Instagram and search engine optimization

Facebook and Instagram were used to increase awareness about HIVST and to generate demand for testing via the new service delivery platform. A social media campaign was translated into eight languages and launched in April 2022. But the response to the campaign was lukewarm. While website data showed that posts had reached 654 773 individuals, only 151 people engaged with the posts, and there were only 2128 clicks on the link to the website. A total of 136 people registered on the website, and 79 ordered HIVST kits. An additional 108 test kits were ordered through related activities using dating apps.

There were two main weaknesses in the campaign: i) The social media profiles for the project were new, and the three-month period was not enough to generate traffic on the new sites, and ii) the process of ordering the kits was too time-consuming and reported to be too long for a virtual population.

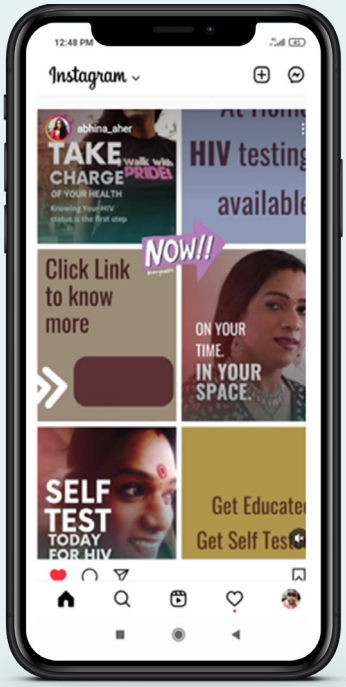

Photo credit: Asia Pacific Coalition on Male Sexual Health

Phase 2: Rethinking demand generation and platform design

To strengthen demand generation, PATH engaged with 28 social media influencers from the LGBTQI+ community. These influencers were supported to create two posts per week from December 2022 to February 2023. Posts included photos with messages, animated and personal videos, quizzes and polls.

During the campaign influencers created 374 posts, which were viewed 830 900 times, and a total of 54 000 people engaged with the posts. There were 7644 people who clicked on links and explored the virtual platform; 321 people registered, and 112 people ordered test kits. Demand generation on dating platforms and through other social media led to orders for an additional 346 test kits.

Influencer marketing resulted in a higher uptake of services in a limited timeframe than the previous strategy. Platform users also interacted with influencers, providing insights into testing behaviours and feedback on packaging and delivery mechanisms. This interaction informed refinement of campaign messages.

Demand generation through effective use of social media platforms requires time, strategic focus and engagement with the intended audience. Further, converting this demand into uptake of HIVST will require additional support and understanding of the testing needs and preferences of the virtual population.

3.5 Concise pre-test Information and messaging

With the integration of HIV testing into routine health care, and the use of rapid diagnostic tests (RDTs) as well as the current wide availability of highly effective prevention and treatment options, pre-test counselling is no longer needed and may create barriers to service delivery. Also, individualised pre-test counselling is no longer recommended. Instead, 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.

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. Children and adolescents should be presented with information that is age-appropriate to ensure comprehension.

When pre-test information is needed by clients (individually or in a group), concise 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 and importance of considering treatment as prevention – that is, U=U;
- the services available to those who test HIV-positive, including where ART is provided;
- 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 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 (in most settings);
- potential risks of testing in settings where there are legal implications for those who test positive or whose sexual or other behaviour is stigmatized or criminalized;
- the opportunity to ask the provider questions;
- importantly, for people who are using self-tests independently, information about where to seek further testing, treatment and prevention services, as they will not receive this information from a health care worker following receiving their self-test result;
- for people with a reactive test result, the importance of attending a testing site for further testing;
- for people with a non-reactive test result, information about prevention options.

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Chapter 4

Essential post-test service package: counselling messages and linkage to prevention, treatment and other services

Chapter contents

Key messages

- **The primary goal of person-centred HIV testing services (HTS) is to link individuals to appropriate treatment and prevention**, linking those who test positive to early initiation of ART and linking those who test negative to prevention services and information. Linkage is the responsibility of the testing service.
- **Post-test services should be implemented as part of a deliberate, differentiated comprehensive strategy** including concise tailored messages, effective support interventions, approaches and tools to facilitate linkage to rapid ART initiation, HIV prevention, care, support and other relevant services. All components are necessary. Post-test counselling alone does not improve linkage or lead to sustained behaviour change.
- Post-test counselling messages need to be **tailored to specific populations** and their situations, with different messages for individuals whose test results are HIV-positive, negative or inconclusive, and for those who already know their status and need to engage or re-engage in care.
- Post-test counselling for those testing HIV-positive should **focus on promoting adherence to achieve viral suppression with ART, including messages about the prevention benefits of being on ART (Undetectable = Untransmittable)** and on offering network-based testing, including partner services, support for disclosure and/or social network testing to reach sexual or injecting partners or other network members who may be at high ongoing risk.
- All people testing HIV-positive should be offered a **core package of support interventions** that ensure rapid linkage to ART. **WHO recommends co-located and well-coordinated ART services, peer support to facilitate linkage and provider-assisted partner services**.
- For those who test HIV-negative, **post-test services should focus on identifying those at continuing risk in order to link them to prevention services, including PrEP or PEP**. Many people who are **HIV-negative do not need lengthy post-test counselling**, which may deter future testing even among those with ongoing risk. Instead, those individuals should be identified and offered combination prevention.

4.1 Introduction

Linkage to care is a primary goal and the responsibility of HIV testing services.

HTS are not complete without effective linkage to appropriate HIV prevention, treatment and care services, the primary goal and responsibility of HTS. Linkage is important whether a person first tests positive, retests positive or tests negative. Diagnosing individuals with HIV and facilitating initiation of antiretroviral therapy (ART) as early as possible is crucial for individuals testing positive for the first time *(1, 2)*. HTS can also be an important point of re-entry into care for those who have tested positive previously but have not started ART or who have discontinued and need to restart ART and choose to re-engage through HTS *(2-4)*. For those testing HIV-negative, HTS is an opportunity to link and engage in effective prevention interventions, including male and female condoms and lubricants, testing and treatment for sexually transmitted infections (STI), voluntary medical male circumcision (VMMC) for men in sub-Saharan Africa, harm reduction for people who inject drugs, post-exposure prophylaxis (PEP) for those with a recent exposure event and pre-exposure prophylaxis (PrEP) for those at substantial ongoing risk of HIV acquisition *(2)*. With improvements in service delivery integration, there are also many more opportunities to support linkage through other services such as TB, viral hepatitis, STIs and sexual and reproductive health.

It is essential that programmes using dual HIV/syphilis rapid tests or self-tests, and/or working toward triple elimination, support rapid linkage to care for HIV, syphilis and HBV, particularly for pregnant women.

The core package of post-test services needs to include:

- clear and concise **messages tailored to identified needs and context**
- **up-to-date information on U=U** about how people with HIV who are adherent to ART with undetectable viral load will not transmit HIV to their partners
- **offer of or referral for rapid ART initiation** for those diagnosed with HIV[1] **support linkage for people already diagnosed but not actively on treatment**
- **support linkage or engagement in HIV prevention services**, including PEP for those with significant exposure to HIV in the past 72 hours or PrEP for those who test negative and are at substantial ongoing risk of HIV infection
- **offer package of network-based testing services, particularly among those who test positive, those in high incidence settings and those with high ongoing risk.**

4.2 Key post-test messages and information

Post-test messages and counselling need to be tailored to the test result, the client and the setting. For those with negative results, this will further depend on whether they face ongoing HIV risk. Messages should always be clear, concise and client-centred to address clients' needs and situations.

Post-test counselling should be delivered in a way that is **acceptable** to the client and conducted 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 facilities and community settings. **New virtual platforms**, including computer-based, online and mobile phone-based applications, videos and social media should be explored. These platforms can be implemented alongside self-testing. Health workers, professional counsellors, social workers and trained lay providers can all provide counselling.

Post-test 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 they may share is **confidential** and will not be disclosed without their permission or consent;
- the **meaning of their test result**;
- that the **results can be trusted**, provided the diagnosis is based on the full national testing algorithm;
- **availability of HIV prevention, treatment, care, support and other relevant services and their benefits**, depending on HIV status and ongoing HIV risk;

[1] In settings where dual HIV/syphilis testing or self-testing is utilized, it is essential to also offer and/or provide referral for syphilis treatment according to national guidelines.

- that people with HIV who take ART **as prescribed** and have undetectable viral load will not transmit HIV to their partners;
- whether **retesting** at certain time points is needed or not, based on context, population and individual behavioural risks;
- **opportunities to ask** the provider additional questions.

Post-test counselling on its own does not lead to sustained behaviour change *(5-7)*. More intensive post-test counselling may be beneficial for certain populations and individuals, such as couples counselling *(8, 9)*, harm reduction and interventions addressing alcohol and substance use *(2, 6, 10)*, initiation of PEP or PrEP, and for individuals who need more support in accepting their HIV-positive diagnosis.

4.2.1 Considerations for people with an HIV-positive test result

An HIV diagnosis can be a life-changing event and requires the health worker, trained lay provider or counsellor giving the results to adhere to the WHO 5 Cs, particularly Correct test results and Connection to further services *(2)*. 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. Strategies for delivering simple messages such as those described in Box 4.1 are important and should be considered.

WHO recommends that individuals who have been diagnosed with HIV be retested, where possible, at a different facility, or by a different provider in the same facility, prior to starting lifelong treatment. Post-test counselling should include discussion of this process. See Chapter 8 for details on retesting prior to ART initiation.

Counsellors need to give clients time to consider the results and to 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 *(2)*.

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

- **the need for retesting prior to initiating treatment for newly diagnosed individuals** to ensure that the results are accurate;
- **the meaning of the HIV-positive diagnosis** – that HIV is a chronic, manageable condition requiring lifelong treatment; and that with adherence to treatment, most people will live healthy lives and usually will live as long as people who do not have HIV;
- that **Undetectable = Untransmittable** – achieving viral suppression through adherent use of ART **means that HIV cannot be transmitted to sexual partners;**
- that there are additional health **benefits of immediate ART initiation, and** that ART is **safe, and side effects are minimal;**
- the benefits of **disclosure, partner testing and network-based testing services** and any potential **risks**, including social harms and legal implications;
- for **women with HIV**, as relevant, information on safe conception, ART use during pregnancy and breastfeeding to prevent mother-to-child transmission.
- **Starting ART as soon as possible**, preferably on the same day as the diagnosis.
- Together with the client, make an **adherence plan** and consider options for future differentiated care, including **where and how to obtain services**, particularly those that are free of charge.
- Recognize that some people will need time to adjust to their positive status and may need **further support for starting ART**. Discuss any barriers to starting 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.
- If and as needed, 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 co-located services, and enrolment into HIV clinical care.)

- Assess **mental health issues**, discuss **immediate concerns** and **offer referral to mental health services** for care or follow-up counselling and mental health services.
- Provide education on **ways to prevent HIV and STI transmission** and offer male and female condoms, lubricant and guidance on their use, but emphasize that **people with HIV who have an undetectable viral load and continue taking medication as prescribed have zero risk of transmitting HIV to their sexual partner(s) (U=U).**
- **Facilitate uptake of network-based testing services**, including family and household testing for children of people with HIV, partner services for sexual and injecting partners, and social network testing services for other contacts with ongoing risk.
- **Provide additional referrals for prevention, screening, diagnosis and treatment for related conditions** as appropriate (for example, tuberculosis (TB), STI, cervical cancer screening and treatment, prophylaxis for opportunistic infections, services for contraception, antenatal care (ANC), mental health, support for people who have experienced gender-based violence, opioid agonist therapy and access to sterile needles and syringes. Clients, such as pregnant women and key populations, who receive services with dual HIV/syphilis rapid tests or self-tests and have a reactive syphilis result need to have prompt linkage to further syphilis testing and/or treatment according to national guidelines and local resources.
- **Invite questions** throughout and provide time for the client to ask them.

Important message:
A person living with HIV who is on ART and virally suppressed cannot transmit HIV to sexual partners (U=U).

Box 4.1. Case example: B-OK bead bottles: a communication tool for HIV testing, linkage, adherence and viral suppression in South Africa and beyond

For many years "know your status" has been a central but insufficient message – communicating the *what* but not the *why* – within the HIV response. Health care providers have struggled to find clear and relatable ways to communicate the benefits of knowing one's status, and clients often experience health communication as overly technical or too abstract to understand.

Photo credit: Population Services International, South Africa

The B-OK bead bottles are designed to help health care providers simplify complex concepts in their counselling sessions among people with HIV. The tool consists of three bottles of beads, with red beads representing HIV and black beads representing healthy cells.

Mixed black and red beads: the body at diagnosis, with many black beads remaining but red beads beginning to multiply. "While you may still feel well at this stage, treatment is needed because the red HIV beads are multiplying and can also be transmitted to others."

Mostly red beads: HIV can overtake the body if someone avoids testing, delays starting treatment or stops taking treatment. "Your body can become vulnerable to other illnesses, making it difficult or even impossible to recover."

Mostly black beads and one red bead: viral suppression, the result of daily adherence to ART. "Your virus is under control but is still present. The single red bead is such a small amount that it cannot be transmitted to anyone else, but it also shows that treatment is still needed. Without treatment, the red beads will begin multiplying again."

In 2021 the tool was tested with health care providers in South Africa. They reported that the tool was easy to use, facilitated a clear and intuitive understanding of ART, prompted better discussion between client and provider and increased motivation for linkage and adherence.

"The bottles encourage adherence easily and assist with clients who are sceptical."
"After the demonstration, clients look forward to the virally suppressed state."

The B-OK bottles have proved to be a simple, low-cost, effective tool for supporting scale-up of effective, high-quality HIV counselling and have now been used by implementers in over 10 countries.

This work is led by Population Services International-South Africa.

4.2.2 Considerations for people with HIV-negative status

Providing appropriate post-test messages for those who test negative may require an assessment of the client's HIV-related risk, for example considering being from a population group with ongoing HIV-related risks or in a geographic area with high HIV incidence. In some settings where HIV positivity is generally low, such as ANC, individuals with an HIV-negative diagnosis may only need to receive their test result and do not need post-test counselling because their HIV-related risk is low. For those who are HIV-negative but face ongoing risk, or at low ongoing risk but with a recent discrete exposure, more discussion on retesting may be needed. Thus, the first step is assessing whether the client has substantial HIV-related risk and could benefit from being offered PrEP, or whether the client had an exposure in the past 72 hours and could benefit from being offered PEP *(11)*.

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 discussion about recent potential risk exposure, and, if so, eligibility for PEP and the need to return for a further test after six weeks;
- a reminder of the importance of telling the provider if one has HIV and is **now taking ART**, as this may affect test results, messaging and follow-up services;
- the importance of knowing the **HIV status of sexual partner(s), particularly in key populations**, and the availability of partner testing and network-based testing services;
- explanation of the benefits of PEP (for those with a discrete exposure in the past 72 hours) or PrEP (for those with significant ongoing risk) and linkage to PEP or PrEP services;
- if the pregnant woman or breastfeeding mother is HIV-negative but at significant ongoing risk, PrEP is an important option to prevent maternal infection and vertical transmission of HIV;
- information on other available and effective **HIV prevention options**, including condoms and lubricants; STI testing and treatment; VMMC; harm reduction for people who inject drugs; other sexual and reproductive health services, including contraception/family planning and prevention of mother-to-child transmission;
- for pregnant women, messages about the importance of strategies to prevent vertical transmission and, in high HIV prevalence settings, guidance to retest in the third trimester;
- advice on **retesting**, based on the client's level of recent exposure and/or ongoing risk of exposure
- correction of the common misconception that retesting is needed every three months due to the window period (see section 4.2.4 for details on retesting);
- opportunities for the client to **ask questions** and request further counselling as needed.

Individuals with a negative self-test result will generally not need further testing and the result should be treated as an HIV-negative diagnosis. PEP can be started and PrEP, including oral PrEP or the dapivrine vaginal ring, can be initiated, re-initiated or continued based on a negative self-test result.

Additionally, any individual manifesting signs or symptoms of acute HIV infection (AHI)[1] after a recent potential exposure to HIV should be advised to follow safe sex and safe injection practices and return for retesting in six weeks, as it is possible that they have AHI and could transmit to others in this period despite testing negative.

Based on the information shared by the client, including whether the person has had a recent potential risk exposure, providers will need to determine the appropriate messages on retesting.

[1] Acute HIV infection signs and symptoms may include with flu-like symptoms such as sore throat, fever, chills, morbilliform rash, fatigue, diarrhoea, oral and/or genital ulcers, swollen lymph nodes or body aches.

4.2.3 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 individuals may first self-test to learn their status or a lay provider may do outreach and use a single rapid test (that is, "test for triage") in the community. When such a test result is negative, the person testing is HIV-negative and does not need any further immediate testing. However, those at high ongoing risk should also be encouraged to promptly access PEP and PrEP, if and when eligible.

When such a test result is reactive (positive), the person needs further testing, beginning with the first test (A1) in the national testing algorithm. Self-testers and those tested in the community with reactive results may need support and encouragement to access onward testing and treatment services.

Settings using self-tests for HCV, syphilis, HIV or multiplex self-tests (i.e., HIV/syphilis) need to provide messages to direct individuals to follow-up services according to national guidelines. For example, individuals with a reactive HCV self-test need to be referred for further testing and if positive be started on treatment *(12)*. In the case of syphilis self-testing (SST), including HIV/syphilis self-tests, syphilis treatment following an initial reactive result may be advised for pregnant women if further testing is not available *(13)*. It will be important to align messages and clinical pathways for self-testing across disease areas.

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. In some cases, this may require offering further testing using a national algorithm in the community rather than in a facility.

4.2.4 Considerations for people with inconclusive HIV status

An HIV-inconclusive status means that an individual had discrepant results following testing services (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 (i) cross-reactivity exists between kits or client-related factors; (ii) the tester or test kit makes an error; and/or (iii) individuals have recently been infected and the immune response has not yet been established. All people with an inconclusive HIV status should be encouraged to return in 14 days for retesting.

Receiving inconclusive results could be confusing and stressful for clients and may be difficult for the provider to explain. Post-test counselling requires time so that the provider can 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 about the availability and benefits of ART should the retest result be positive.

Those suspected of having an AHI should be followed up closely. This is a period of high infectiousness due to high viral load. Clients need to be informed how to protect their partners, and they should come back for retesting in 14 days if their current test result is inconclusive.

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

4.3.1 Defining linkage

Regardless of HIV status, linkage is the first step toward onward services and essential for achieving programmatic impact (Box 4.2). HTS sites, testers and counsellors are responsible for ensuring linkage. They need to provide effective post-test services tailored to specific contexts, settings and/or populations.

Box 4.2. What is linkage?

Linkage to care is the deliberate establishment of a connection between the patient and the services they require. Linkage is essential for all people newly diagnosed with HIV to be initiated on treatment and for people re-engaging in care.

Linkage to further testing. In certain cases linkage to further testing is needed – after a reactive self-test or a test for triage, or for those with inconclusive status *(2, 14)*.

Linkage to ART. For all people diagnosed with HIV, WHO recommends that treatment be offered and ART be initiated as early as possible—preferably on the same day.

(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. Retesting can be a critical entry point, allowing for linkage from HTS sites to starting or resuming treatment *(2, 15, 16)*.

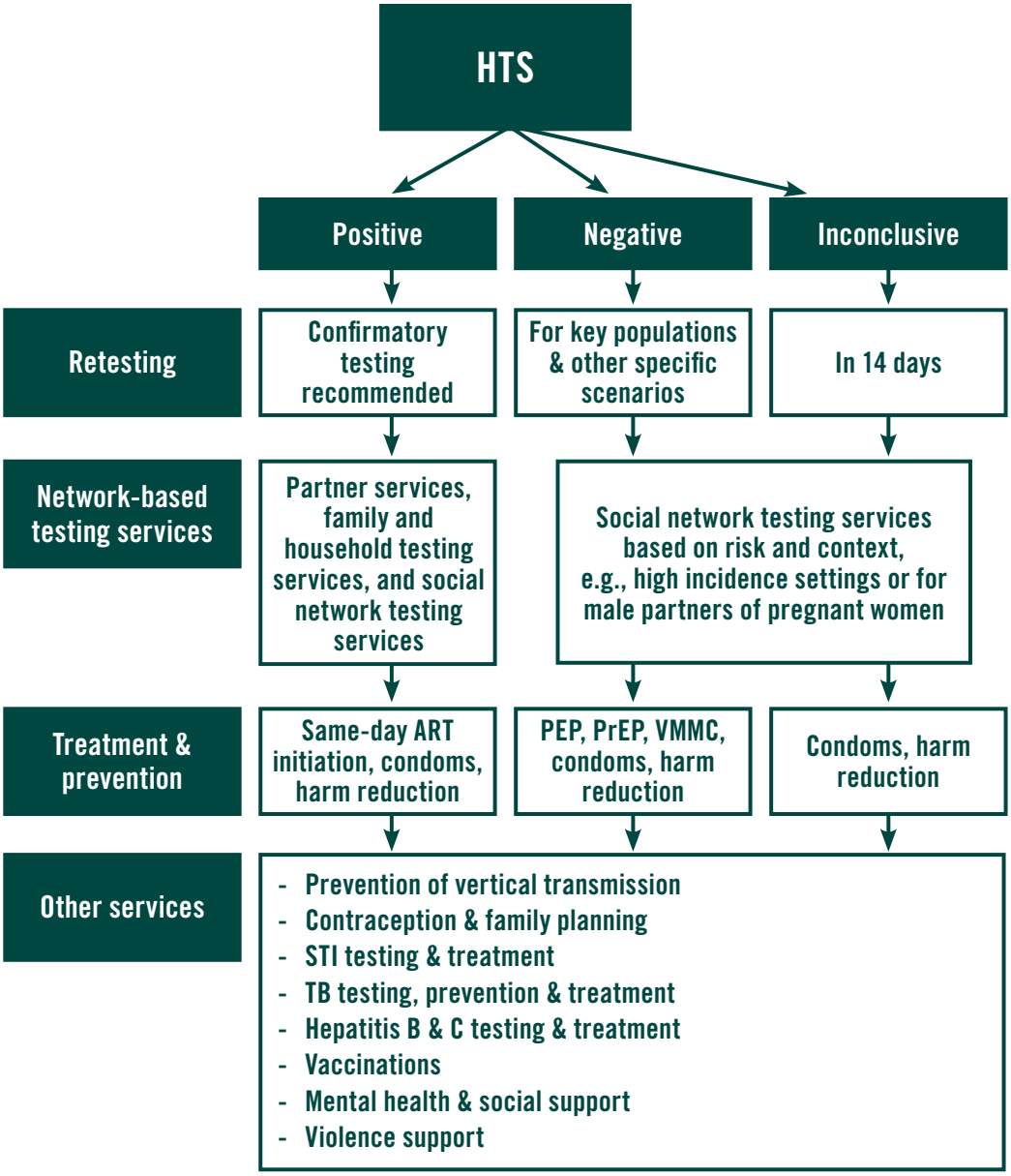
Linkage to prevention will depend on the person's ongoing needs, risks and vulnerabilities. While prevention services, such as information on HIV, sexual and reproductive health services, and condoms, are beneficial for all people testing for HIV, most people testing HIV-negative do not need to be linked to additional prevention services. For those who are HIV-negative but at ongoing risk and not currently using prevention services, linkage to a specific HIV prevention intervention may be beneficial. Those with a discrete exposure in the past 72 hours may be eligible for PEP. Those with ongoing risk of HIV may be eligible for PrEP.

Linkage to other services following testing may benefit many people, depending on the needs and circumstances of clients, such as sexual and reproductive health (contraception and cervical cancer screening), mental health and substance use services.

Some HIV testing services may be integrated, and so a client can receive treatment, prevention and other services at the same time and site. In other programmes specific linkages must be made to relevant services. For example, where testing services are integrated, such as using a dual HIV/syphilis rapid test, programmes need to prioritize linkage to syphilis treatment, as well as further syphilis testing when needed.

Fig. 4.1 summarizes WHO-recommended linkage pathways for people testing positive, negative or inconclusive.

Fig. 4.1. Post-HTS linkage pathways



A combination of interventions is needed to improve linkages to prevention, care and treatment and particularly to minimize loss to follow-up 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 *(2, 15-17)*.

4.3.2 Linkage to ART for people with HIV

Box 4.3 presents WHO recommendations and good practice statements on linkage to care and ART initiation. A recent scoping review highlighted that current evidence for linkage to care interventions is strongest for using case management, such as strengths-based case management, counselling, linkage coordination, and streamlined interventions, including task shifting, service integration, point-of-care testing, home-based testing and same-day ART initiation (where appropriate), mobile clinics *(18)*.

Box 4.3. WHO recommendations and good 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-certainty evidence for adults and adolescents, low-certainty 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-certainty 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) support for partner services, (iv) training staff to provide multiple services and (v) streamlined and co-located services *(moderate-certainty evidence)*;
- peer support (including peer counselling) and navigation approaches for linkage *(moderate-certainty evidence)*; and
- quality improvement approaches using data to improve linkages *(low-certainty evidence)*.

WHO good practice statements on linkage to treatment and care

ART initiation should follow the overarching principles of providing person-centred care. Person-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 individuals 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 even in settings in which rapid ART initiation is being implemented.

People should be encouraged to start ART as quickly as possible, including the offer of same-day initiation where there is no clinical contraindication.

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

Sources: WHO 2017 *(16)*, WHO 2016 *(15)*.

People may delay linking to services for several reasons, including individual and structural barriers such as distance to services, transportation costs, 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 and ART can be initiated on the same day, facilitate linkage to care and can be especially important for people who are ill with advanced disease *(19-22)*. In health facilities people who are newly identified as living with HIV should be initiated on ART at the same place that they are tested, if possible, without moving through multiple rooms and providers. 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 or to treatment and care following HIV diagnosis. Particularly for members of key populations, men, young people and pregnant women, 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 *(15, 16, 23, 24)*.

HIVST and community-based HTS

HIVST and community-based HTS can achieve good linkage rates, comparable to those for conventional facility-based services *(2, 14, 25-28)*, particularly for people with HIV *(27, 29)* and for those who would not test or receive preventive care otherwise *(2, 14, 26, 27)*. However, strategies may be needed to address linkage from HIVST and community-based HTS when it is suboptimal *(30-34)*.

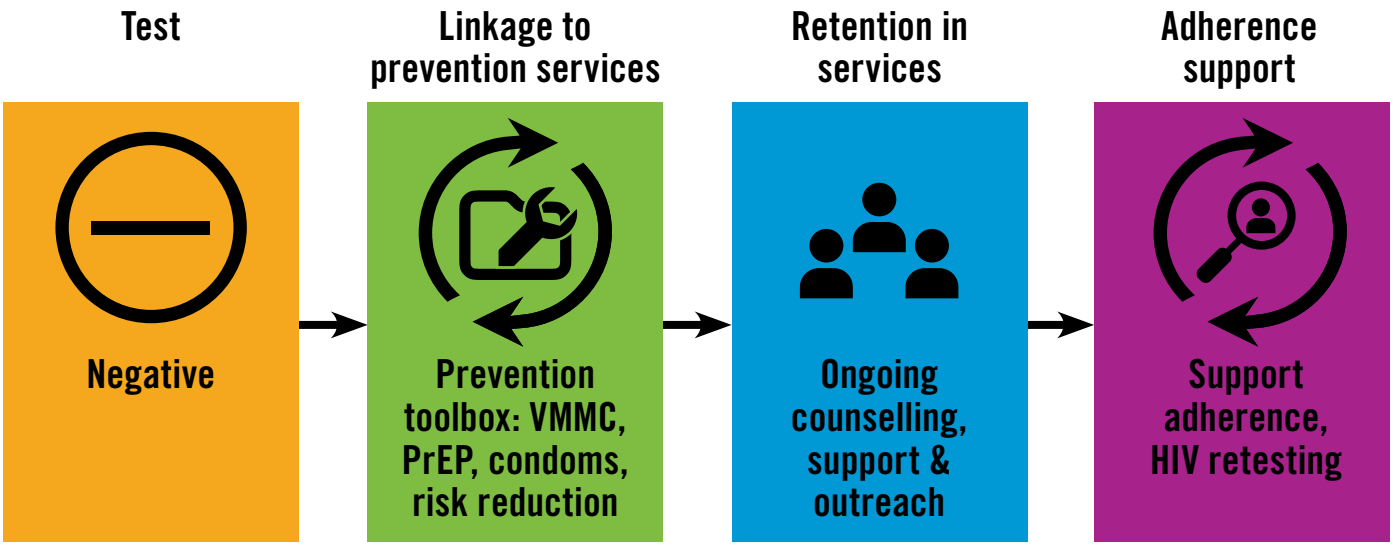
HIVST and community-based HTS can achieve good linkage rates, comparable to those for conventional facility-based services.

4.3.3 Considerations for linkage to HIV prevention and other services

In many countries, due to the declining number of people with HIV who do not know their status, the majority of people testing for HIV are likely to be HIV-negative. To maximize programme impact and improve cost–effectiveness, it is important to reach people who are HIV-negative but at ongoing risk and to link them to effective prevention, including PEP or PrEP. When these individuals attend HTS, it is important to facilitate linkage to prevention services. A range of HTS options, targeted to the specific needs of clients, presents an opportunity to reach people at high ongoing risk, link them to prevention services and support their continued adherence to preventive practices (Fig. 4.2).

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

Fig. 4.2. The HIV prevention continuum



Source: McNairy and El-Sadr 2014 *(35)*.

A WHO scoping review compared and evaluated programmes, interventions, strategies and best practices to support linkage to prevention *(18).* Current evidence on strategies to support linkage to prevention was strongest for services using peer-based support approaches, followed by forms of compensation, particularly for VMMC *(36)*. However, programmes need to consider the ethical and equity implications of incentives if introduced and the potential implications for universal health coverage.

4.3.4 Measuring linkage

Measuring linkage. Although it can be challenging, it is important for any programme providing HTS or HIVST to collect data on linkage to care as part of routine programmatic monitoring. Most programmes monitor linkage to care within 30 to 90 days of an HIV-positive diagnosis, monitor time to ART initiation within seven to 14 days after 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.

Measuring linkage can be particularly challenging for HIVST programmes in settings where facilities making HIVST referrals are geographically dispersed or numerous. In these cases, proxy indicators may be used, such as the overall number of new ART initiations in the region. Programmes seeking to measure linkage to care from HIVST may use a combination of the following strategies to support the measurement of linkage *(37)*:

- Monitor ART initiations at treatment centres/facilities before and during HIVST distribution in the relevant catchment area.
- Include questions in clinic registers that can help to ascertain if the present clinic visit/testing was prompted by prior HIVST use.
- Population-based surveys such as Demographic and Health Surveys, Integrated Biological and Behavioural Surveillance surveys and other, special surveys provide opportunities to monitor HIVST use and linkage at the population level.
- Digital tools, such as messaging apps, websites, hotlines and social media platforms can be leveraged to collect HIVST usage and linkage information.
- Individual-level follow-up to confirm linkage may be considered in small-scale demonstration projects or research studies to assess the effectiveness of linkage interventions.
- Mathematical modelling that estimates impact using local epidemiology and programmatic data.

Person-centred monitoring. The WHO *Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact* (2022) *(38)* describes the ethical and judicious use of individual health data to monitor the epidemic and guide health systems' response. When designing data collection and monitoring systems, a person-centred approach should be taken, in which the following principles are the foundation of data usage:

- using data for impact, with more granular data so that there is a stronger results chain linking services to reduced incidence and mortality;
- building HIV monitoring systems for chronic health care as people remain on treatment for life;
- digitization of health data, making the interconnection of different data sources possible.

Note that following new recommendations made in this guideline on the use HIVST to initiate and continue PrEP, indicators and monitoring approaches are in the process of being updated.

Box 4.4. Additional WHO guidance on ART initiation, HIV prevention services and monitoring and reporting

Guidance on ART initiation

- Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations; 2022. https://www.who.int/publications/i/item/9789240052390
- Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach; 2021. https://www.who.int/publications/i/item/9789240031593

Guidance on HIV prevention services

- Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance; 2022. https://www.who.int/publications/i/item/9789240053694
- Guidelines on long-acting cabotegravir for HIV prevention; 2022. https://www.who.int/publications/i/item/9789240054097
- Consolidated guidelines on HIV, viral hepatitis, and STI prevention, diagnosis, treatment and care for key populations; 2022. https://www.who.int/publications/i/item/9789240052390
- Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach; 2021. https://www.who.int/publications/i/item/9789240031593
- Preventing HIV through safe voluntary medical male circumcision for adolescent boys and men in generalized HIV epidemics: recommendations and key considerations; 2020. https://www.who.int/publications/i/item/978-92-4-000854-0

Guidance on monitoring and reporting

- Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact; 2022. https://www.who.int/publications/i/item/9789240055315
- Cascade data use manual to identify gaps in HIV and health services for programme improvement; 2018. https://www.who.int/publications/i/item/9789241514415
- HIV self-testing strategic framework: a guide for planning, introducing and scaling up; 2018. https://www.afro.who.int/publications/hiv-self-testing-strategic-framework-guide-planning-introducing-and-scaling
- WHO implementation tool for pre-exposure prophylaxis of HIV infection. Module 5: Monitoring and evaluation; 2018. https://www.who.int/tools/prep-implementation-tool

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Chapter 5

Service delivery approaches for HIV testing

Chapter contents

Key messages

Goals for HIV testing services (HTS)

- HTS should focus on **diagnosing and linking to care people with HIV who do not know their status,** linking to care **people who know their status but who never started treatment** and **linking those who test negative and are at substantial risk** of HIV acquisition to appropriate combination prevention.

HTS delivery approaches

- **Task sharing** and use of **trained lay providers** should be adopted to expand HTS, especially in community settings.
- **Integrating testing services should be a priority**, including the offer of HIV testing together with screening for other infections, such as viral hepatitis and sexually transmitted infections (STIs), as well as other noncommunicable diseases.
- A **strategic mix of differentiated HIV testing approaches** and models in and outside facilities is needed. Determining the best mix of testing approaches depends on epidemiology and resources available.
- **Facility-based HTS** remains a priority and should be routinely offered to all clients of unknown or HIV-negative status. Increasing testing coverage in settings where there are gaps should be a priority such as in STI clinics and sites delivering contraception.
- **Focused community-based HTS** effectively reaches certain populations less likely to access facility-based HTS, including key populations and their partners, young people and men.
- **Network-based HTS** should be offered, including a range of partner services and family and household testing services for all people with HIV, and social network testing services for all populations based on risks and epidemiology *(**new recommendations**)*.
- **Self-testing** is recommended for a range of infections, including HIV, hepatitis C, and syphilis, and can be an important tool for integrated service delivery. For example, self-testing can be implemented using a dual HIV/syphilis self-test *(**new recommendation**)*. Self-tests, including for HIV, can be utilized in focused community-based (including virtual and workplace), facility-based, and/or within network-based testing services. Self-testing can also be used to support PEP services as well as PrEP initiation, re-initiation or continuation **(*new recommendations*).**

5.1 Introduction

As many of the world's countries move closer to achieving the 95-95-95 HIV testing and treatment goals *(1)*, considerations guiding HIV testing service (HTS) delivery become increasingly important. Service delivery can be thought of as encompassing the 5 Ws – the who, what, when, where, and why – and it can be helpful to think about those questions when designing service delivery programmes.

Differentiated service delivery (DSD) approaches, in which testing and linkage services are designed to overcome specific barriers and to meet the needs of specific populations, may help achieve HIV prevention and treatment goals. Differentiated testing drives efficiency, quality, and equity, and focuses on strategies to effectively mobilize, test, and link people based on their unique context *(2)*.

Differentiated HTS should be client-centred and focus both on linking those diagnosed with HIV to treatment services and linking those testing negative to effective combination prevention services *(2)*, including pre-exposure prophylaxis (PrEP) *(3)*, when appropriate. While most people who test negative may not need linkage to additional prevention services, at minimum condoms and HIV prevention information should always be delivered.

To design an effective and efficient differentiated HTS plan, programmes need to select testing approaches and service delivery models based on their epidemic and available resources. Elements to consider include:

- decentralization, task sharing and test for triage
- integration of HTS with other testing and services
- facility-based HTS
- focused community-based HTS
- HIVST
- network-based HTS.

5.2 Health systems considerations for HTS delivery

5.2.1 Decentralization, task sharing and test for triage

Decentralization, task sharing, test for triage and self-testing can be considered across all HTS service delivery.

Decentralization of HTS refers to providing testing at peripheral health facilities, such as primary health care facilities, as well as outside of health facilities in the community, and it is a part of DSD. Providing HTS in places close to people's homes may reduce transportation and other costs and waiting times in central hospitals, thus improving accessibility and uptake. HTS in community settings may be particularly attractive for men, young people and key populations, who are less likely to test in facilities.

However, careful consideration is needed as sometimes it may not be acceptable or a good use of resources to decentralize, for example, key populations or other vulnerable populations may fear being seen attending nearby HIV-specific services due to stigma and discrimination, particularly in settings where key populations are criminalized. In low HIV burden settings, decentralizing HTS may be inefficient and costly, and the overall balance of benefits and harms should be weighed when deciding where HTS should be decentralized. Decentralization should also 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 intended to support and expand the role of trained lay providers to improve the accessibility and acceptability of HTS and address gaps in service delivery. WHO recommends that **trained lay providers, sometimes called community health or outreach workers, should be engaged and supported to deliver HTS using rapid diagnostic tests (RDTs)** *(4, 5)*. Lay providers can 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.

Box 5.1. WHO recommendation on task sharing

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

Source: WHO 2015 *(4)*

Some countries may need to update polices and regulations, or review how they are interpreted, to enable other non-clinical health professionals and trained lay providers to offer HTS (Box 5.1). See further WHO guidance on harnessing the full potential of community health workers, including lay providers *(6)*.

In **test for triage**, a trained provider performs a single RDT and then facilitates linkage to appropriate further testing and services depending on the test result. In the context of HIV, anyone who has an initial reactive test for triage is then promptly linked to further testing for confirmation of HIV status. This strategy is used for self-testing and can also be used to expand testing in communities by lay providers.

5.2.2 Integration of HIV testing with other health services

Integration is the co-delivery and sharing of services and resources across different health areas. Integration involves not only providing related health services in a common facility or community 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. In the context of HIV, this may include person-centred provision of HIV testing, prevention, treatment, and care services alongside other health services in the community or in facilities. WHO recommends the integration of HIV services, including HTS, in all epidemic settings and particularly in high burden settings.

HTS can be offered at public and private health facilities and other service points by identifying certain programmes as key entry points, such as STI, TB, ANC, key populations programmes in communities, and family planning. The primary purpose of such integration is to achieve greater coverage and impact, as more people get diagnosed for HIV and other diseases at the same time, which makes it cost-effective and cost-saving. This can help improve coordination and efficiency across the health system *(7, 8)*. Table 5.1 presents services that should be considered for prioritization *(4, 9)*.

Table 5.1. Integration priorities for consideration for HTS*

Service delivery setting	HIV	HCV	HBV	STIs
Health facilities				
ANC	X	X	X	X
Contraception	X			X
Standalone VCT sites	X	X	X	X
Inpatient & outpatient department	X	X		X
Emergency departments	X	X	X	X
TB clinics	X			
STI clinics	X	X	X	X
Immunization clinics	X		X	
Malnutrition clinics	X	X	X	
Community testing approaches				
Community outreach (KP)	X	X	X	X
Community outreach (GP)	X		X	X
Workplaces	X	X		
Additional testing approaches				
Prisons and closed settings	X	X		X
PrEP/PEP programmes	X	X	X	X
VMMC sites	X			X
Network-based testing	X	X	X	X
Self-testing	X	X		X

* This table is not exhaustive. It is important to adapt integration priorities based on local context and resources, epidemiology, co-infections and populations being served.

5.3 HTS delivery approaches

HTS can be offered through a range of service delivery approaches. The following section lists different types of approaches that can be tailored to specific contexts and populations based on resources and local epidemiology.

5.3.1 Facility-based HTS

Routinely offering HTS within different types of health facilities is a core aspect of the HIV response. The following section highlights existing guidance regarding HTS delivery settings.

Box 5.2. WHO recommendations on 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.**

NEW recommendation: HIVST may be offered as an additional option for testing at facilities *(conditional recommendation, low-certainty evidence)*.

For more detailed implementation guidance by population and epidemic see Chapters 6 and 7.

Source: WHO 2007 *(10)*, WHO 2015 *(4)*, WHO 2019 *(11)*.

Standalone testing sites, often called voluntary counselling and testing (VCT), were one of the earliest approaches whereby clients initiate HTS by requesting a test at a dedicated facility often run by community or nongovernmental organization. These sites are often linked to or based within health facilities or hospitals. Despite the potential limitations of stand-alone sites, they can be a useful option for reaching people less likely to attend traditional clinical services, such as men and key populations *(12, 13)*.

Self-testing in facilities. Facilities may offer self-testing in conjunction with other routinely offered testing services. Benefits of self-testing at a facility can be saving valuable health worker time, which was essential during the COVID-19 pandemic *(14)*. Facility-based self-testing can also increase testing capacity in sites where coverage is suboptimal and simplify implementation by replacing risk-based screening tools *(15)*.

Antenatal care (ANC). All pregnant women should be routinely offered HTS and be tested for syphilis and hepatitis B, at least once, and as early as possible during pregnancy to achieve triple elimination of mother-to-child transmission *(22)*. WHO also recommends that dual HIV/syphilis RDTs be used as the first test within the algorithm for pregnant women in ANC in all settings *(16)*, as well as for key populations *(12)*.

Contraception/family planning services provide an opportunity for HTS as part of sexual and reproductive health (SRH) and HIV prevention packages for adult women, adolescent girls and young women of reproductive age and their partners *(7)*. This is important in high HIV burden settings, where HIV incidence may be high among women seeking contraception services *(23)*.

Paediatric services. In high HIV burden settings, HTS should be offered to **infants and children** with unknown HIV status who are admitted for inpatient care or attending outpatient, malnutrition or immunization clinics *(7, 17)*. Parents may also be offered HTS if their status is unknown. 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 children living with HIV.

TB services. 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 should be routinely offered to all clients with presumptive or confirmed TB in any setting and intensified TB case finding among people with HIV to facilitate early TB detection and treatment *(27)*.

Clinical services for key populations. Specialized facility-based services for key populations to improve access to HTS can include drop-in centres, harm reduction services for people who inject drugs and clinical services in prisons and other closed settings. Key populations in many settings encounter barriers to accessing facilities for health services. When they do present for care, it is important to minimize missed opportunities for HTS.

Clinical services providing STI testing and treatment. HIV and STI co-infection is common *(29)*. STI clinics provide an important entry point for HTS and for combination prevention services that should be prioritized. WHO recommends routinely offering HTS to all people with STIs *(7)* and ensuring linkage to treatment and combination prevention as needed.

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)*. Integration is critical as noted above in ANC settings and may include other health facilities based on local epidemiology.

VMMC clinics. Voluntary HTS is part of VMMC service delivery in the 15 priority countries within eastern and southern Africa[1] *(33)*. Self-testing can be utilized as well as traditional provider-delivered testing services.

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 *(13)*. In high-burden settings, the routine offer of HTS in hospital emergency departments can be considered *(40)*. In low HIV burden settings, indicator conditions-guided testing *(17, 18)* and risk-based screening-in tools or questionnaires, which identify people who should be offered HIV testing, may help to increase coverage among those who may not test otherwise *(41)*. Screening tools should not be used to screen out or exclude people who would otherwise be offered routine testing or who request testing.

5.3.2 Focused community-based HIV testing services

Community-based HTS refers to services offered in the community, outside of a health facility. WHO recommends community-based HTS to increase uptake of HIV testing and related services, particularly among key populations and their partners, young people, men and others who may be less likely to come to facilities.

Community-based HTS and, increasingly, community-led HTS are an important component of DSD *(2, 19)*. The venues generally include outreach to hotspots and places where priority populations congregate, such as parks, injection sites, bars, clubs, cruising sites and saunas, and at events, places of worship, workplaces and educational establishments, sometimes with the use of mobile vans including home-based HTS *(4)* and self-testing. To be more efficient, community-based testing should be focused and consider integration as part of multi-disease outreach according to the local context, epidemiology and population being reached.

Workplace HTS is an effective strategy for reaching men in high burden settings and implemented within a framework of workplace policies that ensure confidentiality and protect workers from discrimination *(20)*. HIVST in the workplace can also be impactful *(20-22)*, particularly when offered within mining operations, transport and logistics sector, military and other uniformed services and informal sectors, such as taxi ranks and markets.

Mobile outreach can complement facility-based HTS in areas of low coverage and poor accessibility; and can be flexible to changing epidemiology and reach highly mobile populations.

Faith-based HTS, including the use of self-testing, can also be a promising approach for reaching people with undiagnosed HIV (23, 24).

Home-based HTS has potential to reach undiagnosed people in high-burden settings and can reach men effectively if offered outside of work hours. It is also important for implementing network-based testing for reaching the children of people with HIV. Studies show that delivery of home-based combination prevention interventions including HTS can reduce HIV incidence if high coverage is achieved and sustained *(25, 26)*. It is resource-intensive and should therefore focus on priority populations. Home-based HTS can also be useful within network-based services to reach partners, other family members or social network members.

[1] VMMC priority countries include Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, South Sudan, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

Community campaigns can include self-testing and may be useful when offered periodically, such as every 3–5 years *(27)*, within multi-disease outreach *(28)* and/or in high HIV burden settings. They may not be effective in low-burden settings unless highly focused on priority populations with high ongoing risk. While large-scale campaigns may not be efficient in identifying and supporting linkage to care among people with undiagnosed HIV, hotspot mapping and targeting efforts with local epidemiological data can potentially enhance the efficiency of this approach.

School-based HTS can be offered in the context of broader HIV prevention and SRH services, including within comprehensive sexuality education *(29)*. School-based HTS may be an entry point for adolescents for a range of health services for sexually active adolescents, especially in high HIV incidence settings.

5.3.3 Network-based testing services

WHO recommends network-based testing services, which includes partner services, family and household testing services and social network testing services (Box 5.3) *(11, 30, 31)*. Network-based testing approaches comprise a range of service delivery modalities that broaden the reach of testing services by supporting individuals to disclose to, refer for testing, and/or distribute self-tests to partners, families, and other members of their social networks. Such testing strategies may involve people with HIV, TB, STIs and/or viral hepatitis, as well as testing for their sexual and/or injecting partners, family members including children and other people in the home, and social contacts. Integration of network-based testing services across conditions should be considered based on local epidemiology, feasibility and available resources.

The following sections summarize the core network-based testing approaches that include partner services (including index testing), family and household testing services and social network testing services.

Box 5.3. WHO recommendations and good practice statements on network-based testing services

WHO recommendations

Provider-assisted partner services 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)*.

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-certainty evidence)*.

NEW recommendation: STI partner services should be offered to people with STIs as part of a range of options based on their needs and preferences and within a comprehensive package of voluntary STI testing, care and prevention *(strong recommendation, low-certainty evidence)*.

Remarks

- **Human rights:** STI partner services must always be voluntary and never mandatory. Coercive or forced testing is never warranted. All consenting patients should have their privacy protected and personal information should be kept confidential.
- **Important to offer options:** There are a range of STI partner services that should be offered based on patient preferences, feasibility and resources available. Partner services include several options, such as patient referral, enhanced patient referral, delayed provider referral, provider-patient referral, and provider-assisted referral and social network approaches. Approaches with provider support are particularly effective and can be prioritized or encouraged where feasible. Expedited partner therapy (EPT) could also be considered as part of partner services for some curable STIs, such as chlamydia or gonorrhoea.

- **Linkage:** Linkage to STI management services for sexual partners is an essential component of STI services.
- **Integration:** STI partner services should be based within a broader programme and package of services. It is important to build on existing services (e.g. sexual and reproductive health services and family planning services), and integrated delivery across disease areas (e.g. HIV and viral hepatitis).

NEW recommendation: Social network testing services may be offered as an additional HIV testing approach as part of a comprehensive package of care and prevention *(conditional recommendation, low-certainty evidence).*

Remarks

- Social network testing should always be offered as part of a broader package of network-based testing services that includes a range of options, such as provider-assisted partner services, enhanced partner referral and partner referral and family and household testing services.
- Offering self-testing as an option, already recommended by WHO, via social network testing approaches may increase acceptability, feasibility and uptake. However, it is important to tailor the use of self-testing to the context, epidemiology and resources available.
- To increase efficiency and optimize resource use, programmes should aim to provide a short, focused orientation session when initially preparing individuals to be "test promoters" who recruit and encourage others to test.

Provider-assisted partner services should be offered to all people with HIV-associated TB as part of a voluntary comprehensive package of HIV testing, care and prevention services *(strong recommendation, moderate-certainty evidence).*

In conjunction with health workers' representatives, develop and implement programmes for regular, free, voluntary and confidential counselling and testing for HIV and TB, including addressing sexual and reproductive health issues, as well as intensified case finding in the families of health workers with TB *(strong recommendation, moderate-certainty evidence).*

Household contacts and other close contacts of individuals with TB should be systematically screened for TB *(strong recommendation, moderate-certainty evidence).*

Good practice statements

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 partner services.

Encourage and offer HBV and HCV testing for family members (including children) and sexual partners. This can be done individually, through couples testing and partner services (e.g., provider-assisted partner services).

Individual cases with Mpox should be promptly interviewed as soon as possible to elicit the names and contact information of all potential contacts and identify places visited where contact with other people may have occurred. Contacts of cases should be notified within 24 hours of identification and advised to monitor their health status and seek medical care if they develop symptoms. In the current context, as soon as a suspected case is identified, contact identification and contact tracing should be initiated, while further investigation of the source case is ongoing to determine if the case can be classified as probable or confirmed; if the case is discarded, contact tracing may be stopped.

Sources: WHO 2012 *(32)*, WHO 2016 *(30)*, WHO 2016 *(33)*, WHO 2019 *(11)*, WHO 2024 *(34)*, WHO 2024 *(35)*, WHO 2024 *(36)*

Partner services

Partner services are a process whereby a trained provider offers voluntary testing to the sexual and/or drug injecting partner(s) of consenting people with HIV, STIs and/or viral hepatitis. Sometimes these services also include social network testing approaches which offer testing through clients who test negative more broadly based on local epidemiology and client risk.

Box 5.4 summarizes new evidence on STI partner services. See *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services (36)* for more details.

Box 5.4. Summary of key findings from systematic review on STI partner services

- **Enhanced patient referral probably makes little to no difference** when compared to patient referral.
- **Provider-assisted referral probably achieves greater impact** on partners' positive diagnoses and could increase the number of partners receiving treatment compared with patient referral; however, the magnitude of the effect on clinical outcomes is somewhat uncertain.
- **Delayed provider referral probably achieves greater impact** than patient referral on the number of positive diagnoses and the number of partners presenting for testing and care; however, the magnitude of the effect on clinical outcomes is somewhat uncertain.
- **EPT probably achieves greater impact** than patient referral on patient reinfection and number of partners treated.
- **Social harm appears rare** in all approaches based on the systematic review. Overall, there was no increase in social harm or adverse events following partner services, but patients and health workers still highlighted this as the main barrier for partner services.
- **Values and preferences expressed by health workers, patients and partners indicated that they generally find all STI partner services options acceptable**, although preferences varied for both patient-led and provider-led options based on context, relationships and time/resources available. Having options is important.
- **Feasibility is probably good for both patient-led and provider-led options**, but support was noted to be needed for: training, monitoring, ensuring adequate health worker time and resources, as well as a need for updated laws and policies (improving the enabling environment), using flexible and decentralized service-delivery options, building on existing services and systems from HIV, and investing in virtual service-delivery options.
- **STI partner services (particularly provider-led options) can be cost-effective but do require substantial investment.** Costs will vary based on setting, population and context, including whether there are existing programmes to build on or if new programmes need to be started. Options including EPT are generally more costly.

Source: WHO 2024 *(36)*

Partner services are an effective way to identify additional people in need of testing, prevention, and treatment services. Service delivery approaches often vary based on the setting, epidemiology, client preferences and resources available (Box 5.5). Some approaches include more provider support, such as provider-assisted partner services, whereas other approaches are driven by patient referrals. Evidence demonstrates that provider-assisted partner services, in which providers contact partners to notify them of an exposure and offer testing, are the most effective of all partner services approaches in terms of identifying and treatment people with HIV. The offer of self-test kits can be useful and may be

made in person, via phone calls or through online services. In many of these approaches, users can be anonymous. Whatever the context, partner services should always be voluntary *(2)* and clients should be informed about the options so that they can select the approach that is most suitable for them and their different types of contacts and partners.

Box 5.5. Methods for delivering partner services

Partner services are a process whereby a trained provider offers or supports the offer of voluntary testing to sexual and/or drug injecting partner(s) of consenting people with HIV, STIs and/or viral hepatitis. Partner services can be delivered in many ways, including partner referral and provider-assisted partner services.

Partner service delivery	Definition
Partner referral ***Sometimes called: patient referral***	Trained providers encourage clients to suggest testing to their partners, with or without disclosing their status. Providers advise clients on the need for partners to get tested, strategies for disclosing safely, and where and how partners can obtain testing, prevention services and treatment.
Enhanced partner referral ***Sometimes called: enhanced patient referral***	Trained providers use various support tools (written information, referral slips, web-based messaging, provision of HIVST kits) to facilitate the offer of testing by clients to their partners, with or without disclosing their status.
Delayed assisted partner services ***Sometimes called: contract referral, provider-assisted delayed referral***	Clients enter into an agreement with a trained provider to suggest testing to partners within an agreed period. If the partners do not access HTS or contact the provider within that period, the provider contacts the partners directly to offer voluntary HTS.
Provider-assisted partner services ***Sometimes called: index testing, assisted partner services, assisted partner notification***	Trained providers ask clients about their partners and then, with the consent of the client, inform partners of their potential exposure. The provider then offers voluntary testing and additional services to partners.
Expedited partner therapy (EPT) ***Only applicable to curable STIs***	Clients diagnosed with one or more STIs are provided STI treatment, either prescriptions or medications, to deliver to their sex partners without requiring partners to receive examination by a health worker.

Where feasible and acceptable to the client, provider-assisted partner services should be prioritized as it is more effective and provides the opportunity to offer comprehensive prevention interventions to partners who may continue to be vulnerable to HIV, STIs and/or viral hepatitis infection.

Provider-assisted partner services can be offered at the time of diagnosis of the 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 availability of resources.

Social network testing

Social network testing services draws upon and can supplement partner services. In social network testing, individuals (including those newly diagnosed, with established infection or testing negative) who have established risks are enlisted to encourage and offer testing to others in their social, sexual or drug-injecting networks with no emphasis on disclosure of their test results. By addressing confidentiality concerns and broadening the reach of testing to include members of different populations, such as partners and social contacts, social network testing services may have high acceptability and thereby reach more people who may not otherwise test.

To maximize impact, it is important to offer social network approaches within a broader package of voluntary network-based testing approaches, including partner services, to the extent possible. As noted for partner services, social network testing services should prioritize and consider opportunities for integration, particularly across HIV, STIs and viral hepatitis. Box 5.6 summarizes key evidence and implementation considerations that may improve the effectiveness of social network testing services *(31)*. See Box 5.7 and Web Annex A for more details.

Box 5.6 Key evidence and implementation considerations for social network testing services

Evidence when compared to standard testing

- Social network testing approaches may increase the uptake of HIV testing among sexual partners and social contacts of "test promoters"
- Social network testing may increase the number of first-time testers reached
- Social network testing may increase the number of people diagnosed with HIV
- No social harms or adverse events following social network approaches identified
- Social network testing approaches consistently found to be highly acceptable and feasible across different settings and populations
- Resource needs for social network testing likely vary by setting, but can be cost–effective and can have similar, or lower, costs compared to of community-based testing and partner services
- Social network testing may require less provider time than community outreach and some forms of partner services

Implementation consideration

- Peer-supported groups could potentially increase testing uptake compared to community outreach alone
- Self-testing can potentially increase uptake and linkage but may be costly and some users may prefer other testing approaches. It is important to consider resources and integration opportunities
- To maximise impact and acceptability, it is important to engage communities in the selection of test promoters
- If resources are available, multiple rounds of outreach may be effective and could lower the cost per diagnosis. However, fewer rounds may be more affordable and feasible, as it is less complex
- Incentives do not appear to be necessary to achieve good uptake
- Prioritized simple one-time training for test promoters is effective and practical to implement
- Consider implementation in coordination with other disease areas based on local epidemiology

Box 5.7. Case example: Assessing the performance of social network testing – United Republic of Tanzania

In the United Republic of Tanzania, social network testing services were offered in both community settings and health facilities using different approaches to reach different populations.

In community settings, social network testing was used to reach key and vulnerable populations. First, test promoters were identified through peers in the community and were given coupons to share with social contacts or others in their network. The social contacts of the test promoters then presented the coupons at health facilities for HTS. In health facilities, social network testing complements provider-assisted partner services by giving individuals an opportunity to reach social network members at substantial risk. In health facilities, social network testing was used as an adjunct to provider-assisted partner services l in order to reach social contacts at substantial risk who might benefit from testing but who were not elicited as sexual or injection partners of clients with HIV. These social contacts were then traced and tested either through the clients with HIV, or with assistance from health workers. HIVST kits were also made available to clients with HIV clients or tester promoters as an option for distribution to social contacts in both community settings and health facilities.

We analysed routine monitoring and reporting program data from October 2021 to March 2023 to assess the performance of social network testing in sites supported by the United States of America's President's Emergency Plan for AIDS Relief (PEPFAR) in collaboration with the Government of the United Republic of Tanzania. The assessment focused on the number of social contacts reached and the number of people with HIV newly diagnosed as key indicators.

A total of 121 739 social contacts were tested and 7731 (6.4% HIV positivity) previously undiagnosed individuals with HIV were identified through social network testing. Tested social contacts and newly diagnosed individuals were primarily female (80.6% of those tested, 79.4% of new HIV diagnoses). About two thirds of social contacts were reached with testing (78 763; 64.7%) and over three quarters of newly diagnosed HIV individuals were from the community setting (6376; 82.5%). During the assessment period, the number of social contacts tested increased by 11.5-fold (from 3739 in October–December 2021 to 43 058 in January–March 2023). Social contacts who were tested increased faster in facilities compared to community venues during the same period (7.6-fold community, 40.2-fold facility). Also, during the same period, new HIV diagnoses increased by approximately 6-fold. A higher number of younger people (below 34 years old) were tested compared to older people (34 years and older).

These results indicate that social network testing is a promising HIV case-finding approach, reinforcing the need for further scale-up to accelerate HIV epidemic control in the United Republic of Tanzania.

This work was led by the Centers for Disease Control and Prevention at PEPFAR-supported sites in the United Republic of Tanzania

Family and household testing services

It is also important to offer family and household testing services (often called index testing) to the children of clients with HIV when the HIV status of the child is unknown *(37)*. This approach to HIV testing and service delivery enables parents and their children to access care as a unit. Such approaches may improve retention and offer a convenient service for families affected by HIV.

Family and household testing can be done through a combination of facility and community services. Wherever family and household testing services are delivered, strategies to integrate services across disease areas should be considered.

Given the substantial gaps in diagnosing and treating children with HIV, it is important to scale up family and household testing for all children (under 19 years of age) of people with HIV, as well as nonbiological children in the household due to high HIV risk among orphans *(38)*.

When conducting family and household testing it is important to note that all infants, under 18 months of age, who may have been exposed to HIV during pregnancy (that is, born to mothers with HIV) or breastfeeding should receive HIV testing to ascertain their HIV status and to start ART immediately if diagnosed with HIV. Because of the persistence of maternal antibodies, antibody tests cannot be used, and virological testing such as nucleic acid testing (NAT), is required for infants under 18 months of age *(39)*.

5.3.4. Self-testing

Self-testing refers to a process whereby people collect their own specimen using a simple rapid test and then perform the test and interpret their results when and where they want. WHO recommends a range of self-testing approaches which can improve access to and uptake of testing services, including those for pregnancy *(40)*, HIV *(11)*, HCV *(41)*, syphilis and COVID-19 *(42)* (see for example, Figure 5.1). New dual self-tests, which can detect syphilis and HIV infection at the same time, are also recommended *(43)*. See Box 5.8 for a summary of self-testing recommendations.

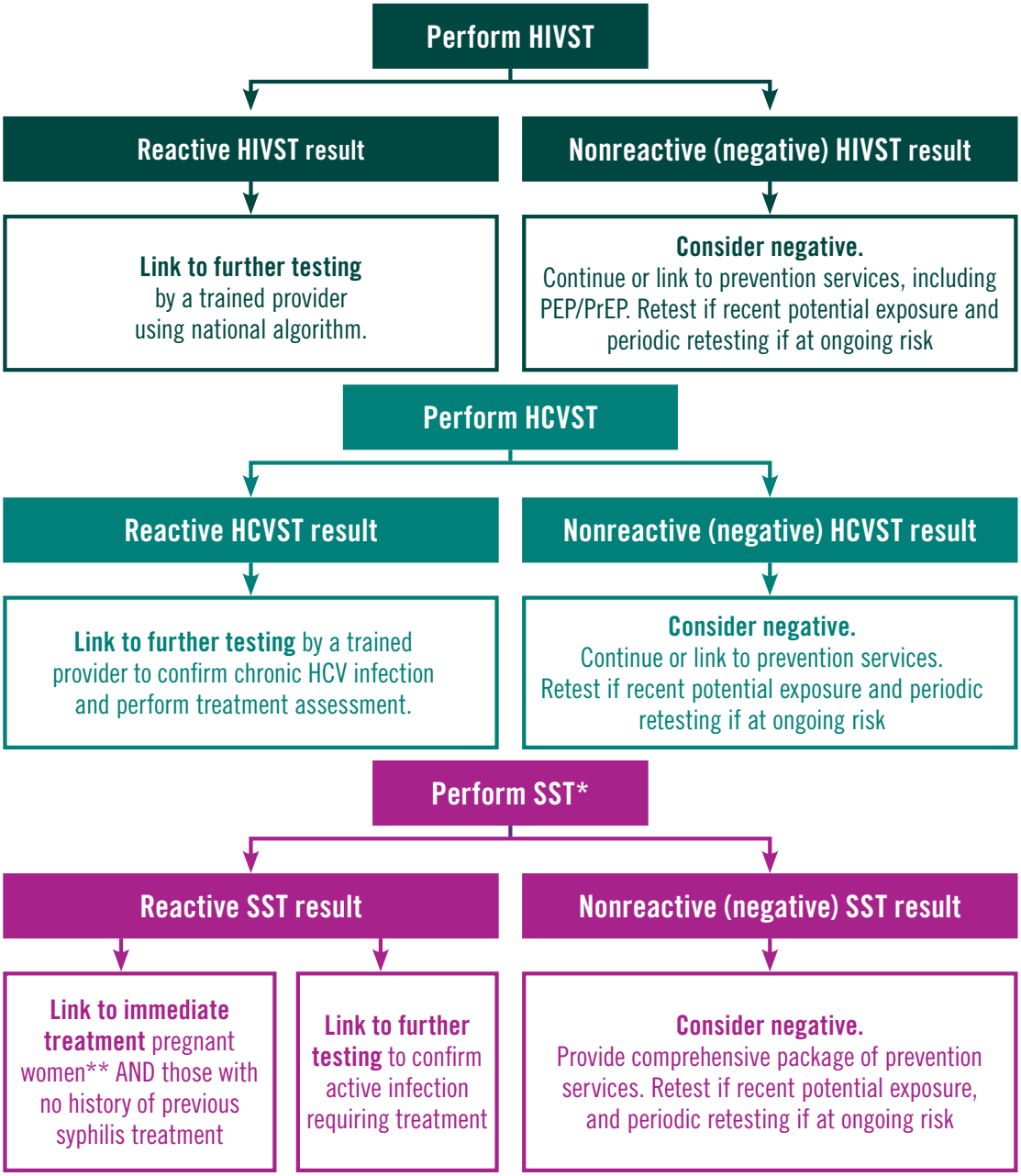
Self-testing has been consistently shown to be safe, acceptable, and effective in increasing the number of people tested, diagnosed with and treated. While efforts to optimize linkage are important, studies have consistently shown that linkage rates following self-testing continue to be high and comparable to standard testing *(44-46)*. The empowering nature of self-testing has also enabled people, including partners and people with limited contact with the health system, to access testing along with onward prevention, care and treatment services.

Self-tests could be distributed through pharmacies, vending machines, pick-up from a local store, distribution by peers, community-based distribution, online ordering, mail delivery and facility-based distribution. Self-testing can enable greater flexibility for clients and health services, particularly as part of simplified implementation of PrEP and PEP services *(3)*.

A range of support tools can be utilized to support self-testing implementation *(47)*, including virtual interventions and artificial intelligence *(48)*. Evidence has shown that both blood-based and oral fluid-based self-tests are acceptable, and different users have different preferences *(49-60)*. There is currently no evidence that there are differences in user uptake when offering either blood-based or oral fluid-based self-tests.

There are currently a range of affordable WHO prequalified self-tests that can be accessed: https://extranet.who.int/prequal/vitro-diagnostics/prequalification-reports/whopr.

Fig. 5.1. Testing strategy for HIV self-testing (HIVST), hepatitis C virus self-testing (HCVST) and syphilis (SST)



* *Syphilis self-testing strategy can be adapted to include quality assured products such as the dual HIV/syphilis self-tests and dual treponemal/non-treponemal self-tests. See* WHO's *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services* for further details *(36).*

** Treatment benefits for infant are greater than risks from maternal treatment. Therefore, treat all pregnant women with first dose of benzathine penicillin G (BPG) at point of care. Treat if patient cannot recall previous BPG injections. For persons who recall previous treatment, re-infection is possible. Treatment could be deferred until the non treponemal test results are available. However, if clinical suspicion is high, or loss to follow-up a possible concern, consider treating at the clinic visit.

Box 5.8. Summary of WHO self-testing recommendations

HIV self-testing (HIVST) is recommended as an approach to HIV testing services *(strong recommendation, moderate-certainty evidence).*

NEW recommendation: Syphilis self-testing (SST) is suggested as an additional approach to syphilis testing services *(conditional recommendation, low-certainty evidence).*

Remarks

- **Integration:** SST, as with all testing approaches, should be offered within a broader programme and package of services, which includes ensuring access and linkage to further testing (where available) and immediate treatment initiation. Opportunities to integrate syphilis self-testing into and/or to expand existing services should be a priority.
- **Quality-assured products:** SST may include products such as dual HIV/syphilis self-tests, treponemal self-tests and dual treponemal/non-treponemal self-tests. As with all testing approaches, SST should be conducted using quality-assured products.
- **Epidemiology and context:** Policymakers and implementers need to have a clear understanding that SST can be reactive with any current or prior infection by any treponematosis (e.g., syphilis, yaws, bejel or pinta) when determining how and where to deliver self-testing to specific populations and in certain geographies.
- **Clear messages:** Self-testers need to be provided with clear guidance about when they should test themselves, how to interpret their self-test results and, if needed, where to go for further testing and treatment. These further services are particularly critical when single treponemal self-tests are used that cannot differentiate previously treated infections from current infections. In endemic areas, it is critical to clarify that reactive serologic tests cannot differentiate between syphilis and other treponematosis (e.g., yaws). Self-testers may also need support tools to ensure they know how to self-test, and this can include instructions for use, videos, in-person demonstrations and support from peers or community health workers. Information about testing with a partner should also be provided, when appropriate, to encourage use of partner services.

NEW recommendation: HIVST may be offered as an additional option for testing at facilities *(conditional recommendation, low-certainty evidence).*

Remarks

- HIVST does not replace provider-administered testing. Individuals with a reactive self-test result should receive further testing from a trained provider using the full national testing algorithm.
- HIVST can replace risk screening tools* to optimize testing among those presenting at health facilities.

* Risk screening tools, provider- or self-administered, typically comprise questions designed to identify individuals with elevated HIV risk factors, such as their practices, symptoms or other characteristics. Tools are generally used to prompt testing among those who would otherwise not be offered testing (screening in) or to stop testing people who would otherwise be offered testing (screening out). WHO does not advise the use of screening-out tools.

NEW recommendation: HIVST may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation *(conditional recommendation, low-certainty evidence).*

Remarks

- HIVST may be an important tool to reach underserved populations with PrEP.
- HIVST is an option to support PrEP delivery; its use should be driven by client needs and preferences.

- There is a range of PrEP options available for which HIVST use could be considered, including oral PrEP and the dapivirine vaginal ring (DVR). HIVST can also be considered as part of post-exposure prophylaxis (PEP) implementation. Further research is needed on the role of HIVST in the use of long-acting injectable prevention options, such as cabotegravir (CAB-LA).

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

Source: WHO 2019 *(11)*, WHO 2021 *(41)*, WHO 2024 *(36)*

Syphilis self-testing

SST, including dual HIV/syphilis self-tests (HIV-SST), can help increase access to and uptake of syphilis testing and enable the scale-up of syphilis treatment. A WHO systematic review of evidence, highlighted the potential benefits particularly among key populations (see Box 5.9) *(43)*. In light of this evidence, the GDG determined that offering SST and HIV-SST would increase access to testing services, most likely improve equity, could alleviate the burden of testing at facilities and optimize health worker time depending on the context. Because most of the evidence was of low certainty, and there was likely considerable variability by setting, this is a conditional recommendation. See *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services (36)* for more details.

Box 5.9. Summary of key findings from systematic review on SST

Overall, the systematic review found that when compared with standard syphilis testing, SST, including HIV-SST:

- Improves uptake of syphilis testing;
- May reach similar proportion of people with a reactive syphilis test;
- May achieve comparable rates of linkage to further testing, care and treatment;
- Probably achieves good accuracy when using quality-assured products;
- Social harm is rare overall and potentially no effect, effect is however uncertain.

Additional findings on values and preferences and resource use include:

- SST, including HIV-SST, is well-accepted and desirable as a convenient and private approach. Programmes may need to invest in efforts to increase knowledge and awareness of self-testing and STIs overall, as well as service delivery models that provide support tools and demonstrations to optimize implementation.
- SST, including HIV-SST, can be cost-effective and affordable compared to standard syphilis testing services alone. Effective prioritization and targeting will be important however, particularly for reaching those less likely to access existing testing and populations with greatest syphilis risk and sexual partners of pregnant women.

Source: Towns 2023 *(43)*, WHO 2024 *(36)*

HIVST

WHO has recommended HIVST since 2016 *(30)*, and more than 100 countries have policies and are implementing HIVST *(61)*. A range of self-testing approaches can be implemented and are recommended, ranging from use in the community, in pharmacies, online, in facilities and through network-based testing services. These strategies need to be supported and scaled up *(62)*. Wherever self-tests are distributed it is important that key information and messages are delivered by providers and communities when questions or challenges arise (Box 5.10).

Additional detailed guidance on self-testing has been previously published and is accessible on the WHO website: https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36

Box 5.10. Key messages for providers, self-testers and communities engaging in HIVST

- **HIVST means testing yourself.** HIVST is for individuals who want to test and learn their HIV status on their own, in private, when and where they choose to test.
- 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 further testing by a trained provider, starting with the first test in the national testing algorithm.
- **Non-reactive HIVST results should be considered negative**, with no need for immediate further testing. Advice about later retesting should be based on national guidance. Individuals can start PEP or PrEP based on a negative self-test. For those with ongoing high HIV risk, messages should support linkage to, and/or continued engagement with, HIV prevention services.
- Those with **invalid HIVST results** need to repeat the test using another HIVST kit or 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 living with HIV and seeking retesting should be encouraged and supported to initiate, re-initiate or stay on ART.
- **Retesting** following a negative self-test result is necessary only for those at substantial risk, such as people from key populations and those with potential HIV exposure in the preceding 12 weeks.
- **Messages for people who use PEP and/or PrEP** may be needed tailored information on what to do after a reactive self-result. If using HIVST to initiate PEP or PrEP, individuals with a reactive result should be guided not to start PEP or PrEP and to seek further testing. If HIVST is used for PrEP continuation, individuals with a reactive result should be guided not to discontinue PrEP immediately and to promptly seek further testing.
- **Self-testing must be voluntary.** Offering an 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 has not recommended that parents or guardians use HIVST kits to test their infants or young 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.
- **Consider screening for acute HIV infection (AHI) in the context of PEP and PrEP delivery.** Screening clients for AHI – signs, symptoms and potential exposure – is often a requirement for PrEP initiation, along with an assessment for PEP (recent high risk of HIV exposure). For some clients additional HIV testing after one month of PrEP will be necessary to confirm that AHI was not present when PrEP was started *(39, 63)*.

Facility-based HIVST

Facility-based HIVST, while recommended, has not been considered in all settings due to uncertainty about whether it will be beneficial or just replace existing testing services. Some programmes which explored facility-based HIVST found it to be effective, however, particularly in settings with suboptimal HIV testing coverage. For example, in Zimbabwe offering HIVST in family planning clinics where HIV testing had not been routinely offered increased testing coverage among clients from 0.5% to 64% within three months of implementation *(64)*.

Some programmes also found that offering self-test kits at facilities was more effective, simpler and less costly than implementing risk-based screening tools which can miss important HIV testing opportunities *(11, 65, 66)*. Additionally, during the COVID-19 pandemic, many programmes opted to use HIVST in facilities to create health systems efficiencies and to maintain essential health services while there were health worker shortages *(14)*.

A WHO systematic review identified key evidence supporting facility-based HIVST which is summarized in Box 5.11 *(15)*. Considering the benefits of FB-HIVST, its acceptability and feasibility, lack of reported harms and potential for cost–effectiveness, cost-savings and improved equity, the GDG found that the overall benefits of facility-based HIVST outweigh the potential harms and recommended this as an additional approach to facility-based HIV testing. Because most of the evidence was of low certainty, and there was likely considerable variability by setting, this is a conditional recommendation. See Table 5.2 and Box 5.12 for implementation considerations, as well as Web Annex B for more details.

Box 5.11. Summary of key findings from systematic review on facility-based HIVST

Compared to standard testing services, facility-based HIVST:

- May increase uptake of testing
- May increase HIV positivity
- May achieve comparable linkage to care
- May be preferred and considered easier and more acceptable to clients
- Did not result in any social harms or adverse events
- May be cost-effective and potentially cost-saving.

Source: McGee 2024 *(15)*

Table 5.2. Facility-based HIVST service delivery models

Case-finding focus	HIV prevention focus
• In high HIV burden settings, to increase the routine offer of facility-based testing in key entry points, for example, primary care, outpatient departments, family planning clinics, STI clinics • Replacing risk-screening tools and so simplifying and streamlining HIV testing in facilities • Offered in clinics and drop-in centres for key populations • Secondary distribution to social, sexual or drug-injecting partners of people with ongoing HIV risk or newly diagnosed with HIV	• Offered in ANC clinics for maternal retesting and/or male partner testing • In harm-reduction clinics, including those offering opioid agonist maintenance therapy and/or needle and syringe programmes • In facilities delivering VMMC to support uptake and to test those accompanying patients • In facilities dispensing PrEP to support initiation, re-initiation, continuation and effective use • In facilities dispensing PEP (at either the beginning or the end of a client's course of treatment) • In facilities dispensing the DVR (at the beginning or throughout a client's use of the DVR)

DVR: dapivirine vaginal ring; HIVST: HIV self-testing; PEP: post-exposure prophylaxis

Box 5.12. Case example: Facility-based HIVST in family planning clinics – Zimbabwe

HIV incidence among clients at family planning clinics is high in Zimbabwe, while uptake of HIV prevention and treatment services is suboptimal. To address this gap, in October 2020 Zimbabwe began offering integrated person-centred screening and treatment for STIs, HTS, ART and PrEP for women seeking family planning services in four clinics.

To develop the new model, the Ministry of Health and Child Care and WHO, with funding from the Children's Investment Fund Foundation, formed a multi-agency team that visited family planning clinics to review staffing, client flow and service delivery data and then developed and introduced a modified HTS service delivery protocol. HTS options included provider-administered testing and HIVST for both clients and their partners. HIVST was available for use onsite in private spaces ("self-testing booths") or to take home. Staff members were trained to counsel and link clients receiving HIVST kits to appropriate services, including ART or PrEP. Clients who agreed to a follow-up were contacted by telephone for linkage to support services and further care.

Between October 2020 and December 2022, 18 756 women presented for family planning services at the four sites. A total of 6680 clients (35.6%) were tested for HIV, of which 6.7% (448) were diagnosed with HIV. All those diagnosed with HIV were referred for treatment, 4.7% (21/448) of whom were initiated on ART onsite. Of the 6232 clients with non-reactive test results, 2114 were assessed to be eligible for PrEP; 133 (6.3%) opted for PrEP initiation onsite, and the rest were referred to external PrEP services. In addition to the 6680 clients tested, a total of 2010 HIVST kits were distributed, with 1453 (72.3%) used directly by family planning clients and the remainder shared with partners. HIVST kits were used onsite or taken for use in a private location at the users' discretion. Among the 998 (68.7%) HIVST users who shared their results with providers, 7.6% (n=76) were reactive, and all of those individuals indicated that they confirmed their result with

provider-delivered testing. In a qualitative assessment, most clients interviewed indicated that they were satisfied with the integrated service package.

The project demonstrated high service acceptability and uptake by providing both HIVST and provider-administered HTS within the clinic setting. The approach is now being scaled up nationally.

Source: Ministry of Health and Child Care, Zimbabwe.

HIVST-supported PrEP and PEP

PrEP is the use of antiretroviral drugs by HIV-negative individuals to reduce the risk of HIV acquisition; WHO recommends PrEP for people with substantial risk *(3)*. Despite the increasing number of countries adopting and implementing PrEP *(67)*, many people who could benefit from PrEP do not have access *(68, 69)*.

Barriers to PrEP delivery include long wait times at often overcrowded health facilities *(69)*, the need for frequent facility visits for HIV testing and PrEP refills, which creates high opportunity costs for clients *(70)*, as well as the stigma associated with PrEP access and use *(71)*. Differentiated PrEP delivery models, including the easing of HIV testing requirements, are essential for engaging more people in PrEP services *(72)*.

HIVST can simplify PrEP delivery *(11)* and provide clients with greater convenience and flexibility. Potential approaches for using HIVST to support PrEP include:

- for linkage and demand creation
- for initiation
- for re-initiation (starting after a pause or extended break)
- for continuation.

A WHO systematic review found that HIVST-supported PrEP may achieve similar levels of PrEP continuation and/or refills *(73)*. Additionally, a WHO modelling study found that HIVST-supported PrEP would result in few missed infections, had a very low risk of leading to drug resistance at population-level and did not significantly contribute to programme costs *(74)*. There also did not appear to be a significant difference in outcomes when using oral or blood-based self-tests at population-level *(74)*. Evidence reviewed is summarized in Box 5.13. See Web Annexes C and D for more details.

Box 5.13. Summary of evidence for HIVST-supported PrEP compared to standard testing and PrEP services

Compared to standard testing and PrEP services, HIVST-supported PrEP:

- could result in a slight increase in or achieve similar number of PrEP initiations;
- likely achieves similar rate of PrEP continuation;
- could achieve similar levels of effective PrEP use;
- could contribute to increasing partner testing;
- did not affect or result in increased risk of social harm or drug resistance;
- was acceptable and feasible for people who use PrEP and providers, particularly when offered with instructional videos and support tools;
- can be cost-effective and affordable;
- has greater potential to reduce client opportunity costs by reducing facility visits.

Source: Kiptinness et al. 2022 *(73)*; Cox et al. 2024 *(74)*, Web Annex C

Based on the available evidence, it was determined that the overall benefits (broad acceptability and feasibility, potential cost savings and likely improved equity) outweighed potential risks. Thus, HIVST is recommended as an additional approach to support PrEP scale-up, including for initiation, re-initiation and continuation. This recommendation is conditional due to some limitations to available evidence and the need to learn how best to implement HIVST-supported PrEP from ongoing operational research. Research on the use of self-testing for long-acting PrEP is still underway and will inform future guidelines.

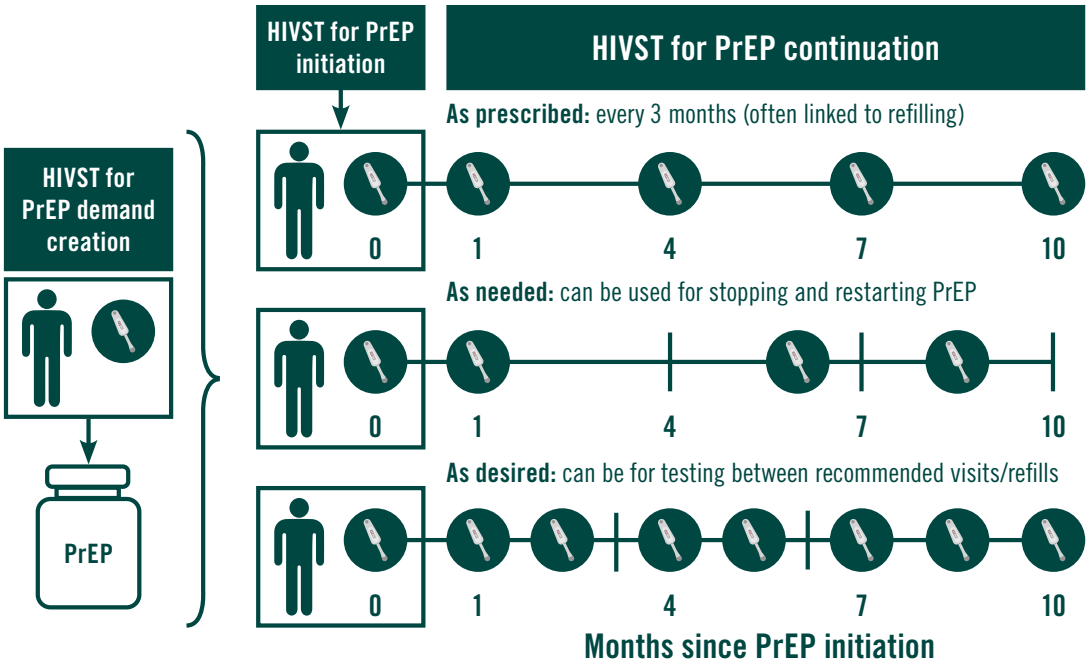
HIVST can also be used with a range of PrEP options, including oral PrEP or the dapivirine vaginal ring (DVR), as well as when dispensing PrEP refills. HIVST can also be considered for implementing PEP. After a non-reactive self-test, PrEP or PEP can be started and no other test is needed. For PEP, after completing the 28 day course, a self-test can also be used and further testing is only needed if reactive. Key strategies for implementing HIVST to support PrEP delivery may include creating demand for PrEP, expanding access to PrEP, simplifying PrEP initiation and continuation, and enhancing an individual's ability to use PrEP. Virtual interventions may also be important as described in Box 5.14.

Within these strategies, HIVST can be offered as part of PrEP delivery in the following ways (Fig. 5.2):

1. **As prescribed:** HIVST fully replaces quarterly provider-delivered testing among people who use PrEP, including for initiating, re-initiating and/or refilling PrEP prescriptions; provider-assisted options may be considered.
2. **As needed:** HIVST is used based on an individual's evolving risk and needs, including when making decisions with a provider about stopping or restarting PrEP.
3. **As desired:** HIVST is regularly used in combination with clinic visits to increase the frequency of testing, promote effective PrEP use or give individuals assurance and confidence.

For additional details on differentiated PrEP service delivery, see *Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance (3)*.

Fig. 5.2. HIVST-supported PrEP delivery approaches



Source: WHO 2024 *(75)*

Box 5.14. Case example: Web-based distribution of HIVST – Viet Nam

To improve access to HIV testing services for key populations, the Viet Nam Administration for HIV/AIDS Prevention and Control, with support from WHO, pilot-tested web-based distribution of HIV self-testing kits in three provinces between November 2020 and December 2021. This project sought to increase access to HTS and to assess feasibility, uptake and linkage to post-test services to inform national scale-up.

Clients who registered on a web-based platform requested HIVST kits and chose between delivery options (home delivery or pick-up). Voluntary reporting of HIVST results was encouraged. For reactive results, staff or peers supported clients to access further testing and linkage to PrEP or ART. Demographic information and risk behaviour information were collected at risk assessment and registration. A voluntary client satisfaction survey was offered online. Data were automatically stored and compiled in the web-based system. Staff documented post-test linkage in the same system.

In the pilot phase, 4320 clients registered on the website, and 3727 (86.3% of registered clients) ordered and received 4140 HIVST kits.* Nearly 600 others ordered and received condoms, lubricants and/or needles and syringes without HIVST. Most registered clients (90%) were male, and 92% were 15–35 years of age. Of those who received test kits, 3088 (74.6%) reported their results, including five clients who reported invalid results: 167 (5.4%) had reactive results; 159/167 (95.2%) of these were confirmed with HIV (nine tested negative on the confirmatory test); and 156/159 (98.1%) of clients with HIV initiated ART. Of 2925 clients who reported or confirmed negative results of HIVST, 584 (20.0%) initiated PrEP. Nearly all clients (98%) reported being "satisfied" or "very satisfied" with the services.

Since January 2022 the web-based HIVST distribution has been scaled up, with support from the Global Fund, to include an additional 22 provinces, and the number of HIVST kits distributed on a monthly basis increased from 300 in January 2022 to 1382 in October 2022. Of the total of 6982 tests distributed (January–October 2022), 46% of testers (3198/6982) reported results: 252 (8%) reported a reactive result, 70% of which were confirmed as HIV-positive; 86% of clients with a confirmed positive result initiated treatment; and 26% (757/2946) of individuals with an HIV-negative test result initiated PrEP.

Web-based HIVST distribution is acceptable and feasible and can identify additional HIV infections and support linkage to PrEP. This model can be scaled up or replicated in similar settings to help achieve national and global goals.

* *Some clients ordered more than once; clients could order more than once but only one test kit every three months.*

This work is led by the Viet Nam Administration for HIV/AIDS Prevention and Control.

5.4 Implementation considerations for successful delivery of testing services

Clear and supportive policies, regulations and standardized training and operating procedures need to be in place for testing and self-testing services. Programmes should ensure that **quality-assured tests are being used** and be able to utilize quality management and post-market surveillance systems to identify and address quality issues and adverse events.

Providers should be trained to support implementation of testing and self-testing. This includes capacitating lay providers to deliver testing and linkage to prevention and care and supporting self-testers who may have questions about the testing process, test interpretation or what to do if results are invalid or positive. Providers should always be available and prepared to provide support when requested.

Deliver **a strategic mix of approaches.** WHO recommends that countries offer a range of testing approaches to reach as many people with HIV who do not know their status as possible, as well as supporting those with high ongoing risk to engage with prevention services and to initiate and stay on PrEP.

Facility-based testing, community-based testing, network-based testing and self-testing services are all recommended and should be prioritized and adapted for implementation according to the local context.

Provide options. Where feasible, offering individuals choices and options is not only important to client-centred services, but will maximize access to and uptake of services. For example, WHO recommends individuals be offered a comprehensive package of network-based testing services which suit their needs. By offering choices, individuals can select the best options for reaching their partners, family and household members, and social contacts according to their preferences. Likewise, WHO recommends self-testing using both oral fluid-based and blood-based self-tests. By offering both, more people with varying preferences can be reached. Also, not everyone will want to self-test and will need to be supported to access testing services through facility or community settings.

Timing and frequency. Where possible and depending on availability of staff, offering testing in facility or community settings on flexible schedules – what some may consider "moonlight" or evening hours for key populations or on weekends or after working hours for men – may be beneficial. Outreach through communities, networks or distribution of self-tests can be conducted continuously, on a regular schedule or intensified during special events or campaigns. Within network-based testing services it may be important to offer clients different options at different times, such as giving time to process learning about a positive diagnosis and then following up at the next visit or re-engaging persons diagnosed with HIV who interrupt treatment or experience an elevated viral load.

Engage communities when designing testing services. Services are more likely to succeed when they have the community's buy-in or are community-led. This is particularly important for community-based testing, network-based testing and self-testing services.

Prioritize and focus services, particularly community-based testing and self-testing. When focused appropriately, these approaches can reach first-time testers, people with undiagnosed HIV infection with greatest unmet need for testing and linkage to care, as well as people who need improved access to prevention such as PrEP.

Resource use. The cost of different testing approaches varies widely by setting, and it is important to carefully consider cost and cost–effectiveness of each strategy, which may be affected by the local epidemiology, the populations reached, HIV positivity and the overall costs of delivering HTS in a specific setting. It is important that programmes consider not just the unit cost of a test kit but the full cost of services and client opportunity costs *(47)*.

Some delivery models, such as pharmacy sales, may be in the private sector and will incur costs to users, and this should be considered in the context of making testing accessible and affordable. Efforts to secure access to low-cost, affordable and/or free tests and self-tests should be prioritized wherever possible.

Support and linkage. Support and linkage to appropriate testing services needs to be a priority and sufficiently supported. Some populations, including self-testers, key populations, youth and those previously lost to follow-up or who never initiated ART, may need additional support. It is critical to also develop strong linkages to support people with high ongoing risk to link to and engage in prevention services, such as PrEP. Community engagement, as well as follow-up strategies and virtual interventions may be useful. Virtual tools may be particularly helpful for self-testers who prefer discreet channels that do not require seeing a provider, such as online videos, messaging or social media *(76-79)*. These may be acceptable, especially to young people, less costly than in-person support and easier to provide at scale.

Programmes should explore the best way to integrate testing and self-testing for their setting. This is particularly important for services that might be reaching the most vulnerable populations or those affected by different infections. For example, to support integration and impact, WHO recommends the use of dual HIV/syphilis testing for pregnant women and key populations. Where feasible, network-based testing services can also be integrated with testing and contact tracing for other infections such as STIs, TB and viral hepatitis to improve efficiency and optimize resource use. Self-testing and self-care can also be offered

across HIV, HCV *(41)*, syphilis (including with dual HIV/syphilis self-tests) and/or emerging STI self-tests *(43)*, as well as through integration of services with self-sampling technologies for STIs (chlamydia, gonorrhoea, human papillomavirus) *(40)*. Some opportunities could also include offering self-injectable family planning options *(80)* and leveraging virtual approaches such as those used for tele-PrEP *(48)*.

Services should be accessible and available to adolescents. To enable access, countries should review and, if necessary, revise national age-of-consent policies so that adolescents and mature minors can benefit from testing services, including self-testing. Aligning revised age-of-consent policies across self-testing and standard testing services, as well as with prevention and treatment services, should be prioritized. Messages about testing and self-testing should be adapted and appropriate for adolescents, promoting autonomy and self-care, for example.

Careful ongoing M&E are necessary to optimize testing and self-testing implementation. WHO advises countries to utilize pragmatic approaches which rely on routine data systems *(81, 82)*. It is important for programmes to review their local data regularly and apply lessons learned to optimize programming. This will require developing an M&E plan, selecting key programme indicators, collecting relevant data, reviewing progress regularly and adjusting service delivery accordingly.

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Chapter 6

Guidance for HIV testing services among priority populations

Chapter contents

Key messages

Efforts to provide and expand HTS should prioritize populations most affected by and at high ongoing risk of HIV infection, including specific individual or structural vulnerabilities. HTS works best when designed to address each priority population's needs and preferences.

Populations that need consideration for prioritization in a particular setting depend on local epidemiology. These include key populations and their partners, men, adolescents, young people, pregnant and breastfeeding women and girls, infants and children, serodiscordant couples, sexual and drug injecting partners of people with HIV, migrants, refugees, displaced populations and other vulnerable groups.

Key populations are often at higher ongoing risk of HIV infection regardless of setting. They include men who have sex with men, people in prisons and closed settings, people who inject drugs, sex workers, and trans and gender diverse people. Access to HTS, HIV prevention, treatment and care is inadequate, and countries should address barriers that impede their access and support acceptable and integrated HIV, viral hepatitis, and STI testing services for key populations

Men with HIV are less likely to access testing, prevention, treatment and care than women, and services are often not structured to serve them. In east and 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 specifically to reach men.

Adolescents (10–19 years) and young people (15–24 years) remain vulnerable to HIV, and they are less likely to test than adults, particularly those from key populations and in high HIV burden settings of east and southern Africa. Programmes should prioritize focused, adolescent-friendly approaches that include key population groups according to local epidemiology and context and integrate HTS into sexual and reproductive health services. Programmes should also review and revise laws on age-of-consent to test for HIV.

Pregnant women should be tested for HIV, syphilis and hepatitis B at least once during pregnancy, preferably in the first trimester. Dual HIV/syphilis rapid testing can be considered as the first test in antenatal care (in combination with a single HBsAg test for hepatitis B, where epidemiology warrants), except for women on antiretroviral therapy (ART) and women already treated for syphilis during the current pregnancy. In resource-limited settings, programmes may focus 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.

Infants and children who are HIV-exposed should receive virological testing for HIV as early as possible so that ART can be started immediately for HIV-positive infants. Approaches to increase HTS coverage among HIV-exposed children include network-based testing, including biological children, when testing families of people with HIV. Intensified case-finding efforts are also needed for in-patient and nutrition clinics in high HIV-burden settings to reach undiagnosed children and those who may be out of care. Training and tools to nudge providers to offer testing to sick children can be beneficial when routine testing is unavailable.

Contacts and sexual and drug-injecting partners of people with HIV and other HIV-related risks can be reached through network-based testing services; this is a priority. WHO recommends countries offer a package of network-based testing approaches, including self-testing, to expand testing, prevention and treatment services.

Migrants, refugees and displaced populations in high HIV burden settings may be at high risk of HIV infection and face social vulnerability. Integrated testing services, particularly for HIV, viral hepatitis and STIs, and onward prevention and treatment services must be made available to them.

Other populations that are vulnerable to HIV identified by countries should have HIV services tailored to their needs and context, such as truck drivers, uniformed services personnel, fisherfolk and indigenous people.

6.1 Delivering HTS for priority populations

Priority populations are those (i) that are most affected by HIV and at high ongoing HIV risk of HIV acquisition and transmission; (ii) in which it is critical to achieve and sustain low HIV incidence; and/or (iii) have specific individual or structural HIV-related vulnerabilities *(1)*. While key populations are a priority for HIV programmes in all settings, other populations, as detailed below, may also be a priority based on country context, setting or local epidemiology.

HIV testing services (HTS) will work best when designed specifically to address each priority population's diverse needs and preferences *(2, 3)*. This chapter highlights key considerations for the implementation of HTS for priority populations. WHO has issued recommendations relevant for most priority populations in all settings (see Table 6.1). Population-specific recommendations are presented in relevant sections of this chapter.

Table 6.1. HTS approaches to consider for selected priority populations*

Priority population	Facility-based services	Community-based services	Self-testing	Network-based testing services
Key populations	Routine in all facilities and testing sites serving key populations; HIVST in facilities	Mobile or outreach testing for key populations in all settings	Offer full range of self-testing options in all settings across HIV, HCV, syphilis	Offer to partners and social contacts of key populations
Men	Routine in high HIV burden settings; HIVST in facilities Focused in other settings, for example, indicator condition- or risk-based	Workplace testing in high-burden settings	Peer distribution or to male partners by ANC clients in high burden settings	Offer to partners and social contacts of men who have sex with men
Adolescents (10-19 years) and young people (15–24 years)	Routine in high HIV burden settings; HIVST in facilities Focused in other settings, for example, indicator condition- or risk-based	In high burden areas, offer in settings such as educational institutions or sports festivals	Online distribution via social media in high burden settings	Offer social network testing to young people
Pregnant and postpartum women	One test routinely in ANC in all settings Retesting: routine in late pregnancy in high HIV burden settings; and for those at ongoing HIV risk, such as pregnant and breastfeeding women from key populations or who have partners from key populations or with HIV	In high 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 Self-testing for HIV and syphilis could be beneficial in settings with low testing and treatment coverage	Offer to partners and social contacts of pregnant women; and follow-up family and household testing for biological children of women diagnosed with HIV
Infants and children	Routine in high HIV burden settings In other settings, focus on children with an indicator condition or with a parent with HIV	HIV-exposed children and children with a parent with HIV	Not for children < 18 months of age See further information in Web Annex E	Outreach to increase family and household testing including biological children of people with HIV is a priority in all settings

* Partner services should be offered to all people with HIV to reach their sexual and/or drug-injecting partners as well as including the biological children whose HIV status is unknown.

6.2 Key populations

A comprehensive HIV response must include key populations and their partners *(1)*. Latest estimates indicate that more than half of all new HIV infections are among key populations – men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and trans and gender diverse people – and their sexual or drug-injecting partners *(4)*. Members of these key populations and their partners often have poor access to health services and are at high ongoing risk of HIV in all settings, as a result of specific higher-risk behaviours and vulnerabilities related to stigma, restrictive policies and punitive laws, *(1, 5)*.

Box 6.1 summarizes WHO recommendations and good practice statements on testing for key populations.

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

- Lay providers, **including members of key populations,** who are trained and supervised can independently conduct safe and effective HIV testing services using RDTs *(strong recommendation, moderate-certainty evidence)*.
- **Dual HIV/syphilis RDTs may be considered for use in key populations** more broadly to increase access to both HIV and syphilis testing services. Further testing to confirm syphilis diagnosis or offer of treatment depends on national protocols, treatment history, local epidemiology and resources.
- Differentiated HIV testing services should be routinely offered for all clients from key populations in all clinical settings. **Integration of services should be prioritized and considered for key populations.**
- All pregnant people from key populations who are of negative or unknown status or whose partners have HIV should be retested in the third trimester. If the first test or retesting in late pregnancy is missed, catch-up testing is needed. **An additional retest in the postpartum period** could be considered for women from key populations and in specific districts/provinces with high HIV burden or incidence.
- **Self-testing should be offered as an additional testing option for HIV** *(strong recommendation, moderate-certainty evidence)* **and can also be offered for syphilis** *(conditional recommendation, low-certainty evidence)*
- **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-certainty evidence)*.
- **Network-based testing is recommended for key populations**, including social network testing *(conditional recommendation, low-certainty evidence)* and partner services *(strong recommendation, moderate-certainty evidence)*, as well as partner testing with support for mutual disclosure *(strong recommendation, low-certainty evidence)*.

Source: WHO 2015 *(6)*, WHO 2016 *(7)*, WHO 2016 *(8)*, WHO 2017 *(9)*, WHO 2016 *(10)*, WHO 2022 *(1)*.

To ensure HTS, including linkage to prevention and treatment services, are successfully implemented and effectively reach key populations, it is imperative that services are delivered in an ethical manner according to the WHO 5 Cs and within a safe environment, without the involvement of law enforcement *(7)*. 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, and continuity of all appropriate care between prison and community must be assured *(8)*. Key population-led and community-led service delivery, including through the use of lay providers, are important strategies for providing effective and stigma-free testing, prevention and treatment services.

Integration of testing services is essential for key populations, particularly for testing and screening for STIs, TB and viral hepatitis, which are reported at high rates among key populations (for example, see Box 6.2).

This should be coupled with access to integrated and comprehensive packages of prevention and treatment across infections and health needs. For example, women from key populations should receive a full package of reproductive, maternal, neonatal and child health services as needed *(9, 11)*. Programmes using the dual HIV/syphilis rapid tests or self-tests also need to ensure access to further syphilis testing and treatment as needed.

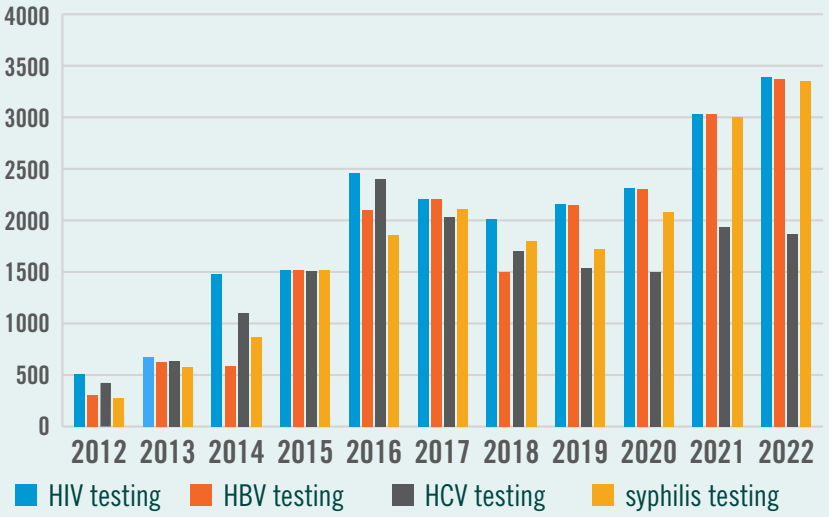
Box 6.2 Case example: Providing integrated services for key populations – Georgia

In Georgia, the HIV epidemic is concentrated among key populations, and integrated community-based testing, together with prevention services, is implemented by a network of community-service organizations. Among them is Association Xenon in Zugdidi, which works primarily with people who inject drugs. Zugdidi is located in the Samegrelo region, which borders the Abkhazia conflict zone and has the highest HIV, TB and viral hepatitis burdens in the country. According to the 2022 Integrated Biological and Behavioural Surveillance report, HIV prevalence was 2.7 times higher in Zugdidi than the overall HIV estimated prevalence in Georgia among people who inject drugs.

Xenon was established in 2004 to serve the most vulnerable populations in the region, and it has earned the trust of the community and support from local stakeholders. The initial package of services included HIV and drug injection risk reduction counselling, testing for HIV, HBV, HCV and distribution of communication materials. Xenon also provides needle and syringe services. In 2012, lay provider testing was introduced and in 2016 Xenon began providing mobile outreach using integrated HIV, HBV, HCV and syphilis testing in more than 10 cities in the region. This effort led to a 60% surge in testing coverage among individuals who inject drugs when compared with the start of mobile outreach services in 2014.

Fig. 6.1 summarizes the number of RDTs performed for HIV, HBV, HCV and syphilis since 2012 at the Xenon testing services centre and through mobile outreach.

Fig. 6.1. Numbers of RDTs performed by Association Xenon, 2012–2022



Source: Association Xenon

Since 2012 Xenon has linked to care 104 people with HIV, 853 people with a positive HBsAg test result, 5130 people with HCV antibodies and 337 people with syphilis. Between 2018 and 2022 Xenon used point-of-care RNA HCV to identify 1494 anti-HCV-positive clients, of which 82% (1225) were tested for HCV RNA, 691 (56%) were confirmed with active HCV infection, and 470 (68%) received free direct-acting antiviral treatment through the National Hepatitis Elimination Programme.

The achievements of Xenon and its partners were crucial in convincing the government to start investing in community-based testing of people who inject drugs and other key populations. The government now fully covers the cost of testing for all four infections as well as HCV RNA testing.

This work was supported by the Global Fund HIV Programme of Georgia and FIND.

6.3 Men

Globally, men with HIV, 15 years of age and older, are less likely than women in the same age group to know their status, to be on treatment and to be virally suppressed *(12, 13)*. These gaps are greatest in sub-Saharan Africa *(14)*. Men from key populations bear significant HIV burden, and outside Africa, they account for more new HIV infections than women from key populations *(1)*.

Men have limited opportunities for accessing health services and may suffer from stigma, fear and bearing a high cost to themselves and their families when trying to access services *(14, 15)*. As a result of poor engagement in HIV services, in many settings HIV-related morbidity and mortality rates are higher among men than women *(12, 16, 17)*.

Investment in reaching men in all their diversity with HTS is a priority and will not only improve health outcomes for men but will also contribute to reducing new infections in women (Box 6.3) *(14, 18)*.

Box 6.3 summarizes WHO guidance on testing and linkage services for men.

Box 6.3. Summary of WHO HTS guidance for men

- A strategic mix of differentiated HTS approaches is needed to reach more men and link them to appropriate prevention and treatment services. This includes offering facility-based testing, community-based testing, network-based testing and self-testing services. **Increasing entry points** for HIV testing for men is important, including reducing fear and stigma.
- **In high HIV burden settings**, HIV testing services should target men in all services, including STIs, viral hepatitis, TB, ANC (through partner services), and all services for key populations. These should be complemented by focused self-testing for HIV *(strong recommendation, moderate-certainty evidence)* and syphilis *(conditional recommendation, low-certainty evidence)* as well as focused community-based testing services (including workplaces) *(strong recommendation, very low-certainty evidence)*. Self-testing may be particularly beneficial when distributed by pregnant and postpartum women to their male partners.
- VMMC remains an important priority in many countries* and HIV testing, including self-testing, needs to be fully integrated within service delivery.
- **In low HIV burden settings**, HIV testing should be offered to men who are clients from key populations and those with medical conditions or symptoms suggestive of HIV, viral hepatitis, STIs, diagnosed or presumptive TB or other indicator conditions.
- **Network-based testing is recommended for men**, including social network testing *(conditional, low-certainty evidence)* and partner services *(strong recommendation, moderate-certainty evidence)*, as well as partner testing with support for mutual disclosure in all settings *(strong recommendation, low-certainty evidence)*.

* *There are 15 priority countries in east and southern Africa where VMMC is to be implemented.*

Sources: WHO 2007 *(19)*, WHO 2007 *(20)*, WHO 2015 *(6)*, WHO 2016 *(7)*, WHO 2016 *(8)*, WHO 2020 *(21)*, WHO 2021 *(22)*, WHO 2023 *(14)*.

To ensure HTS, including linkage to prevention and treatment services, are successfully implemented and effectively reach men it is imperative that services are delivered in settings accessible and acceptable to men. Offering testing, prevention and treatment services in male-friendly settings which do not primarily focus on women and children and offering services at non-traditional times, such as after working hours and weekends, may be useful. Additionally greater network-based testing and self-testing may engage partners and peers to help promote testing to men and create more convenient and flexible services. This can be important for overcoming barriers to testing among men.

Given the high rates of advanced HIV disease among men *(23, 24)*, it is imperative that programmes try to streamline services and offer men who are sick and presenting at facilities a complete package of HTS and advanced HIV disease services. Messages to promote early testing and to increase routine offer of testing to men in facilities needs to be a priority, particularly in high HIV burden settings. Additionally, ensuing men are receiving up to date information on treatment and U=U may also be useful to accelerate demand for testing and ART initiation, and to support engagment in care.

Providing HIV testing along with other testing and screening services, such as body mass index, blood pressure and blood glucose screening, works well in formal and informal workplace settings and may reduce HIV-associated stigma and increase HIV test acceptance. Integrating testing for HBV/HCV, human papillomavirus (HPV) and other STIs, should be considered where appropriate.

6.4 Adolescents and young people

In some settings, adolescents (10–19 years of age) and young people (15–24 years of age) remain vulnerable to HIV and are less likely to access testing services than adults; many remain undiagnosed and, therefore, untreated *(13, 25)*. The gap in knowledge of HIV status is even greater among adolescents from key populations *(8, 12, 26, 27)*, often due to stigma, discrimination and criminalization.

Some of the key barriers that can hinder adolescent access to services is the lack of provider training and the lack of aligned age-of-consent policies for HIV testing, prevention and treatment. Without aligned and clear policies, many young people may not be able to test or self-test, or even be linked to effective treatment and prevention services. WHO reviews of national policies has shown that the lack of alignment and support for young people to access testing services remains a challenge in many settings *(28, 29)*. Revising policies across health areas is also important as adolescents need to be able to receive comprehensive sexual reproductive health services and education.

Box 6.4 summarizes key WHO guidance for testing and linkage services for adolescents and young people.

Box 6.4. Summary of WHO HTS guidance for adolescents and young people

- Governments should review and revise age-of-consent policies, recognizing adolescents' right to make choices about their own health and well-being. Surrogate decision-makers in HTS for adolescents without parents can be considered.
- Lay providers, **including young people**, who are trained and supervised can independently conduct safe and effective HIV testing services using rapid diagnostic tests *(strong recommendation, moderate-certainty evidence)*.
- **A strategic mix of differentiated HTS approaches is needed to reach adolescents and young people** and to link them to appropriate prevention and treatment services. This includes offering facility-based testing, community-based testing, network-based testing and self-testing services.
- Facility-based HTS should target sexually active adolescents, particularly young women and girls in high HIV burden settings, and adolescent key populations in all settings. These should be complemented by focused self-testing for HIV *(strong recommendation, moderate-certainty evidence)* and syphilis *(conditional recommendation, low-certainty evidence)* as well as focused community-based testing services *(strong recommendation, very low-certainty evidence)*.
- 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-certainty evidence)*. Additionally, adolescent girls (ages 9–14 years) should be offered HPV vaccination as per national guidance *(strong recommendation, moderate-certainty evidence)*.
- Risk-screening tools that help reduce missed opportunities and increase the number of adolescents being offered testing could be considered, particularly in settings where adolescent testing coverage is suboptimal, and it is not currently feasible to routinely offer testing at all key entry points.

Sources: WHO 2019 *(11)*

To ensure HTS, including linkage to prevention and treatment services, are successfully implemented and effectively reach adolescents and young people it is imperative that services are delivered in settings accessible and acceptable to them. Provider training is important as well as high-level policy dialogue to update policies to increase the offer of testing, prevention and treatment for young people (for example, see Box 6.5).

It is also important that services are provided in adolescent-friendly ways and meet quality standards *(30)*. This may require changing facility hours or outreach times, offering services through mobile phones, applications and virtual interventions, as well as ensuring that services include things adolescents care about, such as testing for other infections (e.g., STIs), mental health support and broader sexual and reproductive health interventions beyond HIV.

It is important that adolescents who need more support have pathways to access services, such as those who may self-test and desire more in-depth counselling or peer-navigation *(31)*. Tailored support, referral and linkage pathways to HIV prevention, treatment and care are crucial, including other adolescent-specific sexual and reproductive health services.

Box 6.5. Case example: Law reform process for lowering the age of consent for HTS – Central African Republic

Central African Republic has an HIV prevalence estimated at 2.9%, and women constitute nearly 60% of people with HIV. Half of youth and adolescents in the country have their first sexual intercourse before the age of 15. HIV estimates show adolescent girls and young women are at higher risk of HIV infection than their male counterparts and older women and men.

Between 2016 and 2022 the Central African Network for HIV/AIDS Ethics and Law (RCED), Ministry of Justice, the Ministry of Health and UNAIDS worked collaboratively to revise the 2006 law that required parental authorization for HIV testing for adolescents up to the age of 18. Lowering the age-of-consent was a key provision of the new proposed law, which also took into consideration new scientific data and the Central African context.

Efforts to change the age-of-consent for testing and self-testing included:

- Hosting a stakeholder consultation to draft the law
- Forming an expert group to validate and revise the draft law
- Presenting the rationale for the new law at a parliamentarian forum
- Adoption of the law by the National Assembly (November 2022) and signature by the President (December 2022).

The enacted law now lowers the age-of-consent for HIV testing to 12 years old, based on the understanding that the health and life of the child is more important than some social considerations. It also strengthens the rights of people with HIV and people at high risk of HIV infection, and it reflects the latest science on HIV prevention, testing and treatment. In addition, the revised law requires free and informed consent prior to screening, ensures confidentiality of test results and prohibits all forms of stigma and discrimination against people with HIV.

Keys to the success of policy reform included sufficient resources, a dedicated and fully supported staff to follow up on the process and engagement with parliamentarians to generate support for the law.

This work was led by the Ministry of Health and UNAIDS, Central African Republic, 2022.

6.5 Pregnant and postpartum women

Globally, there are an estimated 1.3 million pregnant women with HIV *(32)*, over one million pregnant women with active syphilis infection *(33)*, and 65 million women of childbearing age living with chronic HBV infection *(34)*. Syphilis testing coverage is considerably lower than HIV testing coverage among pregnant women. The elimination of mother-to-child transmission (EMTCT) of HIV, syphilis and HBV ("triple elimination") is a global health priority. All three diseases are transmitted sexually and vertically from mother to infant, and countries are therefore encouraged to simultaneously commit to EMTCT of HIV, syphilis and HBV, using an integrated and harmonized service delivery approach to improving health outcomes for mothers and children.

Box 6.6 summarizes key WHO guidance for testing and linkage services for pregnant and postpartum women.

Box 6.6. Summary of WHO HTS guidance for pregnant and postpartum women

- **All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)* at least once and as early as possible, ideally at the first antenatal care visit** *(syphilis: strong recommendation, moderate certainty evidence; HBsAg*: strong recommendation, low-certainty evidence)*.
- **Dual HIV/syphilis rapid diagnostic tests (RDTs) can be considered as the first test in ANC and for maternal retesting where pragmatic.** However, the dual HIV/syphilis RDT should not be used in pregnant people with HIV on ART, people already diagnosed with and treated for syphilis during their current pregnancy, instead, two separate tests should be used based on the national algorithms.
- **HBV vaccination** can be offered to pregnant women who test HBsAg-negative without further serological testing (if unavailable). Follow-up of all newborns includes vaccination with a timely HBV birth dose and follow up doses 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.
- Services delivered to pregnant and post-partum women should be as integrated as possible. HTS may serve as an **entry point for a broad range of pregnancy care and prevention services**, such as screening and treatment for other infections (STIs, viral hepatitis and TB), HIV prevention and sexual and reproductive health services. **Linkage to the full package of reproductive, maternal, neonatal and child health services** is essential for all women and HIV-exposed infants regardless of their HIV status.
- **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.
- **Pregnant HIV-negative clients at substantial risk of HIV acquisition can start or continue PrEP during pregnancy and breastfeeding** and should receive testing or self-testing according to national guidelines. The benefits of using PrEP during this period should be communicated to clients as part of counselling discussions.
- **Network-based testing is recommended for pregnant women and their partners**, including social network testing *(conditional, low-certainty evidence)* and partner services *(strong recommendation, moderate-certainty evidence)*, as well as partner testing with support for mutual disclosure in all settings *(strong recommendation, low-certainty evidence)*. These services should be integrated across HIV, viral hepatitis and STIs, particularly for syphilis. Self-tests for HIV and syphilis can also be considered, particularly for pregnant women to distribute to their male partners.
- The **optimal time point for retesting** HIV-negative pregnant women is a second test during a **third trimester visit**. Countries can consider an additional retest in the postpartum period for breastfeeding mothers, for example one additional retest at 14 weeks, six months or nine months postpartum in districts or provinces with high HIV burden and among key populations or women with partners with HIV who are not virally suppressed. The postpartum maternal retest may be delivered along with infant immunization services (Table 6.2).

**Particularly in settings with a ≥2% HBsAg seroprevalence in the general population.*
Source: WHO 2017 *(35)*, WHO 2019 *(11)*, WHO 2021 *(36)*

Table 6.2. Recommended time points for HIV testing for pregnant and postpartum women

Setting	Time points		
	Early in pregnancy (first ANC visit)	Late in pregnancy / delivery (third trimester ANC visit)	One additional postpartum retest (14 weeks, six-months 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	Can be considered for those at high ongoing risk	Can be considered for those at high ongoing risk
All settings	Members of key populations and their partners	Members of key populations and their partners	Members of key populations and their partners

Integration is essential to the delivery of services for pregnant and postpartum women. WHO has developed guidance on the criteria and processes for validation of triple elimination *(37, 38)*. Additionally, there is guidance to support countries on how to operationalize the scale-up of triple elimination *(39)*.

Tools such as the dual HIV/syphilis test, as well as dual self-tests, can be considered and may be helpful to closing the testing gap among women and their male partners (for example, see Box 6.7). However, it is critical that early HIV and syphilis treatment is initiated and that women are not lost-to-follow-up. HBV is also a priority and where needed simplified testing and treatment algorithms for women should be used *(40)*.

Box 6.7. Case example: Using dual HIV/syphilis testing to increase syphilis testing coverage in ANC – Ghana

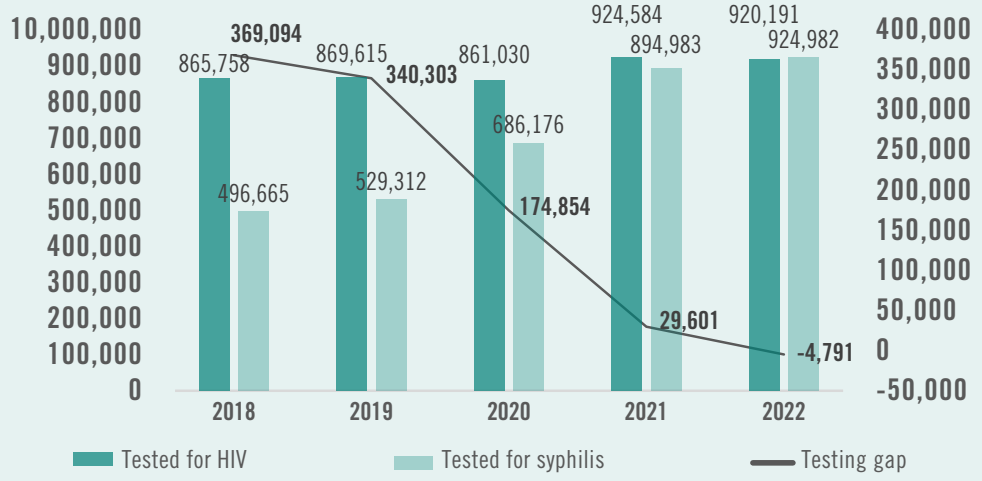
In 2018 the Ghana Health Service, through the National AIDS/STI Programme, began introducing the dual HIV/syphilis test and in 2020 fully adopted the WHO guidance for using dual tests in all antenatal care sites. From the beginning, key stakeholders, including community groups, were engaged in planning dual test introduction and scale-up. This broad and extensive stakeholder engagement was essential for the success of the dual test rollout, which began in October 2020.

A verification study was completed to select the correct dual test for the national algorithm. Quantification and procurement of the selected test kits was followed by training of service providers.

Following the initial introduction of the dual test, between 2018 and 2021 syphilis testing coverage increased from 53% to 91% (Fig. 6.2). Overall, syphilis testing coverage in Ghana increased by 70%, and the gap between HIV and syphilis testing coverage was virtually eliminated over this period. Health care workers reported that dual tests were very convenient to use. The national programme found that dual tests reduced overall quantification and procurement costs by at least 16%.

There were some challenges: Not all PMTCT sites were trained on the new algorithm before the rollout; some providers were using the more convenient dual test instead of the approved test for the non-pregnant population; and treatment of partners is not optimal. However, adoption of the dual HIV/syphilis rapid diagnostic test in ANC proved feasible and has been critical in improving syphilis testing coverage. Ghana's early adoption of the dual test has accelerated progress toward the national targets of the triple elimination strategy. As Ghana's experience indicates, national programmes should establish robust systems to facilitate rapid evaluation, adoption and scale-up of innovative approaches such as the dual testing of pregnant women.

Fig. 6.2. Syphilis and HIV testing gap among pregnant women, Ghana, 2018–2022



Source: Ghana Health Service, National AIDS/STI Programme.

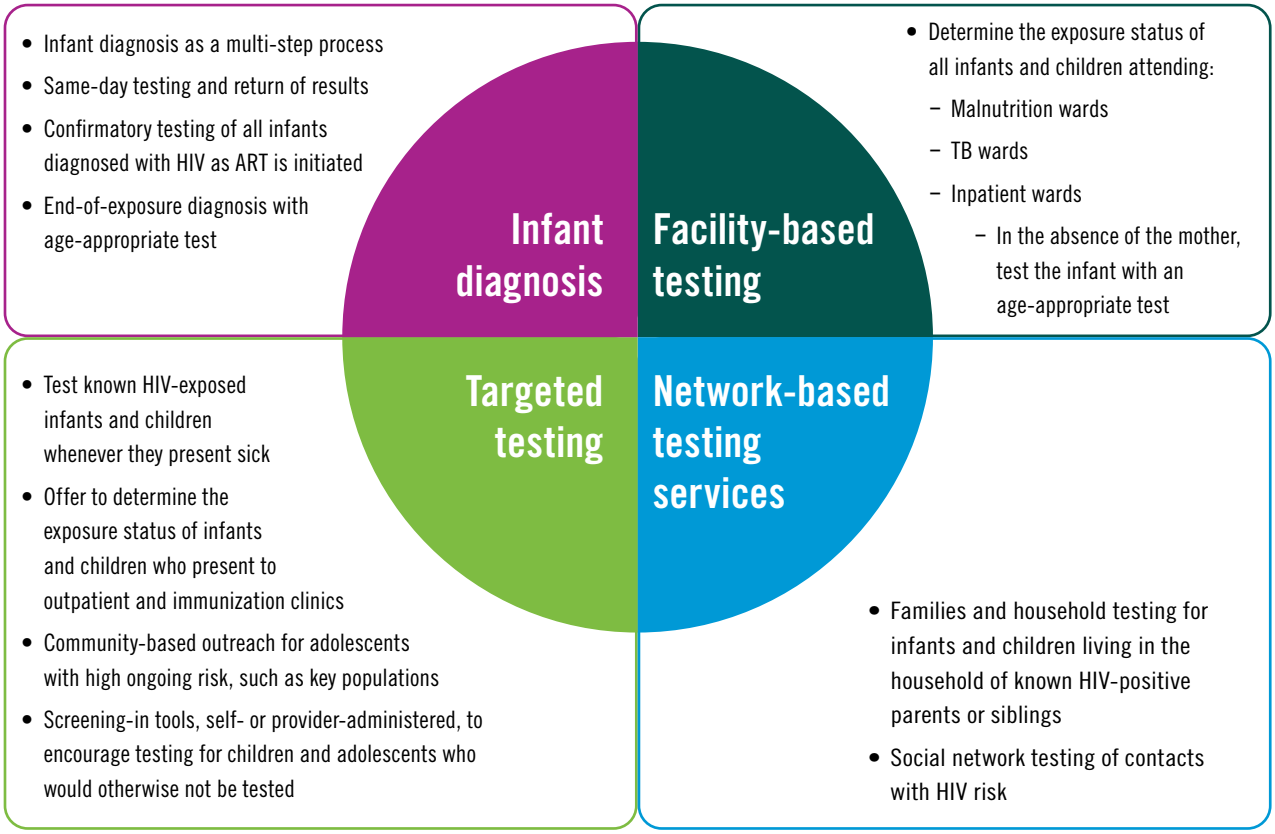
6.6 Infants and children

Among HIV-infected infants who remain untreated, mortality is very high in the first year of life – approximately 35–40% *(41)*. Early diagnosis and treatment among infants who test positive has demonstrated improved survival and clinical outcomes overall, with a substantial impact on the HIV reservoirs in the population and future disease progression *(36)*. Even though there are improved diagnostic and centralized laboratory networks in most settings, there is still suboptimal access to infant testing and treatment initiation of infants. Infected infants are nearly nine times more likely to start treatment within 60 days when tested using same-day point-of-care testing compared with laboratory-based infant diagnosis *(42)*.

Infected infants are nearly nine times more likely to start treatment within 60 days when tested using same-day point-of-care testing compared with laboratory-based infant diagnosis.

Scaling up access to and uptake of testing among infants and children is a global health priority and essential to eliminating paediatric HIV/AIDS by 2030 *(43)*. Existing evidence-based strategies for reaching infants and children are outlined in Fig. 6.3.

Fig. 6.3. Comprehensive HIV testing approach for infants and children



Source: WHO 2021 *(36)*.

Box 6.8 summarizes WHO HTS guidance for infants and children. The testing strategy and algorithm for children over 18 months of age is located in Chapter 8.

Box 6.8. Summary of WHO recommendations on HIV diagnosis in infants and children

Testing approaches

- **HIV virological testing should be used to diagnose HIV infection in infants and children below 18 months of age** *(strong recommendation, high-certainty 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-certainty evidence).*

Testing for HIV-exposed infants and children ≤18 months

- **All HIV-exposed infants should have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter** *(strong recommendation, high-certainty evidence).*
- **The addition of NAT at birth to existing EID testing approaches can be considered to identify HIV infection in HIV-exposed infants** *(conditional recommendation, low-certainty evidence).*
- **Point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age** *(strong recommendation, high-certainty evidence).*
- **Infants with an initial positive virological test result should be initiated on ART without delay, while at the same time, a second specimen is collected** to confirm the initial positive virological test result. Immediate initiation of ART saves lives and should not be delayed while waiting for the results of the confirmatory test *(strong recommendation, high-certainty evidence).*
- **An indeterminate range of viral copy equivalents should be used to improve the accuracy of all nucleic acid-based infant diagnosis assays** *(strong recommendation, moderate-certainty evidence).*
- **Rapid diagnostic tests for HIV serology can be used to assess HIV exposure among infants younger than four months of age.** HIV exposure status among infants and children 4 to 18 months of age should, therefore, be ascertained by undertaking HIV serological testing in the mother *(conditional recommendation, low-certainty evidence).*

Case-finding approaches

- **In high HIV burden settings, infants and children with unknown HIV status who are admitted for inpatient care or attending malnutrition and TB clinics should be tested for HIV** *(strong recommendation, low-certainty 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-certainty evidence).*
- **Network-based testing is recommended for infants and children of people with HIV**, including within social network testing services *(conditional, low-certainty evidence)*, family and household testing services and partner services *(strong recommendation, moderate-certainty evidence).*

Additional guidance

- 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-certainty evidence).* Additionally, adolescent girls (ages 9–14 years) should be offered HPV vaccination as per national guidance *(strong recommendation, moderate-certainty evidence).*

Sources: WHO 2015 *(6)*, WHO 2016 *(44)*, WHO 2016 *(8)*, WHO 2016 *(10)*, WHO 2017 *(45)*, WHO 2017 *(46)*.

To ensure HTS, including linkage to prevention and treatment services, are successfully implemented and effectively reach children it is imperative that early testing and treatment is delivered. WHO recommends NAT at birth or within two days of birth, which would be complemented by additional future NAT according to the national algorithm *(8, 44)* and in conjunction with broader efforts to optimize and scale up existing infant diagnosis approaches as well as efforts to retain infants in the testing-to-treatment cascade until the end of the period of risk for transmission.

The six-week early infant diagnosis (EID) test should be prioritized over adding NAT at birth, depending on current national PMTCT coverage, HIV transmission risk to infants, uptake and retention in the infant testing cascade, and available resources and funding priorities *(8, 44)*. Infant testing throughout the exposure period is critical to identify infants and children living with HIV who need treatment. National regulatory agencies are encouraged to adopt a rapid and streamlined registration and national approval process of point-of-care EID for immediate implementation, and not to delay adoption by conducting further evaluations. See chapter 8 for details on diagnostic testing strategies and algorithms for infants.

Increased case-finding efforts are a global health priority. Given the substantial gaps in diagnosing and treating children with HIV, it is important to scale up family and household testing services. This may include offering testing for all children of people with HIV, as well as nonbiological children in the household due to high HIV risk among orphans, who are under 19 years of age. Additionally, risk screening tools that help reduce missed opportunities and increase the number of infants and children being offered testing could be considered, particularly in settings where paediatric testing coverage is suboptimal, and it is not currently feasible to routinely offer testing at all key entry points. A summary of evidence on caregiver-assisted testing using HIVST kits is also provided in Box 6.9.

Box 6.9. Update on caregiver-assisted testing using HIVST kits

To further strengthen case-finding efforts for children and to achieve WHO strategic goals *(36)*, some programmes have started evaluating the use of caregiver-assisted testing with HIVST kits *(47-53)*. Caregiver-assisted testing is defined as an HIV testing approach whereby a parent or guardian directly performs HIV testing on a child. This is primarily done as part of family and household testing services and to date has been performed largely using oral fluid-based HIVST kits. WHO has not made any recommendation on this approach.

Findings from the WHO systematic review included:

- HIV positivity following caregiver-assisted testing with HIVST appeared to be low or potentially comparable to provider-delivered testing services.
- PPV of using HIVST in this population was quite low and had a risk of false positive results.
- Linkage rates among children testing positive were high with almost all (97.5%) linked to further testing and 97.7% initiating treatment.
- Caregivers receiving support or demonstrations were more likely to perform testing correctly than those receiving no support or demonstration (92.4% versus 77.9%).
- Social harm appeared rare, but data were limited.
- Many caregivers found the approach acceptable, but others had concerns about feasibility and how to handle a reactive result and provide post-test services and support to children.
- Average costs of caregiver-assisted testing with HIVST varied widely and were consistently higher than standard testing services.

Following review of the evidence, the WHO GDG did not make a recommendation on caregiver-assisted testing; as evidence is limited. Future studies should also consider ways to:

- Use caregiver-assisted testing to **complement facility-based testing** services to fill gaps and reach those not being reached.
- **Focus service delivery** through targeting, limiting implementation to children at greatest risk of HIV and providing support tools and demonstrations to optimize accuracy.
- **Increase impact and cost-effectiveness**, for example by exploring integration opportunities with existing services, including those that serve pregnant and breastfeeding women, children with HIV and young people across disease areas or integration within family and household testing services, self-testing and self-care interventions, particularly among adolescents.

See Web Annex E for further details.

Source: McGee et al. 2024 *(54)*

6.7 Couples and partners

Testing partners of people with HIV is an effective way to reach people at high risk of HIV infection and to identify 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 *(11)*. This is important during pregnancy as women have a high risk of HIV acquisition and can benefit from mutual disclosure, early treatment, and prevention tools such as PrEP, knowledge of U=U and safer conception or contraception *(10, 35)*.

Box 6.10 summarizes WHO recommendations and good practice statements on HTS for couples and partners.

Box 6.10. Summary of WHO HTS guidance for couples and partners

- **Network-based testing is recommended for all couples and partners**, including social network testing services *(conditional, low-certainty evidence)* and partner services *(strong recommendation, moderate certainty evidence)* and partner testing with support for mutual disclosure in all settings *(strong recommendation, low-certainty evidence)*. Self-testing may be an option to support testing services, including for HIV and syphilis, including for male partners.
- WHO recommends that policymakers and service providers who support women living with HIV who are considering **voluntary HIV disclosure** should recognize that many fear, are experiencing, or are at risk of intimate partner violence *(strong recommendation, low-certainty 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 should facilitate links to available violence prevention and care services** *(strong recommendation, low-certainty 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 PEP (in the first 72 hours), STI prophylaxis or presumptive treatment, emergency contraception (in the first 120 hours), access to safe abortion as law allows and HBV 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 setting 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)*.

Sources: WHO 2015 *(6)*, WHO 2016 *(7)*, WHO 2016 *(55)*, WHO 2017 *(56)*

Opportunities to integrate the offer of testing to include STIs and viral hepatitis should be considered when implementing services for couples and partners.

When implementing partner services, particularly when reaching out to the partners, family and household members and social contacts of people diagnosed with HIV, it is important that providers deliver counselling messages, protect client confidentiality and provide information about the range of options that might be suitable for reaching and offering testing, prevention and treatment services to individuals in their network. While provider assistance should be encouraged as it is very effective, such services are always voluntary and different options should be made available based on client preferences and needs *(11)*. 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 testing, including more supportive options such as provider assistance, as well as situations that make couple or partner testing inadvisable. The ultimate decision to test lies with the client.

Education about HIV and the latest prevention and treatment options is also critical to supporting couples and partners. Information, such as U=U messages on how ART reduces the risk of HIV transmission to children and sexual partners is important to deliver, as is information about the benefits of partner testing, VMMC and PrEP. Delivering these messages and supporting effective linkage and referrals may help to prevent potential social harm among couples, particularly those that are serodiscordant.

6.8 Other vulnerable groups

Across different contexts and settings different groups may have increased vulnerabilities to HIV. This may be due to personal practices; policies that may be stigmatizing or discriminatory and limit rights and access to health services; or laws that could lead to prosecution. Guiding principles highlighted for priority populations should be adapted as necessary to other vulnerable groups. These may include orphans, street children and other unhoused individuals, people with disabilities, long-distance truck drivers, fisherfolk, indigenous people and mobile or seasonal workers, as well as migrants, refugees and displaced persons. These vulnerable groups are often underserved and, typically, they seldom use conventional health services.

When adapting services to reach vulnerable groups in specific contexts it is always important to review and base decisions on local epidemiological information. Such analyses can help to establish who, in addition to key populations, is at highest HIV risk and most in need of services. Based on these assessments, programmes can adapt HTS, either within or in addition to existing services, to address specific needs.

Testing services should always be voluntary and never mandatory. Individuals who do not choose to test should not be subjected to mistreatment or discriminatory practices. Policies which mandate HIV testing of immigrants for entry, residence, work and/or study permits should be reviewed and revised to promote human rights. UNAIDS and UNDP have called on countries to remove all HIV-related travel restrictions, as they violate human rights and are not effective in achieving the public health goal of preventing HIV transmission *(57)*.

Box 6.11 summarizes WHO best practice statements on HTS for other vulnerable groups.

Box 6.11. 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 and 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.
- A strategic mix of differentiated HTS approaches is needed to reach vulnerable populations and link them to appropriate prevention and treatment services. This includes offering facility-based testing, community-based testing, network-based testing and self-testing services.

Sources: WHO 2014 *(58)*, WHO 2015 *(6)*, WHO 2019 *(11)*

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Chapter 7

Strategic planning for effective and efficient HIV testing services

Chapter contents

Key messages

- HTS should **prioritize reaching people with HIV who remain undiagnosed and reaching population groups with high ongoing HIV risk that may benefit from HIV prevention services.** Opportunities to integrate testing with STI, viral hepatitis and TB should be considered to maximize public health impact of service delivery.
- **Knowing your epidemic** is necessary to inform prioritized HTS approaches and optimization of resources based on local context and HIV epidemiology. An **in-depth HTS situational analysis** can help when evaluating how to optimize HTS implementation.
- **Network-based testing services and self-testing** can be utilized strategically to expand access to and uptake of testing services. These approaches can also be used to promote integration of service delivery.
- Frequency of testing must be optimized and usually one lifetime HIV test is sufficient for most people. Most of **those testing HIV-negative will not need retesting.** Annual retesting is needed only for key populations and those at high ongoing risk. More frequent retesting should be prioritized only for people with substantial HIV-related risk and as part of HIV prevention interventions such as pre-exposure prophylaxis (PrEP). Retesting in pregnancy and the postpartum period should be prioritized to the third trimester visit with catch-up testing for high HIV burden settings and/or key populations.
- **WHO does not recommend the use of screening tools** in high HIV burden settings, as these approaches can undermine efforts to achieve global targets. Self-tests in facilities should be considered as an alternative to screening tools in this context. Programmes with low HIV burden, which do not routinely offer testing in critical clinical entry points, however, can consider ways to use "nudging" and "screening-in" tools to increase testing coverage particularly in underserved groups like children, adolescents and men. **Programmes should always utilize tools which are validated, non-stigmatizing and do not compromise client confidentiality.**

7.1 Introduction

HIV testing services (HTS) are the gateway to prevention and treatment services, which are essential to preventing new infections and reducing HIV-related mortality and morbidity. Given the limited availability of resources, countries need to prioritize their testing and linkage efforts to those that will help achieve and maintain low HIV incidence. Opportunities to maximize public health impact through integration, particularly for viral hepatitis, STIs and TB, should also be considered where resources are available.

When planning and implementing effective testing services, one should adopt WHO guidance to define the testing population and to select a strategic mix of various approaches which meet the different needs of the testing population. That population should be those at high ongoing risk who need prevention interventions, undiagnosed people with HIV, and those with HIV who have tested but are not engaged in care *(1-4)*.

The following principles (Box 7.1) should be considered when planning HTS. Services should then be tailored using the person-centred differentiated service delivery framework based on the needs of the testing population and local epidemiology (Table 7.1).

Box 7.1. Guiding principles for planning HTS

All HTS service delivery models and approaches should focus on:

1. **reaching people in greatest need of HTS based on current epidemiology, and facilitating linkage to prevention and care;** this can include focusing on populations with higher incidence, key populations, individuals with undiagnosed HIV, HIV-positive individuals not on treatment and HIV-negative individuals at high ongoing risk and in need of combination prevention such as PEP or PrEP;
2. achieving **highest public health impact** and current **national programme targets** (for example, the 95-95-95 targets, triple elimination goals and the fast-track prevention targets); and
3. **focusing resources toward high impact and cost-effective testing approaches** which maximize opportunities for service integration.

Table 7.1. Building blocks for differentiated HIV testing service delivery models

	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, homes	Location of linkage activities
Who	Who does the mobilizing?	Who does the HIV testing? Self-testing and/or health workers?	Who supports linkage to prevention or ART initiation/ re-initiation?
What	What package of services and demand creation interventions?	HIV testing alone or integrated with other services?	What linkage interventions?

Source: Adapted from IAS 2018 *(5)*.

Testing for both treatment and prevention

Globally, HIV incidence is decreasing, and test positivity rates are declining. Hence, testing services must be more focused and prioritize finding and testing undiagnosed people living with HIV, as well as finding and testing those at significant risk who need combination prevention services such as PrEP. Testing for case-finding and prevention should be carefully considered and planned.

Contexts to consider implementation: Testing that focuses on both treatment and prevention is best used in high-burden settings with high testing and ART coverage rates (resulting in significantly declining HIV positivity). This approach may be less applicable in settings with low HIV testing coverage or low HIV burden other than in key populations.

Routine testing services: WHO recommends annual testing for individuals at substantial ongoing risk in high HIV burden settings. As part of elimination efforts, testing should also be offered during pregnancy in all settings. Focusing on linkage to both treatment and prevention is important. Emphasizing linkage to prevention will not increase testing provision but may require proactive support for a person with HIV-negative results, including assessing HIV risk, providing linkage to appropriate prevention options, and a scale-up of prevention options, notably PrEP.

Focused testing services: Testing for treatment and prevention would be appropriate in focused testing services for populations with higher HIV risk – such as key population testing services and focus entry points, such as STI services.

Prioritized retesting: Retesting priority populations for both treatment and prevention is justified because of the opportunity to link people to prevention, contributing to cost–effectiveness by increasing linkage to PEP and PrEP.

Retesting among people who are HIV-negative or of unknown status has two key purposes: (i) **identifying and treating new HIV infections as early as possible**, and (ii) **monitoring the effectiveness of HIV prevention interventions.** Most people who have an HIV-negative test will not need retesting *(6)*. One lifetime HIV test is sufficient for most people in low HIV burden settings and who do not have ongoing HIV risk *(6, 7)*.

7.2 Core principles for implementing effective and efficient HIV testing services

WHO recommendations and guidance to prioritize and implement HIV testing approaches in various settings are often based on whether settings have high or low HIV burden *(6, 8-11)*. In the context of HTS programming and planning, in this document **high HIV burden** refers to countries with ≥5% national HIV prevalence. In high-burden countries, there may be subpopulations and geographic settings where HIV prevalence and/or incidence is higher than national prevalence/incidence. **Low HIV burden** refers to countries with <5% national HIV prevalence. In low-burden countries, certain populations (primarily key populations and their partners) and geographic settings may have higher HIV prevalence/incidence than the national average and, therefore, need priority in the HIV response.

Based on these epidemic categories and the broader context mentioned above, programmes will need to prioritize how and where to offer HTS, as well as how best to use existing HTS systems to support integration and to achieve broader public health impact. A range of routinely offered testing options as well focused testing approaches need to be considered and rationalized within the broader context of available resources and financial sustainability.

7.2.1 Testing priorities for high HIV burden settings

Rapid testing and routinely offered testing in health facilities continue to be the backbone of service delivery in high HIV burden settings and are essential to achieving the first and second "95" targets.

Efforts to focus the offer of HIV testing in clinical services, particularly outpatient departments, such as through using risk-based screening tools aimed at reducing the offer of testing, have generally not achieved substantial cost savings. These strategies undermine global goals to achieve the first "95" as they miss a high proportion of people with HIV who would have otherwise been tested *(12-14)*.

Targeted outreach in geographic areas with high HIV burden and low ART coverage, as well as to specific groups with high ongoing HIV risk, remains critical. Network-based testing services, designed to reach sexual and drug injecting partners, and children of people with HIV, as well as social contacts of people with HIV or other related risks are a key way to focus services. Groups missed by existing services – key populations and men more broadly – should be the focus of these efforts.

Prioritization of case-finding for children and adolescents continues to be a gap area. Programmes operating within high HIV burden settings need to increase coverage and optimize the offer of testing to sick children and children of people with HIV presenting in facilities and identified through community outreach. Alternative strategies, such as offering testing to children and adolescents with frequent re-admission and re-engagement and increasing immunization coverage, should be considered. Screening-in tools can also be considered in settings with low paediatric testing and treatment coverage to further reduce missed opportunities.

Retesting efforts can help prevent new infections and need to be optimized across programmes. For instance, most people only need one lifetime HIV test and retesting should be limited to those with specific HIV-related risks, some of which may be time-limited. Key populations and sexually active youth in high HIV incidence settings should receive retesting at least annually, and periods of risk may vary over time resulting in a need to consider more frequent testing. For instance, people who take PrEP will benefit from quarterly or bi-monthly testing *(15)*.

During pregnancy and the postpartum period the risk of HIV acquisition increases *(16)*, and testing efforts should first focus on supporting women to receive early ANC and to deliver integrated testing services for HIV, syphilis and HBV *(17)*. Maternal retesting should then be prioritized based on available resources, starting with retesting in the third trimester, followed by catch-up testing at the next possible visit, or labour and delivery, for those who may miss this visit *(6)*. See Table 6.2 in Chapter 6 for a summary of retesting timepoints.

7.2.2 Testing priorities for low HIV burden settings

Low HIV burden settings will need to prioritize where and when to offer HTS. To support elimination efforts, routine offer of testing for HIV, syphilis and HBV is beneficial and should be considered where resources are available. However, it is important that testing services for key populations, vulnerable groups and those with substantial HIV risk who contribute to the majority of new HIV infections are the focus of programmes.

Services in specific health facilities may be needed to reach these groups. Local data will be needed to adapt and adjust the scale of facility-based testing services. Tools like indicator conditions-guided testing and screening-in or nudging tools could be considered to identify infections that might otherwise be missed during clinical visits.

Targeted outreach, primarily through network-based testing and self-testing should be considered and should focus on populations and geographic areas within countries with highest HIV incidence and lowest ART coverage. Network-based testing services, designed to reach sexual and drug injecting partners, and children of people with HIV, as well as social contacts of people with HIV or other related risks are a key way to focus services. Services should be integrated, such as for syphilis, viral hepatitis and TB, using local epidemiology, as this will optimize limited resources *(18)*.

Retesting efforts can help prevent new infections but need to be optimized (see Table 7.2). Retesting at least annually should be prioritized for key populations and those with specific HIV-related risks, some of which may be time-limited or linked to accessing HIV prevention services such as PEP and PrEP. In low HIV burden settings, an initial test during pregnancy is advised, however maternal retesting after this point should be focused on key populations and women in high HIV incidence geographic areas within countries *(6)*. See Chapter 6 for additional details on testing in pregnancy.

7.2.3 Strategic considerations for routinely offering HTS

When HTS are routinely offered, all people with unknown or HIV-negative status in a specified geographic location or setting are offered HIV testing. HTS can be offered routinely to all clients of unknown status in high HIV burden settings, focusing on those who have never been tested, those who have not been tested in the past 12 months and those who have had a recent risk exposure.

Routinely offered HTS are usually delivered in health facilities, including self-testing in some facilities, which may improve testing coverage and uptake (Chapter 5). Ongoing provision of routine testing may facilitate an approach that equally values linking those testing positive to ART and linking those at high risk of HIV acquisition to prevention services, including PEP and PrEP. Community-based approaches such as home-based (door-to-door) HTS and unfocused mass-testing campaigns, even in high HIV burden settings, are seldom as cost-effective as routine testing, especially where testing coverage is already high. Integration of testing services does increase cost–effectiveness and cost savings, such as offering integrated testing and supporting triple elimination testing for HIV, HBV and syphilis in ANC.

In high-burden settings with high testing and ART coverage, HTS positivity may be low, especially if testing is offered routinely to all people every time they attend clinical services. In addition, annual retesting is suggested for sexually active individuals with ongoing risk or as part of monitoring the effectiveness of HIV prevention interventions (see Section 7.2.5). Review of HTS positivity at testing sites and adjusting the frequency of offering testing may need to be considered to optimize retesting.

7.2.4 Strategic considerations for focusing HTS

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

Focused approaches reach populations not adequately served by general HTS, or where gaps in HTS coverage are greatest, to improve access and equity for these populations. Such approaches also offer the potential for identifying additional people with undiagnosed HIV infection and preventing new HIV transmission. If a focused HTS approach leads to high HTS positivity or effective linkage to PrEP for those who could benefit most, the cost per person diagnosed HIV-positive or per infection prevented may be lower than or comparable to other less focused approaches, even though the unit cost per test may be higher.

Focused HTS can be delivered using a range of WHO-recommended HTS approaches, including facility-based, community-based, HIV partner services and HIVST. Box 7.2 summarizes approaches for focusing HTS approaches to reach specific populations and settings.

Box 7.2. Approaches for focusing HIV testing services

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

- **Focused demand creation** activities can improve HIV testing uptake among priority populations.
- **Network-based testing services**, including **partner services** for the sexual and/or drug injecting partners of people with HIV, **family and household testing** services for children of people with HIV and **social network-based testing services** for sexual and/or drug-injecting partners, as well as social contacts of people with HIV and people testing HIV-negative with ongoing risk. These services should be integrated with viral hepatitis, STIs and TB where feasible.
- **Self-testing across HIV, HCV and syphilis**, can be used safely in a variety of settings, populations and programmes. HIVST cost-effectively expands the reach of testing programmes and achieves rates of linkage to care which are similar to those of other testing strategies.
- **Indicator condition-guided HTS** is the offer of HTS to individuals who present with specific clinical conditions indicative of an HIV infection, such as TB, STIs, cervical or anal cancer/dysplasia, or herpes zoster *(19)*. Programmes should provide staff training and an abbreviated list of indicator conditions specific to their setting. For details, see *HIV indicator conditions: guidance for implementing HIV testing in adults in health care settings (19)*.
- **HTS in selected services within health facilities** can target specific populations, for example, clients of STI or contraception services, ANC and TB clinics, including areas with high HIV burden or unmet testing needs.
- **HTS focused on certain priority 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, men, adolescents, or pregnant women. Chapter 6 presents considerations for priority populations.
- **HTS focused on specific geographic areas or settings**, such as districts or areas with high HIV incidence, low levels of ART coverage or community viral load suppression (for example, workplaces, schools, transport hubs, border crossings or specific urban locales where those in key populations work or reside) *(20)*. Sex-on-premises venues, mobile outreach, and home-based testing in specific settings with low testing coverage and high HIV prevalence or incidence present additional opportunities for focused HTS *(21)*.
- **Integration of testing services**, including TB/HIV activities and use of multiplex testing for HIV and syphilis, and testing for HBV as part of triple elimination.

7.2.5 Strategic considerations for retesting – when and whom

Retesting among people who do not have HIV or of unknown status has two key purposes: (i) identifying and treating new HIV infections as early as possible, and (ii) monitoring the effectiveness of HIV prevention interventions *(2)*.

Some individuals with HIV who already know their status may also seek retesting.

WHO recommends clients diagnosed with HIV and referred for ART be retested to verify diagnosis prior to starting lifelong treatment *(6)*. This is a QA measure to reduce the risk of providing an incorrect diagnosis and to prevent unnecessary ART initiation which could be lifelong. See Chapter 8 for further details.

For clients who were previously diagnosed and either never started ART or stopped taking ART, a request for HIV testing provides an opportunity to engage or re-engage in care and to overcome barriers to taking ART. Additional information or encouragement from providers may help. For such clients, retesting can facilitate linkage or re-engagement. It is important that post-test counselling include all general messages and messages for people diagnosed with HIV.

Table 7.2. Retesting populations, conditions and intervals

Population or condition	Retesting interval	Comments
Key populations	Every 6–12 months	Testing at least annually is recommended. Costing analysis shows possible benefit of more frequent testing.
Individuals with STIs, TB or viral hepatitis	Upon diagnosis or presentation	HIV testing should be conducted for anyone presenting with these related infections, regardless of previous testing.
Pregnancy: initial test	At first ANC visit	Initial testing in pregnancy recommended for all pregnant women in all settings.
Pregnancy: retesting	Low-burden settings: not recommended	In low-burden settings, third trimester testing should be conducted for members of key populations and those with a partner living with HIV.
	High burden settings: in 3rd trimester	In high-burden settings, third trimester retesting should be conducted for all pregnant women.
Postpartum	Once between three and nine months postpartum	Suggested for those with ongoing risk, recommended for members of key populations.
Sexually active individuals in high-burden settings	Annually, depending on risk	Risk should be assessed and a retesting interval should be agreed on with the client.
Individuals with a sexual partner known to be living with HIV and not virally suppressed on ART	Annually	Risk should be assessed and a retesting interval should be agreed on with the client.
Individuals with symptoms indicative of HIV	Upon presentation	For individuals suspected of having acute HIV, retesting may be necessary. Indicator conditions-guided testing is one option to consider.
Individuals with recent HIV exposure	Upon presentation	For individuals taking PEP, retesting is part of standard procedures. For individuals suspected of having acute HIV, retesting may be necessary.
Individuals who use PrEP	Every 2–3 months depending on type (injectable or oral)	Self-testing can be used for retesting for oral PrEP and the dapivirine vaginal ring
People previously tested and know they have HIV but not taking ART	Upon presentation	Retesting is an important window to welcome people with HIV back into care.
Verification of HIV diagnosis	Before ART initiation	One-time verification testing prior to initiating ART is recommended.

7.2.6 Strategic considerations for using screening tools

Risk-based screen-in tools or questionnaires have been developed and used in some settings to identify ("screen in") people who would benefit from HTS in certain settings where HIV testing is not routinely offered or to exclude ("screen out") people from routinely offered HTS but HIV positivity is low and resources are constrained.

Tools to screen people in for testing can be useful, but tools for screening out should be used only with caution.

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 *(22)*. This is particularly useful for low HIV burden settings and in populations at low risk who are not routinely tested, as the screening tools increased HTS coverage *(13)*.

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% *(23)*. 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 with who have sex with men and who had additional HIV risk factors *(24)*. Further, risk assessments can be a component of testing strategies when they are used for identifying not only those in need of testing, but also those in need of combination prevention. In these cases, anyone screening in for testing would also qualify for PrEP or other prevention modalities if their test results are negative *(25, 26)*.

In settings and populations where HTS is not routinely offered, screening-in 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 the resources to test everyone; in a low HIV burden setting where sick children with HIV risk factors are presenting but are not routinely offered HTS; and to rationalize the distribution of a limited number of available HIVST kits based on demographic risk factors (Box 7.3).

Box 7.3. Case example: Screen-in "nudge" tool utilization – Malawi

In 2019 incident infections among women during the postnatal period accounted for over 70% of new HIV infections among infants in Malawi. To better reach women in need of maternal HIV retesting and identify HIV-exposed infants, a national taskforce developed a screen-in tool to identify mothers of exposed infants at outpatient departments and other high-volume entry points outside of PMTCT services (for example, under-five clinics, immunization services), where HIV testing is not universal.

The one-page tool can be administered by lay cadres in the waiting area by discreetly reviewing the mother and child health records and ticking off questions on the tool that lead to a final recommendation on whether to refer the mother and/or infant to an HTS provider. The questions focus on the HIV status of mothers of infants 0–24 months old. In accordance with national guidelines, the tool refers to HTS the mothers of unknown HIV status and those who missed HIV testing opportunities at PMTCT in the previous six months. If the mother's test result is positive, the infant is referred to HIV testing.

Across 32 facilities 10 675 mothers were screened from July to September 2019 using this tool, and all responses and outcomes were recorded on screening slips. Of the mothers who were screened, 44% (4584) were screened in for HIV testing, 0.7% of these (26) had positive test results, and 0.1% (5) had inconclusive test results.

In a situation where routine HIV testing is infeasible, the screen-in tool successfully identified mothers who had missed other opportunities to be tested or retested for HIV during the course of their pregnancies or during breastfeeding. Referred mothers and infants who were identified as HIV-positive were linked to care and treatment, started on ART the same day and supported with follow-up as needed.

Source: Tallmadge 2020 *(27)*.

Screening-out tools: Caution should be exercised with the use of tools to screen people out of testing in settings where it is routinely offered. **There is a risk of missing diagnoses, and there is less evidence of the effectiveness of screening-out tools** *(22)*. Recent analyses also suggest that screening tools do not create long-term savings or efficiencies *(12)*. Programmes considering the use of such tools need to consider their use carefully, as they may include questions that are personal or sensitive which may deter some people from testing due to confidentiality concerns. Further, these tools may mistakenly screen out some people at high ongoing risk who need testing *(28)*.

While some screen-out tools are intended to increase specificity, that is, to try to make sure that the people screened out are in fact HIV-negative, and have been validated, these are context-specific tools and need to be locally validated and adapted. Programmes should always utilize tools which are validated, non-stigmatizing and do not compromise client confidentiality.

7.3 Knowing your context and epidemic

Selecting a strategic mix of HTS approaches and applying the differentiated service delivery framework to achieve testing goals requires in-depth knowledge and understanding of a country's HIV testing programme and current epidemic – including variations by region and populations *(29)*. Programmes often have data from several sources at their disposal, including surveillance, programme and survey data. This often allows disaggregating HIV prevalence and HTS positivity by sex, age, population type and geography. Used on its own, any data source will have limitations. When used in combination, multiple data sources can present a reliable picture of the HIV situation in the country and reveal epidemiological trends when analysed appropriately.

Ongoing person-centred monitoring of HIV testing and linkage is important *(25)*. Monitoring efforts should ideally include data from population-based surveys and in-depth review of national and subnational programme data. Cost analysis and estimating the treatment adjusted prevalence *(29)*, should also be considered and regularly reviewed alongside of demographics and policy information to develop an in-depth situational analysis.

HTS, including focused approaches, requires regular monitoring and review of data to determine whether approaches are reaching the intended populations and areas, with modifications where needed. Subnational or site-level programme data can be used to gauge progress.

Some key data sources to consider for routine review and analysis include:

Population-based surveys. These surveys are generally helpful if response rates are high and there are no major biases or exclusions of specific populations. They can help estimate HIV prevalence at a national or subnational level. A limitation is that they are typically not designed to identify key populations or other country-specific priority populations. Other approaches which focus on populations with substantial HIV-related risk, such as integrated biological and behavioural surveillance (IBBS) surveys or IBBS-lite can provide reliable information for groups outside of the general population.

Routine programme data. These should include information on HIV testing, prevention and treatment coverage at the provincial and district level and even at the facility level. National person-centred programmatic data can provide granular and timely information on HIV case-finding for decision-making *(25)*.

Treatment-adjusted prevalence (TAP). Understanding the relationship between treatment coverage and testing coverage is important, especially as epidemic trends shift and HTS positivity in the population testing declines. TAP is a calculated metric that uses national and subnational HIV prevalence estimates and removes the total number of people on treatment from the numerator and denominator to provide an accurate projection of HTS positivity at national and sub-national level. TAP, when reviewed with background knowledge and understanding of a country's testing programme, can help guide resource allocation and target setting (Box 7.4).

Box 7.4. How to calculate and use TAP to estimate HTS positivity in the testing population

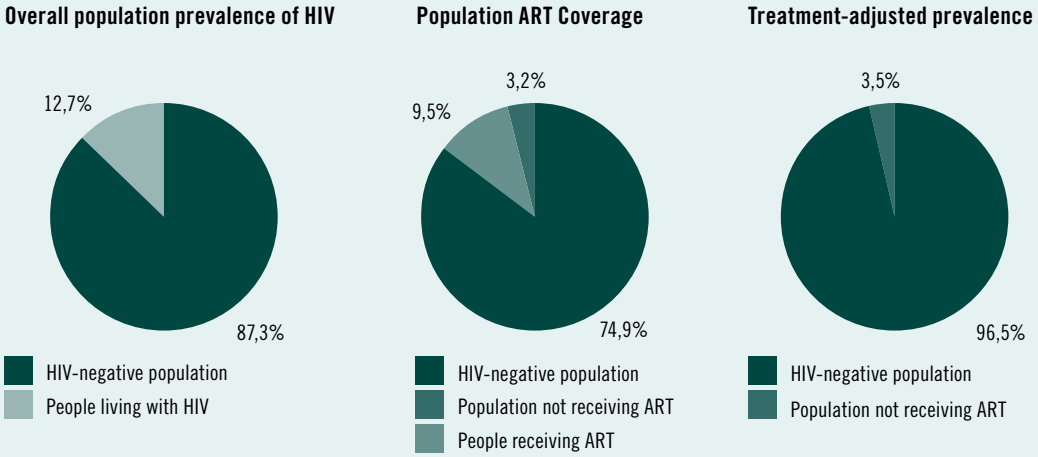
TAP – treatment-adjusted prevalence – is calculated by subtracting the number of people on treatment from both the numerator and the denominator of a prevalence equation:

$$TAP = \frac{(H - A)}{(P - A)} \times 100$$

Where *H* is the number of adults living with HIV, *A* is the number of adults living with HIV and receiving ART, and *P* is the total adult population. This can be calculated for a country, province, county or other subnational geographic area.

For example, in the Nyanza province of Kenya, overall population prevalence of HIV was 14.9% in 2019 (Fig. 7.1). However, of the 14.9% of people living with HIV, 12.3% were on ART, leaving only 2.6% of the total population that were living with HIV and not on ART. Removing the 12.3% living with HIV and on ART from both the numerator and the denominator produces a TAP for Nyanza of 3.5% in 2019.

Fig. 7.1. TAP of HIV infection in adults aged 15–49 years in Nyanza province, Kenya, 2019



Source: Barr 2019 *(29)*

7.3.1 Conducting in-depth situational analyses to optimize HTS delivery

Conducting an in-depth HTS situational analysis is the first step when working to optimize testing programmes. Such analyses will vary by country and setting but typically include a review of national HIV epidemiological, programme and survey data (as described above), financial resources, costs and relevant laws and policies. The data reviewed should be disaggregated by sex, age, population type, geography and HTS approach.

Ensuring that HTS programmes reach their intended populations and identify previously undiagnosed HIV infections requires 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.

A situational analysis should include review of the availability and effectiveness of complementary packages of services to facilitate linkage to care and create demand for HTS and prevention services. Box 7.5 presents a case example of a situational analysis for planning HTS in Guinea.

Box 7.5. Case example: Conducting a situational analysis for planning HTS in Guinea-Conakry

In 2017, nearly 50% of adults in Guinea did not know their HIV status, 80% of HIV-exposed children had not been diagnosed, and approximately 56% of pregnant women had not been tested as part of antenatal care. To accelerate progress towards testing targets, Guinea's National HIV/AIDS and Viral Hepatitis Program, with technical support from WHO, conducted an HTS situational analysis.

This analysis was conducted in four stages: (i) a review to analyze epidemiological trends by location, sub-population and over time, and to refine the definition of target populations; (ii) an analysis of programmatic data to identify effective HTS models and missed opportunities; (iii) a review of normative and policy documents to identify policies requiring revision, particularly in light of recent WHO recommendations; and (iv) complementary interviews with key stakeholders to better understand the context and identify main challenges and opportunities.

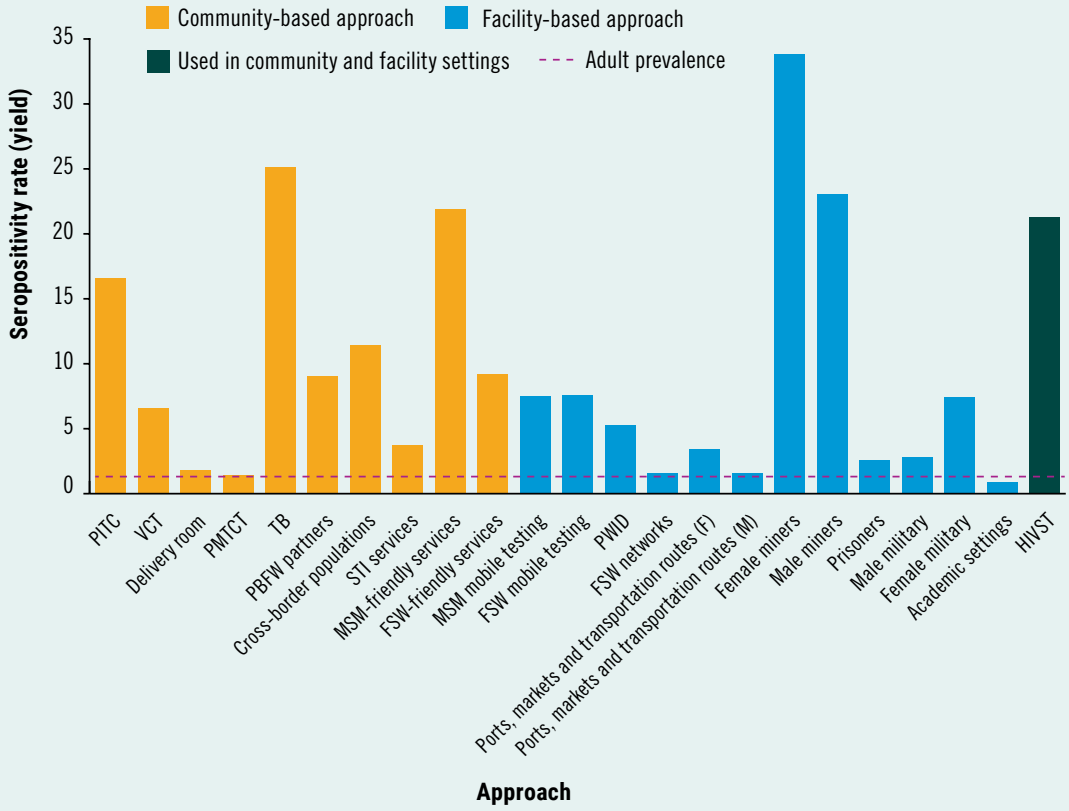
This situational analysis produced a comprehensive picture of HIV testing in Guinea which guided national policy development. Key indicators were disaggregated by gender, age, region, sub-population, site type and entry point, and were analysed for changes over time. Indicators included: HIV prevalence, number of sites offering HTS, HTS modality, number of HIV tests performed, HTS positivity, number of new patients on treatment. Changes in trends were then analysed over time.

The analysis showed that HIV infections were concentrated in urban centres (aside from Conakry, the capital), where HIV service coverage was lowest, with only 10% of health facilities routinely offering HTS within various services excluding PMTCT, at the national level. While the Conakry region accounted for 51% of HTS offered, less than a quarter of the country's people living with HIV (PLHIV) lived there (Table 7.3). Findings highlighted that HTS was not offered systematically at essential entry points: only 66% of TB sites offered HTS to TB patients, and only 45% of estimated pregnant women in ANC services were tested, with large gaps in certain regions, largely due to stock-outs.

Table 7.3. Number of PLHIV and tests performed in 2017, by region

	PLHIV	% of country total	Tests	%	Tests/1000 habitants	Tests/ PLHIV
Conakry	27 132	22	53 060	51	28	1,9
Kindia	15 453	13	11 068	11	6	0,7
Boké	12 949	10	6 094	6	5	0,4
Mamou	6 385	5	3 198	3	4	0,5
Labé	13 248	11	4 459	4	4	0,3
Kankan	18 392	15	11 676	11	5	0,6
Faranah	9 829	8	4 909	5	5	0,5
N'Zérékoré	19 548	16	9 461	9	5	0,5
Total	**122 937**		103 925		9	0,8

Fig. 7.2. Comparison of HIV positivity by service setting



F: female; **FSW:** female sex worker; **HIVST:** HIV self-test; **M:** male; **MSM:** men who have sex with men; **PITC:** provider-initiated testing and counselling; **PBFW:** pregnant and breastfeeding women; **PMTCT:** prevention of mother-to-child transmission (of HIV); **PWID:** people who inject drugs; **STI:** sexually transmitted infection; **TB:** tuberculosis; **VCT:** voluntary counselling and testing.

This work led to the formulation of 42 recommendations that serve as the basis for Guinea's Differentiated HTS Strategy, validated at the national level in 2018. Priority areas of these recommendations relate to services aimed at reaching undiagnosed HIV cases (PITC, PMTCT, children and adolescents, TB, key and vulnerable populations) and address more structural and cross-cutting areas (governance/policy, human resources, supply chain, and quality assurance/ monitoring and evaluation) to improve implementation and quality of services.

Source: National HIV/AIDS and Viral Hepatitis Program, Guinea

Table 7.4. Data and data sources relevant to HTS situational analysis

Indicator	Data source(s)	Disaggregation	Use
HIV testing services data			
HIV prevalence (and/or HIV incidence)	Consider triangulation. National population-based surveys, ANC surveillance data, programme data, special projects among key populations, modelling exercises (UNAIDS Spectrum AIDS Impact Model)	National and subnational, sex and age group (5-year age groups or at least <15 years and ≥15 years), pregnant women attending ANC, key populations, 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 populations, other vulnerable and priority populations	To identify gaps in HIV testing coverage in different geographies, demographics and populations
TAP (proportion of people with HIV in a given 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 (for populations and settings in which retesting is recommended)	Population-based surveys, programme data, special surveys or reports	General population, with sex and age groups (5-year age groups or at least <15 years and ≥15 years), key populations, other vulnerable and priority populations, facility type (outpatient/inpatient, ANC, TB, STI, harm reduction, etc.)	To identify gaps in HIV testing coverage for different populations and types of facilities; facility-level retesting rates
Mobilization and demand creation approaches	Population-based surveys, programme data	General population, with sex and age groups (5-year age groups or at least <15 years and ≥15 years), key populations, other vulnerable and priority populations	To ascertain 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 years and ≥15 years), key populations, facility type, HTS approaches	To gauge the effectiveness and acceptability of different HTS approaches and differences by facility type and population
HIV test positivity – total number tested and proportion of positive tests/HIV-positive among those tested	Programme data	Key populations, other vulnerable and priority populations, facility type (outpatient/inpatient, ANC, TB, STI, harm reduction, etc.), HTS approaches	To assess how well testing focuses on those in need; which HTS approaches are identifying more people with HIV or achieving high positivity rates
Linkage to treatment – 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

Indicator	Data source(s)	Disaggregation	Use
Linkage to prevention – among those testing HIV-negative and identified as being at elevated risk for HIV acquisition, number/ proportion of people who receive an HIV prevention intervention within a defined period	Programme data	National and subnational	To assess the success of interventions that link people to relevant HIV prevention services
Number/proportion of facilities with stockouts of test kits	HTS site-level data (facility and community), central medical stores, community-led monitoring reports	National and subnational, special report from community-led monitoring activities	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)	Population-based surveys, programme data	National and subnational, key populations, other vulnerable and priority populations	To determine the gap in ART coverage among those diagnosed
PrEP coverage using HTS and HIVST	Individual-level data obtained from programme records.	Sex, age (15–19, 20–24, 25–49, 50+ years), key populations, PrEP product and formulation, experience with PrEP (first time, continuing or restarting), setting (facility-based or community-based)	Measures PrEP uptake and effective use among the group estimated to be vulnerable to HIV acquisition
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		To identify product availability for specific HTS approaches, for example, HIVST
Quality assurance and post-market surveillance	Programme data, WHO prequalification, ministry of health 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	Ministry of health and other ministries	Human and financial, national and subnational	To assess 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 calculate 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; to determine per-person costs of linkage to PrEP

7.3.2 Financial sustainability

To maximize HTS cost–effectiveness, 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 pretest information and post-test counselling and, in certain populations, promotion of HIVST *(6)*. Ongoing review of prices secured for rapid diagnostic tests (RDTs), dual HIV/syphilis RDTs and HIVST kits is important to ensure that appropriately priced, quality-assured products, which meet programmatic specifications, are procured.

To maximize HTS cost–effectiveness, programmes should use:

- streamlined and integrated services
- 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.

When considering HTS costs, data collected and analysed may include individual costs, health system costs, and/or broader societal costs. For routine use, however, most available data will focus on HTS delivery costs – including cost per person tested, cost per person diagnosed HIV-positive, and cost per person diagnosed HIV-negative and linked to prevention. These costs will vary by approach and setting across countries and within countries, and will depend on such factors as the balance of HTS approaches (facility versus community-based, routinely offered versus focused), types 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 (concise versus long, in-person versus digital platforms).

Additional resources for monitoring HIV testing services are available in Box 7.6.

Box 7.6. Additional WHO guidance on monitoring and reporting

- Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact; 2022. https://www.who.int/publications/i/item/9789240055315
- Cascade data use manual to identify gaps in HIV and health services for programme improvement; 2018. https://www.who.int/publications/i/item/9789241514415
- HIV self-testing strategic framework: a guide for planning, introducing and scaling up; 2018. https://www.afro.who.int/publications/hiv-self-testing-strategic-framework-guide-planning-introducing-and-scaling

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Chapter 8

Selecting diagnostics for HIV diagnosis

Chapter contents

Key messages

- **Programmes should provide affordable and accurate HIV testing services (HTS)** by adhering to WHO recommended HIV testing strategies, which use appropriately selected products and achieve an overall positive predictive value (PPV) of 99% or higher.
- **WHO testing strategies recommend that national algorithms use quality assured** rapid diagnostic tests (RDTs) and/or immunoassays (IAs). **WHO does not recommend the use of nucleic acid testing (NAT) techniques for diagnosis for those >18 months of age and recommends against the use of western blotting and line immunoassays.**
- **WHO recommends countries use three consecutive reactive test results to make an HIV-positive diagnosis.** As countries approach, achieve and surpass the first 95 target, and HTS positivity declines, it is important to have testing strategies and algorithms that can provide an accurate diagnosis.
- **Self-testing and test for triage** approaches which use lay providers are important for national programmes. These approaches are needed to increase access to and uptake of testing, prevention and treatment.
- **Dual HIV/syphilis RDTs, and self-tests, can be used.** Priority areas for use may include within antenatal care (ANC), partner testing or for key populations more broadly. Dual tests should not be used among people with HIV on ART or among people already diagnosed and treated for syphilis during pregnancy.
- **Programmes must know how to build and verify national HIV testing algorithms** and be prepared in case of a product shortage due to stock-out, recall or product obsolescence. This is important as countries aim to introduce innovative and locally or regionally produced technologies.
- **HIV recency testing is not recommended as part of routine HTS.** Recency testing should be limited to surveillance in accordance with WHO and UNAIDS technical guidance on using recency assays for surveillance.

8.1. Introduction

Great progress has been made in the scale-up of the HIV response. As a result of expanded testing, as of 2022, 89% of women and 82% of men with HIV learned their status. The majority of people with HIV are now receiving HIV treatment and achieving viral suppression *(1)*. As a result, many countries are reporting declining HIV-related mortality and fewer new infections *(2)*. The annual number of new infections has fallen by 32% since 2010. However, more efforts are required to achieve the 2030 target of 90% decline in new infections.

WHO recommends that countries use a three-test strategy. Without this, programmes cannot ensure a PPV of at least 99% which prevents misdiagnoses of HIV in more than 1 per 100 people.

Because HTS and ART have been scaled up and gaps between testing and treatment are closing, there are fewer people with undiagnosed HIV and in need of treatment.

This shift in the epidemiology directly impacts testing strategies and algorithms, as the PPV (which is the probability that a reactive test result is a true HIV-positive) depends on the prevalence in the population tested. More specifically, the likelihood of a false-reactive test result following HIV testing will increase as prevalence in the population tested decreases.

Despite this progress, gaps remain and populations like key populations, men, infants, children, adolescents and young people with HIV are less likely than other people to know their status and be on treatment. These groups also struggle with accessing health facilities and are not reached by costly or time-intensive laboratory-based testing strategies, such as western blotting, and they benefit from access to RDTs and self-tests. These approaches have been shown to provide accurate results and facilitate greater uptake of prevention and treatment services *(3)*.

Countries may need to update their HIV testing strategy and algorithm to ensure access to accurate and quality testing is delivered using low barrier approaches. The following chapter outlines recommendations for how to provide an accurate and reliable HIV diagnosis, including guidance on how to incorporate RDTs, self-tests and tests for triage approaches, and retesting.

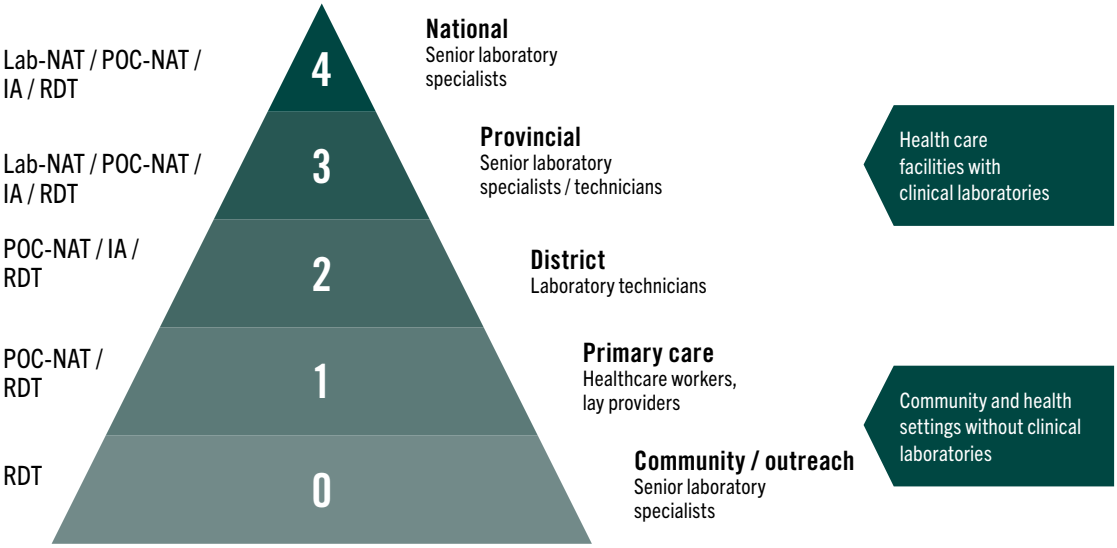
8.2 Where to conduct HIV testing

HIV testing for diagnosis can take place at all levels of the health system. Fig. 8.1 depicts the organization of testing services and the different HIV assay formats that should be available at each level.

Ideally, HTS should be located and easily accessed at clients' first point of contact with the health system, which is predominantly at the primary care level (level 1) *(4)*. Community-based – increasingly, community-led – HTS (level 0), including test for triage and self-testing, provide important opportunities for HIV testing. These low barrier entry points are particularly important for reaching members of key populations as well as underserved populations of adolescent girls and young women and men who might not visit traditional health facilities. These services can also be integrated with testing for other disease areas, such as STIs and viral hepatitis.

The availability of staff with the appropriate skills and proficiency is important. Assays that do not have good thermostability (unlike RDTs, which can be stored at 4 to 40 °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. See *Consolidated Guidelines on HIV testing services, 2019, Web Annex I*, for description of assay formats for HIV diagnosis *(5)*.

Fig. 8.1. A tiered HTS, by assay format and staff qualifications



This figure reflects the WHO essential in vitro diagnostics list (EDL), which describes assays that test for common diseases and infections in communities and health facilities without clinical laboratories and in health facilities with clinical laboratories.

IA: immunoassay; Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point of care; RDT: rapid diagnostic test, including HIVST.

Source: WHO 2019 *(6)*.

8.3. Testing strategies for HIV-1 diagnosis

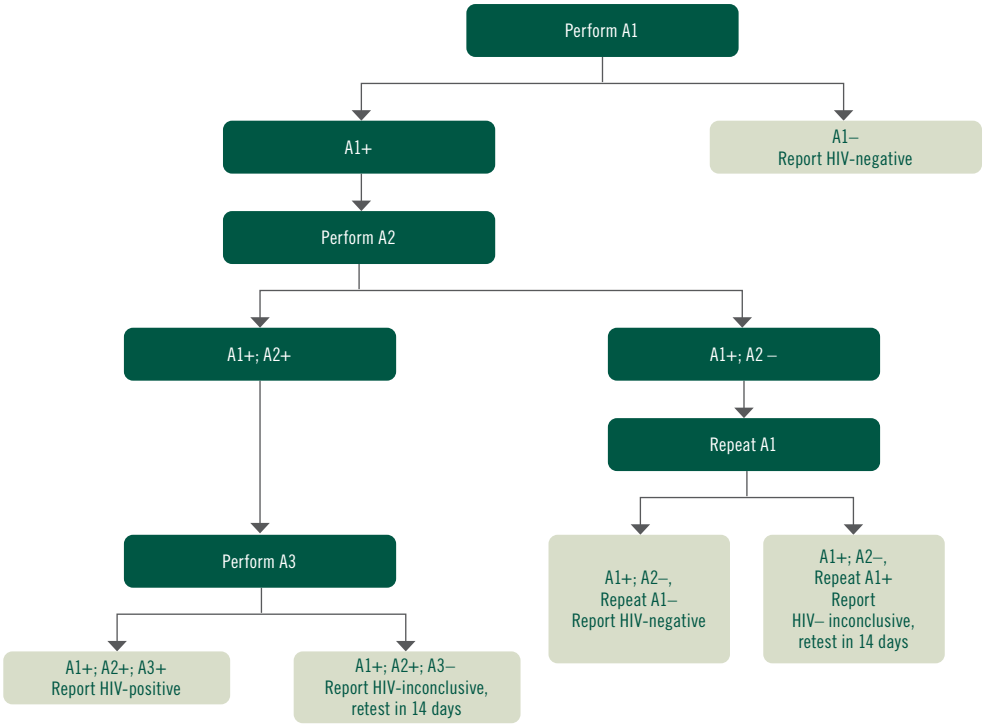
A testing strategy describes a sequence of tests conducted to achieve a specific objective, such as screening for infection or diagnosis of infection *(7)*. Sensitivity and specificity describe the performance of an assay, but they do not give sufficient information about the clinical value of the test result *(8)*. Additional information is needed to determine the predictive value of the assays used within a testing algorithm.

The PPV is the proportion of individuals with positive results who are correctly diagnosed with an HIV infection; negative predictive value (NPV) 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 in the population being tested. WHO recommends testing strategies achieve at least 99% PPV (that is, less than one false positive per 100 people diagnosed with HIV). To achieve such performance, WHO recommends tests selected have at least 99% sensitivity and 98% specificity.

8.3.1 Three-test strategy

For a three-test strategy at least three consecutive reactive HIV tests are used to provide an HIV-positive diagnosis (Fig. 8.2). This testing strategy applies to individuals over 18 months of age and can use all combinations of serology assay formats – for example, RDT or IAs – except for western blot and line IAs. WHO recommends against the use of western blot and line IAs *(9)*. Note, this strategy is not suited for making an HIV-2 diagnosis.

Fig. 8.2. 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).

The following considerations should be used when developing this strategy into a national testing algorithm that will achieve at least a 99% PPV:

- **Assay 1** must have the **highest sensitivity** to rule in all HIV-positive individuals, so may include some individuals who are falsely reactive.
- **Assay 2 and Assay 3** must have **very high specificity** – higher than A1 – to rule out any false HIV-reactive A1 test results.
- A1, A2 and A3 should be three different HIV assays (products) that share minimal common false reactivity.
- It is important to repeat Assay 1 in the event of discrepant test results (A1+; A2−). Repeating A1 will determine if the individual is repeatedly reactive on the assay that has the highest sensitivity. Discrepant test results are driven by the specificity of A1: if A1 has 98% specificity, one expects at least two false HIV-reactive results per 100 tests. Individuals who are repeatedly reactive on A1 but cannot be confirmed HIV-positive should be given an HIV-inconclusive status *(10, 11)*.
- Unlike A1, A2 does not need repeating after a reactive result, as the product for A2 is chosen for its high 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 A3, as the result would be HIV-inconclusive, irrespective of the A3 result, instead, an A1 is repeated.
- Where technical expertise permits, 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 *(12)*.
- Countries should review and consider products that are WHO prequalified; see https://extranet.who.int/prequal/vitro-diagnostics. See section 8.7 for further details on selecting assays to populate the WHO standard HIV testing strategy.

Adopting the WHO recommended testing strategy, and following the key implementation considerations for building a testing algorithm, helps ensure accurate HIV diagnoses *(13, 14)*. The cost implications of implementing a three-test strategy are minimal and much lower than the long-term costs of misdiagnosis (see example in Box 8.1).

After an HIV-positive diagnosis, WHO also advises retesting to verify this diagnosis prior to ART initiation. This does not mean that six tests are required to provide an HIV-positive diagnosis. Rather, retesting in this context is a quality assurance measure designed to prevent the initiation of unnecessary lifelong treatment. Further details on different types of retesting are provided in section 8.4.

Box 8.1. Estimates and projections (2000–2025) for HIV rapid test kits usage, cost and HIV testing outcomes: Impact of the transition to a three-test strategy in Malawi

As Malawi moves closer to achieving the 95-95-95 targets, the number of people who still do not know their status has decreased, and the percentage of new HIV-positive diagnoses is also decreasing and will continue to decline. 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. To make data-driven policy decisions about the testing strategy, the country conducted an analysis which looked at epidemiologic shifts and the potential impact on the PPV of testing strategies in the country as well as potential costs of the transition.

Using 2019 and 2020 country data, national HTS positivity was projected to drop to 1.5% while overall adult HIV prevalence was projected to be 8.4% in 2025. Based on this decline in HTS positivity, the PPV of the two-test strategy would only achieve 97% PPV, and the country would only achieve the WHO standards of 99% PPV when transitioning to a three-test strategy (Fig 8.3). The cost of the three-test strategy did not substantially change HTS programme costs because the cost of the first test (A1) was found to drive programme costs (Fig 8.3). The cost of HIV misdiagnoses, as reported previously, are also high, as they include unnecessary treatment costs, in addition to individual and broader social costs.

Beginning in 2019, Malawi decided to transition to a three-test strategy to maintain a PPV of at least 99% and has closely monitored its implementation in real-life conditions. Since making the transition, an analysis led by the Ministry of Health showed that, in select facilities, at least 371 people would have been misdiagnosed and incorrectly started on lifelong treatment in 2023. Preventing these cases of misdiagnosis has led to substantial savings for the health system, in addition to avoiding high individual and social costs to Malawians.

Fig. 8.3. Implementation of a three-test strategy in Malawi

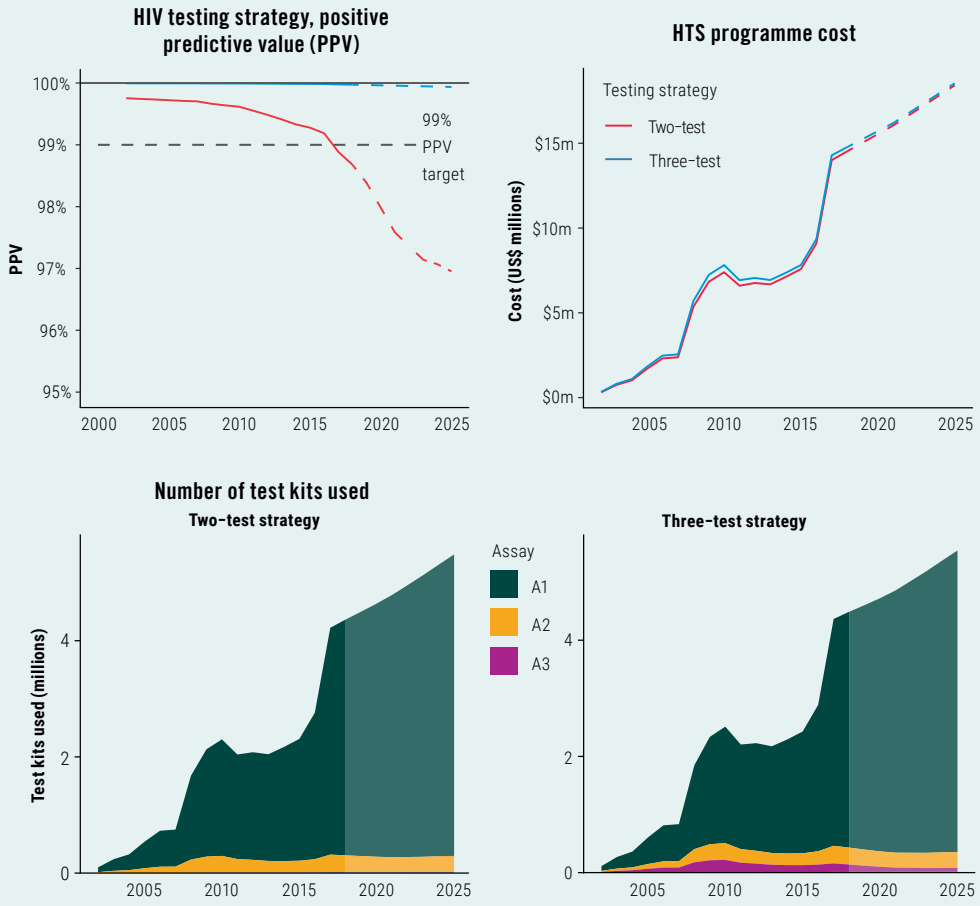


Fig. 8.3 shows PPV of two- and three-test strategies, programme cost, and test kits used. The two-test strategy (red lines) refers to using two consecutive reactive tests for an HIV-positive diagnosis. The three-test strategy (blue lines) refers to using three consecutive reactive tests for an HIV-positive diagnosis. Estimates of PPV assume 98% specificity for each independent assay (test) in the algorithm and do 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.

Source: WHO/UNAIDS/Malawi Department of HIV/AIDS 2024, adapted from Maheu-Giroux et al. 2019 *(15)*.

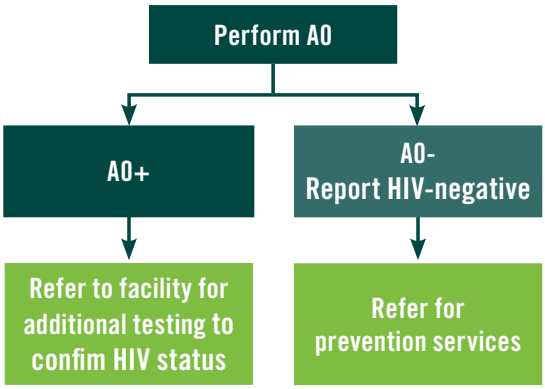
Countries that are working to adopt WHO guidance and change their testing strategy and algorithm need to develop a plan and identify the optimal time for the transition. It is important to align and coordinate changes in tendering, selection and procurement of new tests (including an A3), verification of the testing algorithm, logbook and register updates, training and supportive supervision and national and site-level policy and guidance. Countries should consider using the existing WHO tool kit: https://www.who.int/tools/optimizing-hiv-testing-algorithms-toolkit.

8.3.2 Test for triage

Countries can also consider ways to provide efficient delivery of the first test in the strategy, since it accounts for the largest total cost among the three assays. Scaling up task sharing and utilizing approaches such as self-testing or test for triage can be considered (Fig 8.4).

In these approaches, only those with reactive results are referred to further testing using the full national testing algorithm. As a result, these options can scale up testing further while minimizing the need to procure and provide training for all three assays in all testing settings.

Fig. 8.4. Testing strategies for test for triage or self-testing



A0: Assay 0 can be an RDT or self-test.

In case of reactive test for triage (e.g., A0), an additional test is required following the entire national testing strategy. Any negative A0 can be reported as HIV-negative status, and the result can be used to facilitate linkage to prevention services.

If using a dual HIV/syphilis self-test, any reactive syphilis self-test results should be immediately treated in pregnant women and those with no history of syphilis treatment if further testing is not immediately available or there is considerable risk of loss to follow-up. Further testing to confirm diagnosis is advised in all other groups and should be performed according to national guidelines. Dual tests are not advised for people with HIV or those previously diagnosed with syphilis *(16)*.

Additional details on syphilis testing, diagnosis and treatment are available on the WHO website: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/stis/overview.

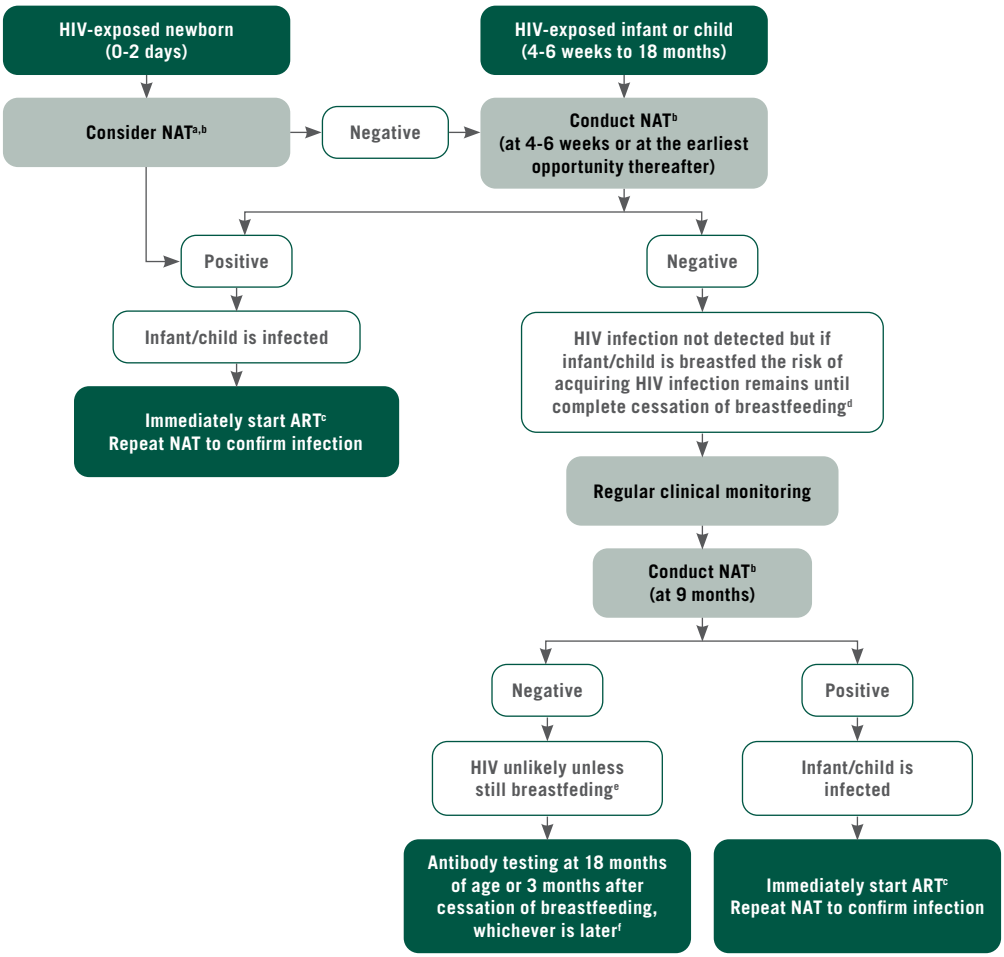
See also Section 8.4.5 and Section 8.5.1 for further details on self-testing strategies for PrEP and multiplex testing strategies and algorithms for HIV and syphilis.

8.3.3 HIV testing strategy for HIV-1 diagnosis in children 18 months of age or younger

For children 18 months of age or younger, serology assays alone, such as HIV RDTs, are insufficient to diagnose an HIV infection because they may detect maternal antibodies transferred across the placenta to the infant during pregnancy. Virological testing, typically using NAT, is recommended to diagnose an HIV infection in children 18 months of age or younger *(12)*. Fig. 8.5 depicts the WHO HIV testing strategy and algorithm for early infant diagnosis.

For all HIV-exposed children, NAT should be offered at birth, 4–6 weeks, 9 months and at 18 months or 3 months after cessation of breastfeeding. It should be noted that HIV-exposed infants should be tested anytime they present sick and to ensure that further testing of a positive NAT result is undertaken. The diagnosis is not completed without "final diagnosis" at the end of the period of risk for transmission. 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 (17)*.

Fig. 8.5. WHO testing strategy and algorithm for early infant diagnosis



a Based on *2016 WHO Consolidated ARV Guidelines (3)*, addition of NAT at birth to the existing testing algorithm can be considered.

b Point-of-care NAT can be used to diagnose HIV infection as well as to confirm positive results.

c Start ART without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase: retesting after a first positive NAT is hence important to avoid unnecessary treatment, particularly in settings with lower transmission rates. If the second test is negative, a third NAT should be performed before interrupting ART.

d For children who were never breastfed, additional testing following a negative NAT at 4–6 weeks is included in this algorithm to account for potential false-negative NAT results.

e The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month test is conducted earlier than 3 months after cessation of breastfeeding, infection acquired in the last days of breastfeeding may be missed. Retesting at 18 months or 3 months after cessation of breastfeeding (whichever is later) should be carried out for final assessment of HIV status.

f If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding.
If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants younger than 18 months of age NAT should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirms infant is infected.

Source: Based on WHO 2021 *(18)*.

8.4 Retesting for individuals over 18 months of age

It is important to differentiate between repeat testing and retesting. In this guidance, repeat testing refers to testing within the same testing event to resolve a discrepant result. For example, following a reactive A1 and nonreactive A2, WHO's recommended testing strategy is to repeat A1. Retesting, however, refers to a new testing event after the initial one and uses a new specimen. Reasons to retest can include:

- resolving an HIV-inconclusive status when returning after 14 days
- verifying an HIV-positive status before ART initiation
- re-engaging in treatment and care for those who re-engage through the HTS programme
- managing PrEP and PEP
- preventing ongoing risk of acquiring HIV.

This chapter focuses on retesting to resolve an HIV-inconclusive status, to verify an HIV diagnosis prior to ART, as part of re-engagement in care, and for PrEP or PEP management. Guidance related to retesting messages and other programmatic forms of retesting are addressed in other chapters.

8.4.1 Retesting individuals to resolve an HIV-inconclusive status

In a small number of cases with inconclusive results it may not be possible to give a definitive HIV diagnosis on the same day. In this situation, individuals need to be asked to return in 14 days for retesting. While rare, this is not a failure of the assays or of the testing strategy, but rather a limitation of any testing and there may be a need to rule in or rule out seroconversion.

Retesting to resolve an HIV-inconclusive status after 14 days should follow the same national testing strategy in Fig. 8.2 If the results continue to be inconclusive (i.e. A1+; A2+; A3− or A1+; A2−/A1+) upon retesting, individuals should be considered and reported as HIV-negative.[1]

8.4.2 Retesting to verify HIV-positive diagnosis prior to ART initiation

To ensure that individuals are not incorrectly started on lifelong ART, WHO recommends that all individuals who are newly diagnosed with HIV be retested to verify their HIV status prior to starting ART *(19)*. Every effort should be made to prevent misdiagnosis which can be difficult to address after ART is initiated *(20)*. 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 *(21, 22)*.

Retesting to verify an HIV-positive status prior to ART initiation follows the same testing strategy as shown in Fig. 8.2. This form of retesting is a quality assessment step that aims to detect misdiagnosis by ruling out errors related to the lot, testing site or testing *(23)*. It may detect clerical errors, such as transcription errors during result interpretation and reporting, and specimen mix-ups. It is not considered to be part of the diagnostic testing algorithm or to optimize the PPV of the testing strategy.

When retesting to verify a diagnosis, the same testing algorithm used when making an HIV-diagnosis should be used. Further, it is ideal if retesting is at a different site and using a different lot of A1, A2 and A3. If retesting at a different site or lot is not feasible, at least a different testing provider should be prioritized. Programmes that struggle to implement retesting before ART initiation can consider ways to focus efforts, for instance prioritizing specific facilities and geographies where quality issues have been reported or adapting based on large-scale self-testing *(24)*.

Any individual diagnosed with HIV who has negative or discrepant results following retesting should be referred for further testing at an alternative facility using the same validated testing algorithm. If available, a higher-level facility should be considered.

[1] However, because of the decreased HIV antibody response of the impaired immune system, an HIV-inconclusive status may be observed for individuals with clinical signs meeting the WHO criteria for stage III or IV HIV infection.

Retesting to verify an HIV-positive status prior to ART initiation follows the same testing strategy as shown in Fig. 8.2. Upon retesting:

- **Individuals who are non-reactive on Assay 1 (A1–) upon retesting** may be HIV-negative. The individual should be referred for additional testing, preferably at a higher-level facility using a different testing algorithm if available. If testing at a higher-level facility is not available, retest a third time in the same testing facility, using the same national validated testing algorithm.
- **Individuals who are reactive on Assay 1 (A1+) upon retesting** should then be tested on Assay 2 (A2). Individuals who are reactive on both Assay 1 and Assay 2 (A1+; A2+) should then be tested on 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, preferably at a higher-level facility and using a different testing algorithm.
- **If individuals are reactive on Assay 1 but non-reactive on Assay 2 (A1+; A2–) upon retesting**, 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, preferably at a higher-level facility and using a different testing algorithm.

8.4.3 Retesting to re-engage in care

Some individuals who have previously been diagnosed with HIV delay starting treatment. Additionally, there are some people who were diagnosed with HIV and started treatment but later disengaged. No matter someone's history, HTS should always be a non-judgemental and welcoming place to receive support and retesting if needed.

Retesting to re-engage in treatment and care follows the same testing strategy as shown in Fig. 8.2.

Chapter 4 discusses key counselling messages to support retesting as part of re-engagement.

8.4.4 Retesting those on ART is not recommended

Retesting is not recommended for individuals on ART. However, studies and programmes report that people with HIV taking ART, disclosed or not, present for testing *(25, 26)*. Recent reports indicate that 13–63% of people presenting for HTS have already been diagnosed with HIV and some proportion of these are likely to be taking ART *(23, 27)*. 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 *(28)*. 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 (AHI), including adults diagnosed during the early Fiebig[1] 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 may be more affected than those that use serum/plasma or whole blood. Western blotting is also affected by ART, reflecting 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 for diagnosis *(3)*.

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 (VL) may seek retesting and are likely to be NAT-undetectable. A NAT-undetectable result does not rule out HIV infection *(30)*. **WHO cautions against using NAT technologies to rule out HIV infection in adults and children over 18 months of age.**

[1] Fiebig et al. (2003) described a staging system for primary HIV infection based sequential emergence of test reactivity *(29)*.

Both false-negative and false-positive results can occur with NAT depending on the assay used *(31, 32)*. False-positive results may occur due to contamination or carryover. False-negative results may occur due to insensitivity of the assay target, sample degradation or presence of inhibitors. As with any assay used diagnostically, PPV and NPV are also strongly influenced by the underlying prevalence in the population tested.

This guidance, however, does not cover testing in the context of clinical trials for HIV cure and vaccinology.

8.4.5 Testing and retesting as part of PrEP and PEP management

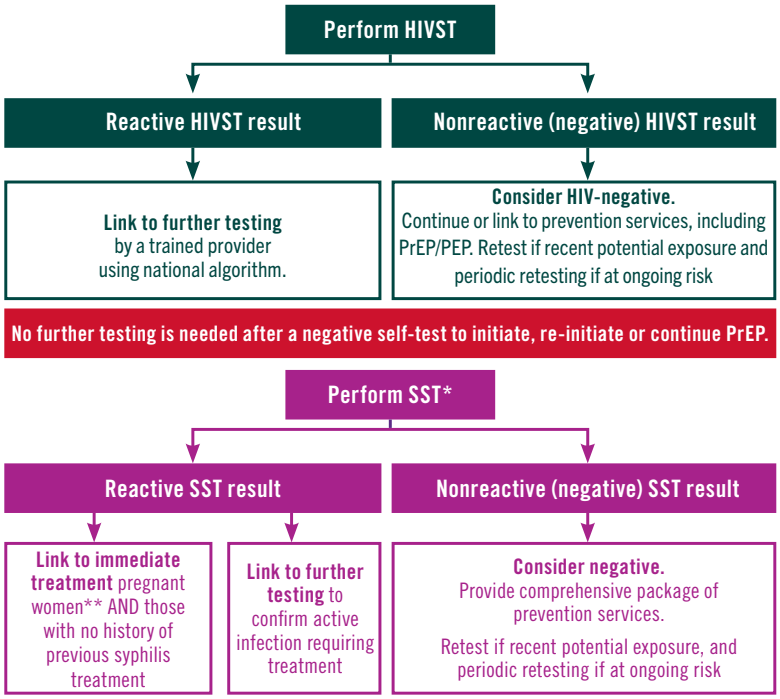
Individuals interested in or who are taking PrEP or PEP need HIV testing. There are many PEP and PrEP options available, including the dapivrine vaginal ring (DVR), oral PrEP and long-acting injectable PrEP, such as cabotegravir (CAB-LA).

Differentiated and simplified service delivery is a priority to reduce barriers to effectively accessing and using PEP and PrEP *(36)*. Only individuals who have an HIV-negative test result should be initiated on PEP or PrEP. WHO recommends PEP for those who have a possible exposure to HIV in the past 72 hours and PrEP for individuals who could most benefit.

Individuals who actively use PrEP should regularly self-test or receive regular retesting (usually every two or three months, depending on the type of PrEP being used) or as needed when restarting PrEP. Individuals with one or more reactive test results prior to initiating PrEP or while taking PrEP may need further testing to confirm their HIV diagnosis. Individuals taking PEP should also retest after completing their course to determine if they have acquired HIV and need to be initiated on ART, or whether they would benefit from PrEP. Anyone with inconclusive results should be referred to return for further testing to confirm their HIV status after 14 days.

Self-testing can be used to initiate, re-initiate or continue PrEP (see Figure 8.6). Evidence has shown that self-testing is safe and effective and that it can help increase uptake of PrEP which is key to reducing new HIV infections. Self-tests do not increase the risk of missing AHI compared to standard testing services at population level *(33, 34)*. Further research is needed, however, before using self-testing as part of initiating or managing long-acting injectable antiretroviral drugs (ARVs) *(35)*. See Chapter 5 for service delivery guidance.

Fig. 8.6. Testing strategy when self-testing within PrEP services



See WHO's *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis* testing and partner services for further details *(36)*.

* *Syphilis self-testing (SST) can be adapted to include quality assured products such as the dual HIV/syphilis self-tests (HIV-SST) and dual treponemal/non-treponemal self-tests.* See WHO's *Updated recommendations for the treatment of Neisseria gonorrhoeae, Chlamydia trachomatis, and Treponema pallidum (syphilis) and new recommendations on syphilis testing and partner services* for further details *(36)*.

** Treatment benefits for infant are greater than risks from maternal treatment. Therefore, treat all pregnant women with first dose of benzathine penicillin G (BPG) at point of care. Treat if patient cannot recall previous BPG injections. For persons who recall previous treatment, re-infection is possible. Treatment could be deferred until the non treponemal test results are available. However, if clinical suspicion is high, or loss to follow-up a possible concern, consider treating at the clinic visit.

In case of a reactive self-test result, further testing is required. All reactive self-test results need to be followed by further testing by a trained provider, starting with the first test in the national algorithm (Fig. 8.6). A confirmed HIV-positive diagnosis should then be followed by linkage to treatment.

A negative HIVST result is considered negative and further testing is not needed to start or continue PrEP. Individuals who report a recent exposure or ongoing risk can be encouraged to retest, in accordance with national guidance.

If using a HIV-SST, any reactive SST results should be immediately treated in pregnant women and those with no history of syphilis treatment if further testing is not immediately available and there are concerns about loss to follow-up. Further testing to confirm diagnosis is advised in all other groups and should be performed according to national guidelines. Dual tests are not advised for people with HIV or those previously diagnosed with syphilis. See section 8.7 for further syphilis testing guidance.

Breakthrough infection (when a person acquires an HIV infection while taking PrEP) is very rare *(36)*. If HIV acquisition is suspected during retesting among individuals who use PrEP, it is critical to ensure that the diagnosis is correct before switching from PrEP to ART. In the case of an inconclusive result, the course of action to rule in or rule out HIV infection is as follows:

- Conduct serology testing after 14 days 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 inconclusive A1+; A2+; A3− or A1+; A2−; A1+, the person who is using PrEP is HIV-negative, and PrEP can be continued, with quarterly or bi-monthly retesting.

If the serology profile evolves (A1+; A2+; A3+), the individual who is using PrEP should be diagnosed as HIV-positive. In this case, it is critical to confirm that the diagnosis is correct by retesting using the same national testing algorithm before switching from PrEP to ART.

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 serological and virological testing should be performed after 14 days. Two weeks should be sufficient for the virus to recommence 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 and STI prevention, such as condoms, while the person is not using PrEP.

It is important for programmes to select a testing strategy and algorithm that promotes access to PrEP among those who would benefit most. WHO guidance advises countries to use existing testing strategies and national testing algorithms, including RDTs and self-tests, when implementing PEP and PrEP. WHO does not recommend PrEP and PEP programmes to adopt specialized testing strategies, such as routine use of NAT assays or fourth generation serology assays for initiation and/or continuation.

There is current uncertainty about using NAT assays before CAB-LA initiation, and while taking CAB-LA *(35)*. While NAT assays could help prevent a small number of cases of drug resistance, countries need to consider the feasibility. For example, according to a systematic review, the time between laboratory-based NAT sample collection and delivery of results was a median of 35 days *(37)*. There are also uncertainties as to what impact these mutations will have on subsequent ART. If NAT is implemented as part of CAB-LA programmes, it is important to have the necessary assays, resources, regulatory approvals and a clear testing strategy for resolving discrepant results and establishing HIV infection. Ongoing monitoring of implementation is needed to optimize HIV testing approaches. WHO will continue to review evidence and update testing guidance for PrEP programmes, particularly for long-acting ARVs.

For additional details on testing requirements for PrEP see WHO technical brief on differentiated and simplified pre-exposure prophylaxis for HIV prevention *(36)* and Guidelines on long-acting injectable cabotegravir for HIV prevention *(35)*.

8.5 Testing for other conditions

There are benefits of providing integrated services which test for other diseases or conditions along with HTS. 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 hepatitis B[1] (HBsAg).

Multiplex testing is increasingly being considered and used in settings for both molecular and serology tests. Dual HIV/syphilis RDTs and self-tests are recommended and can also be used. New multiplex tests for triple elimination and across STIs are emerging and evidence of their clinical utility is being reviewed.

Additional WHO guidance on testing for other infections is available in Box 8.2.

8.5.1 Multiplex testing for HIV-1 and other infections

Multiplex testing refers to an assay that can provide more than one result from one specimen.

HIV and syphilis dual detection

Syphilis is a bacterial STI, caused by *Treponema pallidum*, that results in substantial morbidity and mortality, particularly in pregnancy, as it can lead to congenital syphilis if not adequately and promptly treated *(38)*. Syphilis diagnosis is usually based on a combination of clinical history, physical examination, laboratory testing and sometimes radiology. Although other laboratory tests exist, serological tests are the most used in many settings. Serological tests for syphilis include treponemal tests, which detect antibodies produced against *T. pallidum*, and non-treponemal tests, which detect indirect markers of the host immune response that are not specific to *T. pallidum* but provide support to the diagnosis of active versus resolved infection. Ideally, syphilis diagnosis should be made using both treponemal and non-treponemal tests, but in settings where non-treponemal tests are not available on-site, treatment decisions can be made using clinical evaluation, treatment history and a treponemal test result alone *(39)*. However, for pregnant women in limited-resource settings, due to the high risk and severe consequences of congenital syphilis, immediate treatment is recommended based solely on a treponemal positive test *(39)*.

Rapid tests and self-testing for syphilis, including the dual HIV/syphilis RDTs, are easy to use and do not require refrigeration. They are treponemal tests and cannot differentiate between past/cured and current/active infection because, in most cases, treponemal antibodies persist for life even after syphilis has been cured. Non-treponemal assays can distinguish between active and non-active infection but require refrigeration and are generally conducted in laboratories. RDTs that combine treponemal and

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

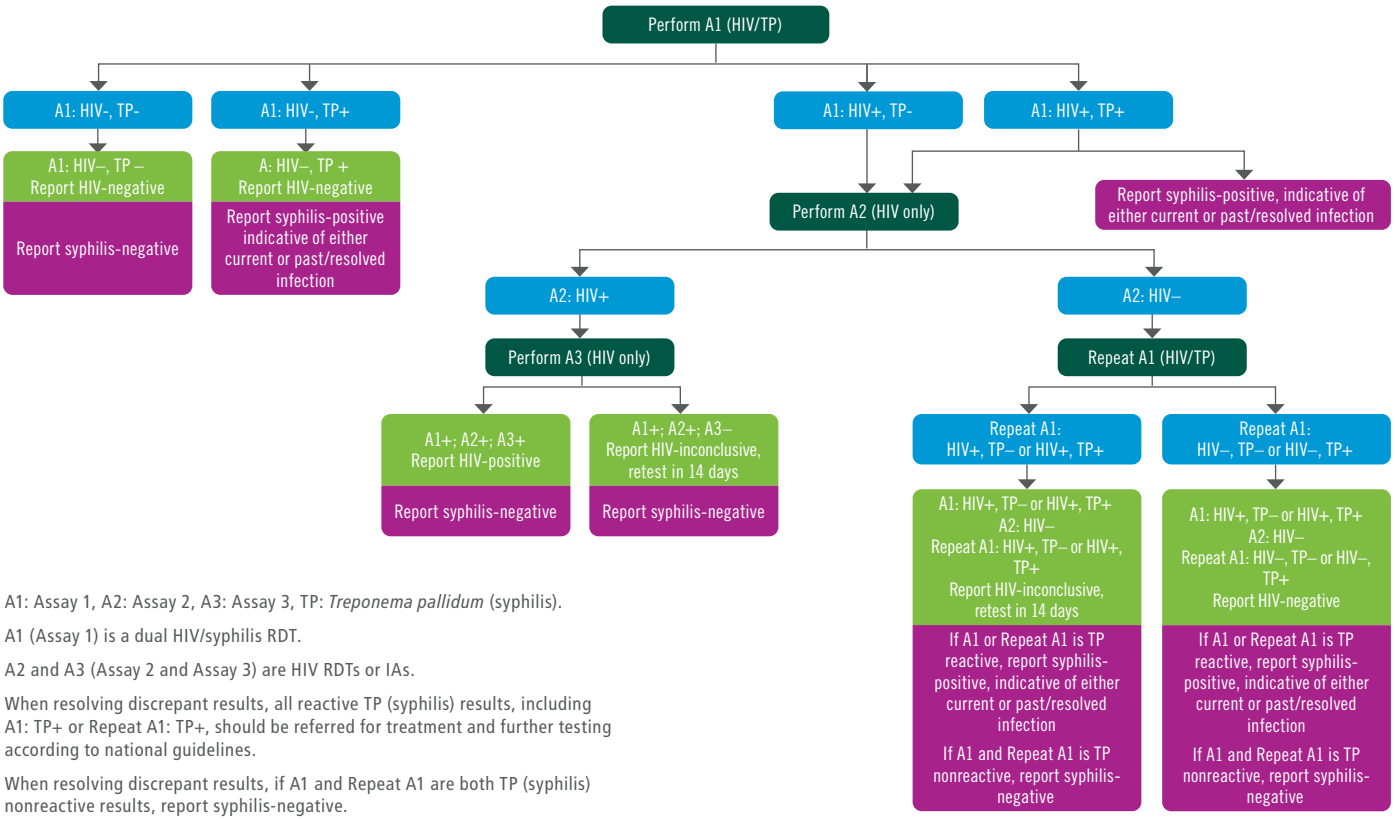
non-treponemal detection can be considered but are not yet widely available. Dual HIV/syphilis RDTs can be offered as a self-test in general, or as the first assay within the HIV testing strategy in ANC and for key populations to increase syphilis testing and treatment coverage *(16)*. It is important to note, however, that dual HIV/syphilis tests are not advised for:

- people with HIV on ART;
- women already diagnosed with and treated for syphilis during their current pregnancy (in settings where non-treponemal tests are not available)[1];
- retesting to verify HIV-positive diagnosis prior to ART initiation at sites where stand-alone HIV RDTs are available; and
- people from key populations who have a previous positive treponemal test or a documented history of syphilis treatment.

Countries introducing dual HIV/syphilis self-tests or RDT will need to update their HIV and syphilis testing strategies. Fig. 8.7 presents the testing strategy when using dual HIV/syphilis RDTs in ANC settings and for key populations.

Countries introducing dual HIV/syphilis RDTs as the first test in ANC and for key populations will need to verify that a dual 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://extranet.who.int/prequal/medicines/prequalified-lists. Further information on syphilis testing and treatment are available on the WHO website: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/stis/overview.

Fig. 8.7. WHO-recommended testing strategy for dual detection of HIV and syphilis infection in ANC settings and for key populations



A1: Assay 1, A2: Assay 2, A3: Assay 3, TP: *Treponema pallidum* (syphilis).

A1 (Assay 1) is a dual HIV/syphilis RDT.

A2 and A3 (Assay 2 and Assay 3) are HIV RDTs or IAs.

When resolving discrepant results, all reactive TP (syphilis) results, including A1: TP+ or Repeat A1: TP+, should be referred for treatment and further testing according to national guidelines.

When resolving discrepant results, if A1 and Repeat A1 are both TP (syphilis) nonreactive results, report syphilis-negative.

[1] There is a need to assess risk of syphilis re-infection based on timely treatment of sexual partner(s) and to decide about retreating the pregnant woman accordingly.

Box 8.2. Additional resources on testing for other conditions

- Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection; 2024. https://iris.who.int/bitstream/handle/10665/376353/9789240090903-eng.pdf
- New recommendation on hepatitis C virus testing and treatment for people at ongoing risk of infection; 2023. https://iris.who.int/bitstream/handle/10665/366869/9789240071872-eng.pdf
- Updated recommendations on treatment of adolescents and children with chronic HCV infection, and HCV simplified service delivery and diagnostics; 2022. https://iris.who.int/bitstream/handle/10665/363590/9789240052734-eng.pdf
- WHO guideline on syphilis screening and treatment for pregnant women; 2017. https://apps.who.int/iris/bitstream/handle/10665/259003/9789241550093-eng.pdf
- WHO recommendations on antenatal care for a positive pregnancy experience; 2016. https://apps.who.int/iris/bitstream/handle/10665/250796/9789241549912-eng.pdf;jsessionid=91A8A52F06F207BDB0A1837FA884F374
- WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention; 2013. https://apps.who.int/iris/bitstream/handle/10665/94830/9789241548694_eng.pdf

8.6 Recency testing in routinely offered HTS programmes

WHO and UNAIDS have published guidance for the use of recency assays (see Box 8.3) – specifically for surveillance – and this guidance remains unchanged *(40)*. Adding recency testing to routine HTS – increasingly common in HIV programmes – is not recommended.

Box 8.3. Current WHO and UNAIDS guidance on recency testing in surveillance

The utility of recency testing has been demonstrated in population-based surveys to measure HIV incidence.

WHO cautions against the use of recency testing in programmatic settings for routine surveillance due to several challenges. It should only be considered when HIV testing coverage of the population being studied is high (for example, in ANC services); when a combination of assays, including viral load testing, can be incorporated in a recent infection testing algorithm (RITA) to reduce false recent results; and when analysis plans make appropriate statistical adjustments and infer population-specific trends in recent infection.

WHO does not recommend recency assays for clinical use or management of people living with HIV or their partners. In this context this includes return of results to clients, counselling messages about recent infection and prioritizing initiation of ART, partner services, index testing or additional services based on recency results.

Historical or clinical information must always be incorporated into any RITA to identify and screen out false recent assay results. Single assays should never be used on their own to estimate HIV incidence or other indicators of recency.

Source: UNAIDS and WHO 2022 *(40)*.

In some settings, programmes are increasingly using HIV recency assays in HTS on the assumption that it can increase efficiency and effectiveness. Historically, assays for recent HIV infection have been used primarily in epidemiologic surveys to estimate HIV incidence. However, some countries with both low and high HIV burdens have started using recency testing in routine HTS and case surveillance systems.

Evidence on the effectiveness of recency testing in HTS was derived from a systematic review that also summarized findings on ease of use, harms, values and preferences, and resource use (see Web Annex F for details). A values and preferences study was also conducted (see Web Annex G for details). The findings based on evidence reviewed and the GDG's expert opinions are summarized in Box 8.4.

Box 8.4. Summary of evidence for recency testing in routine HTS programmes

Compared to standard testing, recency testing in routine HTS programmes:

- No clear evidence of effectiveness and differences in recent or long-term infections among the proportions of HIV infection identified in the contacts of partners with HIV.
- Effects on social harm were uncertain. Concerns about social harms such as stigma, conflict among community members, dissatisfaction with services and increased intimate partner violence were reported by both providers and clients.
- Limited acceptability feasibility due to requirements for substantial resources, time, planning, training and monitoring. Limited capacity to implement viral load testing which is needed to confirm recent infection was a key barrier.
- No direct evidence on cost or cost–effectiveness, however programmatic data and values and preferences identified substantial issues and concerns about high costs.
- No direct evidence on equity and human rights, but values and preferences and GDG identified concerns about lack of clinical benefit and reduced equity due to diversion of funds needed for other activities.

Based on the limited available evidence of effectiveness, as well as additional values and preferences and programme data reviewed, the GDG judged the benefits of recency testing in routine HTS to be trivial or uncertain and harms to be uncertain and poorly documented in the published literature but potentially substantial.

As to whether recency testing could improve the efficiency and effectiveness of HIV testing, there was consensus that it would not. The GDG judged the certainty of the evidence to be very low.

The consensus of the GDG was that recency testing would not improve programme efficiency or effectiveness.

When determining the balance of benefit and harms, based primarily on the effectiveness review, the GDG determined that the harms likely outweigh the benefits.

This was because the GDG determined that recency testing in routine HTS has:

- no clear clinical benefit or evidence of effectiveness;
- variable acceptability, with many stakeholders finding the intervention unacceptable;
- increased costs as recency testing does not replace diagnostic HIV testing and requires additional tests and service delivery costs (recency test costs, VL assay costs, implementation costs);
- uncertain but potentially negative effects on equity;
- very limited feasibility given the context of limited availability of VL testing; often inadequate human resources and shrinking resource allocation for testing services and HIV programmes; and increased time that may be needed for an individual to receive the final result (a confirmed HIV-positive status plus recency testing result), which could contribute to loss to follow-up as a client will have to return for the final result.

Based on these considerations, the GDG advised that WHO make a conditional recommendation against use of recency testing in routine HTS (Box 8.5). While the GDG reached consensus on this recommendation, a vote was required to determine the strength of the recommendation: three of the 14 GDG members did not agree with the decision to make the recommendation conditional. These members preferred to make a strong recommendation against and requested that this be noted.

Box 8.5. NEW WHO recommendation

HIV recency testing is not recommended as part of routine HIV testing services *(conditional recommendation, low-certainty evidence)*.

Remarks

This recommendation is to exclude recency testing from routine HTS. HTS is defined as a package of services including 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.

WHO and UNAIDS have published guidance for the use of recency assays specifically for surveillance: *Using recency assays for HIV surveillance: 2022 technical guidance (40)*.

The GDG identified the following considerations for use of recency testing in routine HTS.

No clinical benefit of recency testing has been identified. Regardless of the recency of infection, everyone diagnosed with HIV should be offered immediate ART, and everyone with HIV should be supported for voluntary partner services. There are no diagnostic or clinical benefits to the individual of knowing the results of recency testing. In contrast, there are concerns about potential harms if individuals feel that, through recency testing, they can identify the source of their HIV infection or be identified as a source of infection.

Harms associated with recency testing may be substantial but are not well documented in the literature. The WHO-commissioned values and preferences study (Web Annex G) pointed to provider and community concerns about harms, but, other than this study, a paucity of data was available on harms. The GDG noted concern about potential harms resulting from return of results to clients and providers.

Recency assays do not identify acute infection, when HIV transmission risk may be high. There may be some clinical and prevention benefit to diagnosing and treating AHI, which generally develops within two to six weeks after infection. Currently, however, rapid recency tests are unlikely to detect AHI. Furthermore, phylogenetic evidence indicates that 63% of new infections are from those who were themselves infected more than one year previously. Hence, diagnosing people who are recently infected is not the priority for achieving and sustaining low incidence of HIV because incident infection is driven by those with longstanding infection *(41, 42)*. All new diagnoses are important when thinking of transmission (not just recent ones), and from a programmatic perspective, offering partner services to all people diagnosed with HIV is a priority.

A proposed use case for recency testing – identifying hotspots – is not supported by evidence. A proposed use for recency surveillance is the identification of hotspots (clusters of recent infections), which would then be followed up by field teams to investigate and/or flagged for focused HIV services. This would require traceable residence location information from all clients who undergo recency testing. Evidence from phylogenetic studies *(41)* and surveys *(43)* show that the scientific basis for this use case is weak. A higher priority should be to routinely deliver basic HIV testing, prevention and treatment services at community venues of strategic importance. Testing and other services can be focused on sites with higher numbers of HIV infections/higher positivity rate.

The feasibility of recency testing in routine service delivery has not been demonstrated. False recent results are common, particularly when used without a RITA. At an individual level, after a positive recency test, to determine if someone truly has a recent infection would require further testing, which would include, at a minimum, a VL test. For this reason, recency testing is a two-step process. First, collection of

an additional sample for recency assay testing. Second, for those with a reactive recency result, collecting a dried blood spot (DBS) sample for VL testing as part of the RITA to minimize misclassification of recent infections and to confirm if an infection is recent. Thus, collection of a DBS specimen is conditional on receiving a reactive result on the recency assay, revealing to the client that the preliminary recency assay result was reactive, although not confirmed until the VL test is performed. As a result, sharing the results of recency testing is not advised as providing potentially false information on recent infection may be harmful, and no clinical benefit has been shown.

Clients must give verbal informed consent for recency testing once the full process is explained to them. Thus, implementation through routinely offered testing services may not be feasible.

Providers, too, may find communicating about the recency testing process complex. Adding the rapid test for recent infection to the testing algorithm can increase complexity for providers who must already manage many different tasks during client visits including delivering an HIV diagnosis, and potentially also delivering testing and diagnosis for viral hepatitis or other STIs. In many resource-limited settings, where testing services are often delivered by lay providers, it may be very challenging to provide adequate quality assurance for more complex testing algorithms.

Further research on recency testing is not beneficial. The GDG stated that future research on the use of recency assays in routine HTS is not a priority, as there has already been considerable investment and implementation without demonstrable benefit, nor extensive published research. Given that there have been multiple programmes and projects in many countries and regions that have implemented recency testing as part of HTS over the past decade (requiring large financial and human resources), resulting in very little information to support recency testing, the GDG emphasized that it was not beneficial to continue research in this area.

8.7 Choosing HIV assays

WHO advises countries use verification studies to develop an effective testing algorithm. Operational details on how to complete a verification study are available in the WHO tool kit: https://www.who.int/tools/optimizing-hiv-testing-algorithms-toolkit.

The following principles should be considered when selecting assays for different purposes.

8.7.1 Choosing A1, A2 and A3 for the WHO testing strategy

1. Select two products that could both be used for A1.

- Both must have superior sensitivity of at least 99% (for this information, refer to the manufacturer's instructions for use (IFU).
- Dual HIV/syphilis RDTs can be considered for A1 but would not be appropriate in the A2 or A3 position.
- Assume that these products could be interchanged with each other but not with A2 or A3.

2. Select three products that could be used for A2 and A3.

- These must have superior clinical specificity of at least 99% (refer to the manufacturer's IFU).
- Assume that these products could be interchanged with each other but not with A1.

National programmes should consider having flexible testing algorithms. This means selecting two products that can be used as A1, and three products that can be used as either A2 or A3. This protects against risks related to supply disruption.

Programmes should plan to review their testing algorithm every three to five years. Review and update of testing algorithms will enable programmes the opportunity to further optimize testing services and potentially use new and less costly products.

8.7.2 Choosing A0 for test for triage and self-testing

Self-tests and other tests for triage approaches are considered as A0 as they need further testing to confirm all reactive results. These tests should ideally have high sensitivity and specificity. It is important to ensure that these tests are low-cost, easy to use and can be implemented in a wide range of settings, including those with limited infrastructure and support.

Both oral fluid-based and blood-based self-tests are safe and acceptable and can be considered.

8.7.3 Quality characteristics of IVDs

Programmes should use WHO prequalified products. 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 are designed to suit the needs of resource-limited settings. They scrutinize aspects of critical importance in such settings including risk management, clinical evidence, product stability and labelling. When the decision has been made to prequalify a product, WHO issues a prequalification public report,[1] 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. WHO's list of prequalified products can be found at: https://extranet.who.int/prequal/vitro-diagnostics.

Another approach that can be considered is to apply internationally recognized standards, such as those issued by the International Organization for Standardization, when assessing the product for its compliance with quality, safety and performance requirements. Such an approach requires national regulatory capacity for conformity assessment of each product.

8.7.4 Performance characteristics of IVDs

To support product selection for HIV testing algorithms, Table 8.1 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.

When a product is well-regulated[2] 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.

[1] See WHO Prequalification Public Reports at https://extranet.who.int/prequal/vitro-diagnostics/prequalification-reports.

[2] That is, WHO prequalification or stringent assessment by a founding member of the Global Harmonization Task Force.

Table 8.1. Performance characteristics for product selection

Performance characteristic	Suggested minimum requirement
Clinical sensitivity	
Assay 1	≥99% for RDTs, 100% for IAs
Assay 2 and Assay 3	≥99% for RDTs, 100% for IAs
Clinical specificity	
Assay 1	≥98% for RDTs, ≥98% for IAs
Assay 2 and Assay 3	≥99% for RDTs, ≥99% for IAs
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 IA	≤5%

RDT: rapid diagnostic test; **IA:** immunoassay

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.

If a dual HIV/syphilis RDT is to be included in the algorithm for ANC and/or key population settings, it is important to review the performances (sensitivity and specificity) of the assays for syphilis detection.

WHO does not make specific recommendations for generations of serology assays to be used. Countries considering fourth generation RDTs should assess how these tests will contribute to public health impact based on their programme, as well as whether there will be additional complexity to read and interpret test results that are HIV antigen-reactive and antibody-negative test results when intending to provide diagnosis and same-day treatment initiation. Programmes may also need to carefully consider the current epidemiological context where AHI is rare and rates are declining, as well as balance growing public health interests to support integrated testing and multiplex testing approaches.

8.7.5 Operational characteristics of IVDs

Operational characteristics are important to consider in product selection. A product may have excellent sensitivity and specificity, but its operational aspects will determine its ease of use and potential for widespread implementation. The technical skills of the testing providers at the various testing sites must also be considered. A product that is difficult to use may be used incorrectly. Operational characteristics to consider include number of steps requiring precision (for example, phlebotomy, counting of multiple drops, use of a 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 at testing sites also must be considered, 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 8.2 lists additional operational characteristics. These operational characteristics should form part of the technical specifications for procurement. The assessments for WHO prequalification are an independent source of these data.

Table 8.2. 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
Time to result	
Rapid diagnostic tests	**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
Immunoassays	Minimum of 2.5 hours
Number of steps	Can vary from 2 to 6 steps to get the result
Storage/stability	
Shelf life of the product	Can range from 15 to 30 months
Storage condition	Can range from 2 °C to 27 °C, 30 °C or 40 °C and also 8–30 °C (cannot be stored in a refrigerator)
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
Transport requirements for test kits (temperature, humidity)	Any excursion ranges accepted during transit?
	Any specialized shipping requirements?
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 IAs, 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

8.7.6 Impact of coinfections and their treatment on HIV testing

Additional external factors can affect the interpretation of HIV serology results. It is important to understand these limitations of the products, which are typically described by the manufacturer in the IFU. An example of the impact of such an exogenous factor is the higher rates of false HIV-reactivity observed for people coinfected with human African trypanosomiasis, dengue or visceral leishmaniasis *(44-46)*. Vaccine-induced seroreactivity is another factor to consider in settings where vaccines and other therapies are administered to the population, for example, in clinical trials, and might elicit HIV immune responses. Antibodies 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 individual who has participated in a trial for vaccines or other immunological intervention might be false HIV-reactive on current commercially available assays *(47)*.

8.7.7 Moving away from western blotting and line IAs

WHO recommended against western lotting and line IAs in 2019 *(9)*. A WHO-led evidence review comparing testing algorithms with and without western blotting or line IAs achieved similar accuracy (sensitivity and specificity), but testing algorithms containing western blotting or line IAs:

- 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; and
- were costlier and less preferred by clients and providers.

Programmes making the transition away from western blotting or line IAs can choose from a number of HIV RDTs. New assays selected should be evaluated based on how well they work in combination with other assays in the testing algorithm.

Moving away from western blotting is likely to lead to greater equity and uptake of HTS.

The move away from western blotting or line IAs enables more people in need of HTS 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.

Transition away from western blotting or line IAs requires 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 the shift to faster, more accurate tests results and informing communities may help to increase demand for HTS, particularly among key populations and populations where the burden of undiagnosed HIV is the greatest.

8.8 Verification of HIV testing algorithms

WHO recommends that HIV testing algorithms be verified prior to widespread rollout. When correctly chosen, combinations of RDTs or combinations of IAs and RDTs can provide reliable results at low cost *(48)*.

Verification has several purposes:

- Verification empowers national programmes to determine product selection according to their context (for example, cadre of testing provider, environmental conditions, workload of facility, etc.).
- Verification generates data on the optimal combination of assays to be used in the WHO testing strategy, as some assays may share cross-reactivity.
- Verification allows national programmes to gain familiarity with products they intend to select before they are procured at national scale.

Verification of testing algorithms should be completed every three to five years to ensure access to innovations and latest diagnostic tests based on their programme priorities.

Countries should review the WHO tool kit on how to verify testing algorithms to optimize product selection and develop the best testing algorithm for their context: https://www.who.int/tools/optimizing-hiv-testing-algorithms-toolkithttps://extranet.who.int/prequal/vitro-diagnostics.

8.9 Post-market surveillance

Post-market surveillance is an important component of ensuring the quality of testing services. Testing algorithms must be continually monitored for effectiveness, specifically for any cases of HIV misdiagnosis. Data should be collected on the rate of HIV-inconclusive status reports 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 IVDs (see Box 8.6) *(49)*.

Box 8.6. 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 for post-market surveillance and market surveillance of medical devices, including IVDs, is available at: https://apps.who.int/iris/handle/10665/337551.

User feedback forms are available online: https://www.who.int/teams/regulation-prequalification/incidents-and-SF/safety-information-for-medical-devices-including-in-vitro-diagnostics.

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Chapter 9

Quality assurance for HIV testing services

Chapter contents

Key messages

- Quality testing to ensure accurate diagnosis is essential for all programmes. Implementing **quality management systems (QMS) is a requirement** for any form of HIV testing services (HTS), such as testing in laboratories, health facilities, community settings or via self-testing.
- **In vitro diagnostic medical devices (IVDs) should meet national regulatory standards.** WHO conducts independent prequalification assessment of IVDs, with emphasis on HIV rapid diagnostic tests (RDTs) for use within and outside of laboratory settings.
- **External quality assurance (EQA)** programmes which include **proficiency testing (PT)** for tests to diagnose HIV (such as RDTs), as well as other laboratory tests used to monitor further offered treatment, are a priority to guarantee the accuracy and reliability of the test result.
- HTS providers may sometimes need to refer individuals to another site for additional testing. **Consistent, clear, confidential, accurate and timely record-keeping is critical** at both the initial testing site and the referral testing site.

9.1 Considerations for assuring the quality of HIV testing

Quality – ensuring timely, affordable and correct HIV diagnosis – is a cornerstone of any HIV programme. It is essential to organize HIV testing services (HTS) so that people with HIV are accurately diagnosed and successfully linked to and retained in treatment and care. Accurate diagnosis is particularly important in the context of "treat all" recommendations for immediate offer of antiretroviral therapy (ART) *(1)*. Due care must be taken to ensure that individuals without HIV infection are not misdiagnosed as HIV-positive and, thus, initiated wrongly on lifelong ART.

The quality of HTS is suboptimal in many settings, but simple measures can improve quality.

Misdiagnosis of HIV status – both false-positive and false-negative – has been reported *(2, 3)*. Several studies reported suboptimal performance of testing strategies and algorithms that differ from the WHO recommendations *(4)*.

Provider errors were also frequently reported in studies. These included difficulties with specimen collection, incorrectly performing the test procedure, reading test results outside of the recommended reading time and incorrectly interpreting test results. Inadequate supervision and poor management of testing kits contributed to stock-outs and the use of damaged or expired RDTs. In some cases, inadequately trained staff conducted testing. Staff had poor understanding of testing during the window period and how to retest after discrepant results or 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 were noted. In one study nearly 30% of errors led to incorrect results *(5)*. Some studies reported challenges related to interpretation of weak reactive test lines, which can be misinterpreted as a negative result.

Implementing quality management systems (QMS) is a requirement for any form of HTS, such as testing in laboratories, health facilities, community settings or via self-testing. QMS is needed regardless of the type of assay used, such as RDT or immunoassay (IA), and who conducts testing, such as trained laboratory personnel, other health care professionals, lay providers or self-testers *(6)*.

QMS consist of all the organizational processes needed to ensure quality. **Quality management** (QM) includes quality assurance (QA), quality control (QC) and quality improvement (QI). QA is the "part of quality management focussed on providing confidence that quality requirements will be fulfilled" *(7)*. It is a way to manage and plan for maintaining quality by preventing errors and defects in products and services, and it tends to be proactive. **Quality control** verifies that the product meets quality requirements and is a mechanism to identify product defects and to formally reject a defective product. Quality control is more reactive in nature than QA. It is typically focused on the quality of the actual product being used. **Quality improvement** is proposing solutions that improve quality and reliability and, therefore, increase customer satisfaction. The plan–do–check–act cycle is helpful in this regard. WHO guidance on QI is available in the policy brief *Maintaining and improving quality of care within HIV clinical services (8)*.

QM focuses on the **quality of the processes** required for effective testing, of which the quality of the product (the IVD) is only one aspect. 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. QM includes customer/client satisfaction, as well as occurrence management (dealing with errors) *(9)* (see section 9.3.8) and process improvement. Record-keeping and documentation also have a major influence on the quality of testing and so are relevant to QM. A testing service that uses products of the highest quality and performance, but where test kits are regularly out of stock, the provider does not know how to use them correctly, or the site is not open at convenient times, is not a high-quality testing service.

Everyone involved in testing services is responsible for quality. While certain tasks may need to be performed by an HTS supervisor, rather than the HTS provider, all tasks are important to implementing quality services.

This chapter covers the HTS quality. This guidance adapts international standards to the needs of resource-limited settings, where RDTs and other IVDs at the point of care (POC) are most commonly used and staff often have a variety of responsibilities in addition to testing. For more on the core elements of self-testing quality management, see the *WHO self-testing framework (6)*.

9.2 Assuring quality – what must be done at the national level

Certain aspects of a QMS must be addressed at the national level:

1. **national policies, strategic plans and monitoring processes:** how national authorities support QMS at testing sites;
2. **workforce development:** ensuring testing providers are trained and supportively supervised;
3. **regulation of IVDs:** using WHO's prequalification listing to identify quality IVDs, reporting user feedback (adverse events or product problems) and strengthening regulatory capacities;
4. **testing strategies and algorithms:** adopting WHO-recommended testing strategy and verifying testing algorithms;
5. **procurement and supply chain management:** ensuring uninterrupted supply and appropriate storage of test kits and other items; and
6. **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 QMS. 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 providing 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 a country's needs. The role of the national reference laboratory is to promote the use of standardized logbooks/testing registers and to conduct a range of EQA activities. These may include, but are not limited to, on-site supportive supervision visits, certification of testing sites, organizing provision of third-party quality-control materials (proficiency testing) and following up on corrective actions that might arise from quality activities *(11)*.

Proficiency testing (PT) for tests to diagnose/confirm HIV (rapid diagnostic tests), as well as other laboratory tests used to monitor further offered treatment, is a priority to guarantee the accuracy and reliability of the test result. The provider of the proficiency panel should either be accredited according to the International Organization for Standardization (ISO) (ISO 17043) or should be actively pursuing ISO accreditation. ISO accreditation provides assurance of the provider's competence to plan and implement proficiency testing programmes.

See example in Box 9.1 as well as Web Annex J of the 2019 HTS guidelines for details about delegating responsibilities for QA activities *(12)*.

9.2.2 Workforce development

For health workforce development that recognizes the importance of 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 prioritization of staff recruitment and retention strategies, especially for rural and underserved areas.

At any testing site, ensuring the proficiency of HIV testing providers requires regular training and supportive supervision. All testing providers should have adequate competency-based training on the different stages of the testing process. This includes: (i) maintaining testing records in standardized logbooks/testing registers, (ii) interpreting results generated by the testing algorithm as an HIV-status report, (iii) understanding the purpose and use of QC materials and (iv) participating in EQA schemes and ensuring 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 troubleshooting when product problems and/or adverse events occur.

Authorities should consider developing or delegating development of national curricula for a variety of testing settings covering HIV testing and other aspects of HIV care and treatment as suitable. Certification of testing providers should be considered; it can act as an incentive to reinforce the quality of HIV testing activities.

Box 9.1. Case example: Leveraging digital health for scaling up HIV Rapid Test Continuous Quality Improvement (RTCQI) – South Africa

The RTCQI initiative, developed by the United States Centers for Disease Control and Prevention (CDC) and supported by WHO, has been used to improve HIV testing quality. However, the paper-based RTCQI tools required are time-consuming and difficult to implement at scale, causing variability in the quality of interventions and challenges with data capture. This limits the potential to scale up QI and QMS approaches.

Using a multiyear grant from the CDC and the US President's Emergency Plan for AIDS Relief (PEPFAR), the South African National Health Laboratory Service (NHLS) subcontracted Strategic Evaluation Advisory & Development Consulting (Pty) Ltd. (SEAD) to adapt existing RTCQI modules in a digital health platform using mobile apps for data collection (and including training materials), with immediate upload of data where internet connectivity is available. The app can also work offline. This platform includes field-worker apps with a digital tester competency and facility-assessment checklist, a management platform with dashboards for real-time data review and analysis, a centralized national database for coordinated reporting countrywide and a supervisory module and video-based assessor training course for the Ministry of Health and other partners. To standardize implementation, an e-Learning platform of 11 modules for instructor-led or self-paced training was developed. The SEAD team worked closely with CDC/PEPFAR and the ministry of health to refine course content, including video lectures, animations and demonstrations.

Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT)* assessments from 2015–2017 showed that >80% of the facilities received ratings at or below level 2 (<80%). However, since launch of the digital version of the SPI-RT checklist, over 7118 assessments have been conducted, facilitating timely identification of quality issues and targeted interventions: in 2021–2022, 53% of the facilities were assessed at level 4 (≥90%); 37% at level 3 (80–89%) and only 10% at level 2 and below. As of 2022, tester competency assessments had been conducted for over three quarters (5283/6841) of primary testers countrywide, with a pass rate of 80%. Over 4871 learners have enrolled in the RTCQI e-Learning platform, with a completion rate of 82% and a pass rate of 94%.

This digital health approach has enabled active HIV RTCQI programme and partner management. It has the potential to be used for other POC testing services across the continent.

* SPI-RT is a central tool on this digital platform. It uses a standardized checklist that evaluates eight quality domains related to rapid HIV testing, generating a rating in one of five levels, from level 0 to level 4.

Source: National Health Laboratory Service and Centers for Disease Control and Prevention (South Africa).

9.2.3 Regulation of IVDs

Regulation of IVDs directly affects the quality of HIV testing. The WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF), (Annex 3 of the 76th report of the WHO expert committee on biological standardization), recommends guiding principles and harmonized definitions, and it specifies the attributes of effective and efficient regulations that should be enforced through legal provisions.

The WHO publications, WHO Technical Report Series 1019, Annex 6 *(13)* and WHO Technical Report Series 1033, Annex 10 *(14)* provide further information.

WHO prequalification

WHO conducts prequalification assessment of IVDs used in resource-limited settings, especially those used at or near the POC. WHO prequalification is a standardized procedure to determine whether the product meets WHO requirements for highest quality, safety and performance. 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 QMS through a site inspection; and
3. an independent evaluation of performance and operational characteristics.

In addition, an in-depth review of product labelling, including instructions for use (IFU), is performed across the three prequalification assessment activities.

The WHO publication *Overview of the prequalification of in vitro diagnostics assessment (15)* provides further information. Web Annex J of the 2019 HTS guidelines provides additional details about WHO prequalification *(12)*.

Collaborative registration procedure

National assessment of applications for registration (marketing authorization) of IVDs is a key regulatory process. Consideration of the outcomes of WHO prequalification by national regulatory authorities (NRAs) during the national decision-making process is an example of a regulatory approach based on reliance. Such reliance on WHO prequalification outcomes allows for substantial savings of regulatory resources and good quality of regulatory decisions, while retaining the autonomy of the regulator to make its own regulatory decisions based on the risk–benefit balance in their setting.

National regulatory authorities can and do rely on WHO pre-qualification outcomes when considering applications to market an IVD.

The WHO collaborative registration procedure enables participating NRAs to take advantage of the expertise and outcomes of WHO assessment. This facilitates and accelerates national registration processes and post-registration regulatory life cycles of WHO prequalified IVDs, such as critical changes made to a registered product. The WHO publication *Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics (16)* provides further information.

Post-market surveillance

Once a product is placed on the market, the manufacturer must conduct post-market surveillance to collect and evaluate experience from use of its product. This surveillance aims to detect any quality, safety or performance issues that require actions to reduce risk to patients, users or others. Manufacturers collect data from a range of sources, including user feedback (complaints, technical support calls, maintenance, installation, user training), scientific literature and publicly available regulatory sources. Other economic operators (authorized representatives, distributors, importers) may also collect user feedback and forward it to the manufacturer.

Typically, testing providers will be the first to detect any issue with products, such as misdiagnosis, visual defects or obvious anomalies. Testing providers should report any adverse events or product problems to

IVD manufacturers or their local authorized representative and keep samples of the defective test kit. It is best to send samples back to the manufacturer for their root cause analysis.

NRAs and reference laboratories should ensure the availability of user feedback forms, such as the WHO user feedback form, that are easy to use and that capture, at a minimum, lot number, expiry date and exact description of what went wrong and how many tests and patients were affected *(17)*.

Manufacturers are required to report any adverse events and certain incidents to regulatory authorities as part of their obligations for national registration. The regulator will review the investigation undertaken by the manufacturer as well any further actions they take. Without prejudice to national legislation, WHO recommends that the manufacturer (or its economic operator) send an investigation report to the relevant NRA in the following circumstances:

- discovery of a serious public health threat
- when use of a medical device led to:
  - death of a user, patient/client or other person
  - serious deterioration in health of a user, patient/client or other person, and/or
- no death or serious deterioration in health of a user, patient/client or other person occurred, but it might have.

This may include indirect harm, such as misdiagnosis, delayed diagnosis, delayed treatment, inappropriate treatment, absence of treatment or transfusion of inappropriate materials.

Manufacturers may undertake a field safety corrective action (FSCA) by identifying the root cause of any product problems and taking steps to address it while keeping the regulatory authorities informed. An FSCA is typically a return or destruction of the affected product or modification of the product, for example, permanent or temporary changes to the labelling or IFU.

For IVD products recommended by WHO through prequalification or emergency use listing, manufacturers must report incidents to WHO. These data are entered into the database for WHO's Global Surveillance and Monitoring System for substandard/falsified medical products. WHO oversees the course of the investigation conducted by the IVD manufacturer and any resultant correction[1] and/or FSCA. 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. WHO reserves the right to issue WHO Information Notices for Users *(18)*.

The WHO publication *Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics (19)* provides further information. Web Annex J of the 2019 HTS guidelines provides a detailed description of activities that contribute to post-market surveillance *(12)*.

National authorities should consider collaborating with professional EQA providers to build capacity for proficiency testing of their testing services, including following up on corrective and preventive actions to address issues identified from quality-monitoring activities. EQA 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. Web Annex J of the 2019 HTS guidelines presents additional details on organizing EQAs *(12)*.

[1] A correction is defined as any repair, modification, adjustment, relabelling, destruction or inspection (including patient monitoring) of a product without its physical removal to some other location.

9.2.4 Procurement and supply chain management

Procurement and supply chain management of IVDs may be arranged differently depending on the systems in place. In many countries national authorities conduct centralized procurement for the public sector. In some settings implementing partners support procurement and apply their own QA policy for products purchased with their funds.

It is critical that the national policies support procurement of quality-assured diagnostics, equipment and other required items. This includes using results of testing algorithm verification studies to justify product selection. Implementing partners should abide by national decisions for procurement. For guidance on procurement of IVDs, see the WHO publication *Guidance for procurement of in vitro diagnostics and related laboratory items and equipment (20)*.

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 continuously available at testing sites. Prevention of stock-outs that may disrupt or delay HIV testing is paramount. When site-level stock-outs are anticipated or identified, countries should consider moving stock from one site to another, according to site consumption and available stock, to avoid stock-out and/or wastage. Community-led monitoring approaches can be effective in addressing and responding to stock-outs and can be considered as a way to improve quality.

Procurers and forwarding agents must ensure that goods are stored and transported according to the manufacturer's IFU, with attention to conditions such as temperature and humidity *(21)*.

9.2.5 Accreditation of testing sites

Accreditation is "recognition of the [testing site's] quality and competence" *(22)*. National accreditation bodies assess a testing site to determine if it complies with quality requirements. The most widely applicable international quality standard is *ISO 15189 Medical laboratories – requirements for quality and competence (23)*. Authorities should consider moving toward accreditation of testing sites within their tiered testing network. Through partnerships, WHO gives guidance on moving towards accreditation of testing sites *(24)*.

9.3 Assuring quality – what must be done at the testing site level

The basic principles of QMS must apply to all services conducting HIV testing and providing HIV diagnosis. Both facility-based (laboratories and health facilities) and community-based or mobile testing services should assure quality. Site supervisors are responsible for quality activities and, thus, should be trained in the principles of QMS. All testing services must have a quality policy that addresses the following 12 aspects, as described in the WHO *Laboratory quality stepwise implementation tool (25)*:

1. **organization:** ensuring managerial commitment and organizational structure are in place;
2. **personnel:** ensuring competent staff, including lay providers;
3. **equipment:** ensuring appropriate, fully functional equipment;
4. **purchasing and inventory:** ensuring the purchase and management of quality-assured test kits and consumables and their availability at all times;
5. **QC:** ensuring process control of daily testing processes;
6. **information management:** creating and managing documents and records, keeping records confidential and performing regular data review and analysis;
7. **documents and records:** ensuring standard operating procedures (SOPs) are up to date and records are kept;
8. **occurrence management:** recording and following up on complaints;
9. **assessment:** evaluating and following up on results of EQA schemes/PT and on-site supervision;
10. **process improvement:** ensuring that preventive and corrective actions are taken;
11. **client service:** measuring customer satisfaction; and
12. **facilities and safety:** ensuring the safety of staff and clients through proper waste disposal and cleaning and decontamination procedures.

These 12 aspects are described below as they apply to testing services that use primarily RDTs. For HIV self-testing, certain elements of a QMS approach are not applicable, such as organization, personnel, assessment, process improvement and client service.

9.3.1 Organization

A common quality policy may be developed for similar types of testing sites. For example, quality requirements are similar at all sites where only RDTs are used, where there is minimal infrastructure and where lay providers conduct testing. All quality policies, processes and procedures should be available (on paper or electronically) where all staff members can easily consult them.

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 that there is no stigma and discrimination on the part of staff members against any clients.

QM 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 **QA 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; positive, negative, discordant and invalid results; QC and EQA data (see component 9, section 9.3.9).
- Develop an **organigram** that shows the roles and responsibilities of all personnel.

9.3.2 Personnel

All testing sites must employ sufficient trained, proficient and qualified personnel to conduct all phases of the testing process for the expected throughput:

- pre- and post-test information including linkage to services (see Chapter 4 for further information);
- pre-analytical (collecting and processing specimens, recording details of the client);
- analytical (conducting the 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, performs testing, runs QC, issues reports, double-checks test results and reports and has other data entry tasks, and conducts cleaning. Usually, national regulations specify which cadres of health workers can perform which functions.

All personnel should receive both **pre-service** and **in-service training**. 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

Irrespective of where testing takes place and what assay format is used, **appropriate and fully functional** equipment is required.

For testing services using RDTs, it is important to have **good lighting** and **timing devices** and to run tests on a paper-lined surface. If ambient temperatures can exceed the manufacturer's recommendation, monitored **refrigerators** are required for storage.

For testing services using laboratory-based IVDs, **calibration and maintenance of equipment** is essential for providing accurate testing results.

How to implement

- Ensure that areas where test kits are stored and testing is conducted are monitored using a thermometer.
- Ensure that all equipment 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 **SOPs** for all equipment, for example, instructions to turn it on and off, clean and maintain or calibrate.

9.3.4 Purchasing and inventory

Stock-outs of HIV test kits or any essential consumables are a major reason for poor quality and outcome of test results, missed opportunities, and client dissatisfaction. The lack of an assay will compromise the algorithm, strategy, and accuracy of the diagnosis. For example, a lack of one or more assays means the HIV status is provided based on two assays or even one assay, which is likely to be inaccurate. A lack of specimen transfer devices might lead providers to use the hanging drop method (that is, letting a drop fall from a finger), which may result in an inaccurate test result.

A system (LMIS, paper-based or combined) is required at each testing site to track test kits, reagents, **and consumables** (blood collection supplies) – when they are ordered and when received *(25)*. As stocks are received, it is critical to note expiration dates, store under appropriate conditions and order, have a good level of security stocks, and re-order in advance, allowing adequate time for the next delivery to replenish stocks before stock-out.

Regular stock and site consumption monitoring will help ensure that necessary items are always available. A "stock alert" level that triggers a request for additional stock from the national medical store could be defined. Community-led monitoring systems can be helpful to identify and respond to stock-outs and can also be considered.

How to implement

- Put in place a stock recording system (LMIS, paper-based or combined) and SOP
- Maintain an **inventory of all items** required.
- Ensure adequate **space to store test kits** (including refrigeration if needed) 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 IFU, cannot be split.
- **Do not interchange components** between test kits, for example, by stockpiling buffers or other components *(20)*.

9.3.5 Quality control

Quality control, also known as process control, refers to processes to ensure that **testing procedures** are performed correctly, that **environmental conditions** are suitable and that the assay works as expected. QC seeks to detect, evaluate and correct errors due to assay failure, environmental conditions or operator performance before test results are reported.

QC is a multistep process with certain checkpoints throughout the testing process:

- Before testing (pre-analytical):
  - Check that the temperature of the testing area is within the manufacturer's recommendations and recorded daily. Testing should not take place if the room temperature is outside the recommended operating temperature range.
  - Check daily that stocks of test kits and required consumables are on hand.
- While testing (analytical):
  - Ensure that any QC specimens have been run (for example, test kit controls, external/third-party QC specimens) and that the results are within pre-established QC acceptance limits.
  - Ensure that a second reader double-checks all subjectively read assays (see Box 9.2).
- After testing (post-analytical):
  - Double-check the report of the HIV status to be given to the client.
  - Double check the entry of data into the testing register.

Internal QC refers to processes within the assay that check whether the procedure is working. For RDTs, the appearance of a control line/spot is an example. Very few RDTs control for addition of specimen; for the most part, RDTs control only for the flow of liquid along the test strip.

Test kit controls (known as positive and negative controls) may be supplied by the assay manufacturer. They are standard for most IVD formats, except for RDTs. Few HIV RDTs have accompanying test kit controls.

External third-party QC materials should be used in addition to any internal QC or test kit controls. These are prepared and validated by a QC provider, preferably an experienced and proficient commercial entity, or made in-house by an institution designated by the national authorities, such as the national reference laboratory. The material can be manufactured in bulk and stored for long periods of time, thereby reducing the costs of acquiring, characterizing and validating the materials. Each batch of in-house material should be tested for homogeneity and stability.

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; and
- when any environmental conditions (for example, temperature or 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 valid QC run are considered "out-of-control". When an assay is determined to be out-of-control, retesting all individuals tested during this period should be considered.

Box 9.2. 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 should be resolved with a third reader *(26)*.

How to implement

- Establish criteria for **specimen acceptance** or rejection, specimen storage, retention and 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.

Web Annex J of the 2019 HTS guidelines provides information about the preparation of QC specimens for RDTs *(12)*.

9.3.6 Information management

Information management consists of any **paper and/or electronic systems** for recording, storing and retrieving information, including records and documents, raw data and 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. Using unique identifiers, which replace names and personal information with anonymous unique alphanumeric codes, and specimen identifiers for each subsequent specimen received from the same individual may reduce the possibility of

mix-ups and errors. It also protects the confidentiality of people undergoing HIV testing. Linking a series of HIV test results for one client is needed when retesting to verify an HIV-positive diagnosis and for clients with HIV-inconclusive results. WHO guidance on use of unique identifiers is presented in the *Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact (27)*.

Electronic RDT readers that can accommodate multiple products are increasingly available and may be useful for providing data for programme management or planning procurement.

How to implement

- Each client should be assigned a **unique identifier** so that the results of each client's subsequent specimens can be tracked.
- Each specimen should be assigned a unique **specimen identifier**.

9.3.7 Documents and records

Documents include policies, procedures and work instructions for all aspects of the testing service and its QMS. These documents should be approved before use, reviewed at least annually, revised when necessary and removed from circulation when obsolete.

Documentation is critical to ensure that the report of HIV status goes to the correct person. Work instructions and job aids guide test providers step-by-step in conducting the test, reading and interpreting test results and assigning HIV status. Web Annex J of the 2019 HTS guidelines presents an example of a generic job aid for an HIV RDT *(12)*. National programmes should assist testing sites to develop site-specific SOPs and job aids for testing providers.

Records are generated from all activities, information or results from performing testing. 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 QMS are:

- patient-specific records
  - laboratory logbook/testing register[1] – the register identifies the individual undergoing testing (patient 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 and name of operator;
  - report of HIV status as given to the individual.
- site-specific records
  - SOPs and job aids;
  - quality manual;
  - staff training records and other personnel records;
  - internal and external audit reports;
  - QC results;
  - non-conformance and complaint records as well as QC/EQA results (see EQA in section 9.3.9), with action taken;
  - equipment maintenance records, temperature records and inventory records.

[1] For an example of a standardized laboratory logbook/testing register, see *Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results (28)*.

How to implement

- Ensure that SOPs 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 report HIV status.

9.3.8 Occurrence management

Occurrence management refers to processes for detecting and documenting non-conformances and then making any necessary corrections *(9)*. 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 procedures or not following documented procedures.

The following sources of data may be used to check for non-conformance:

- 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
- a higher-than-expected rate of discrepant test results for clients returning for retesting (>5%)
- a higher-than-expected rate of discrepant test results between Assay 1 and Assay 2 (>5%).

How to implement

- Establish a system to continually monitor and detect quality issues or product problems, identify the root cause and take corrective and preventive action.
- Create a user feedback form for product issues.
- To identify non-conformance, routinely (ideally, monthly) 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 and frequency of test kit stock-outs, supply stock-outs and 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 process 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 identify and prioritize areas for improvement.

EQA schemes, often referring specifically to proficiency testing, is a priority to guarantee the accuracy and reliability of the test result. The provider of the proficiency panel should either be accredited according to the International Organization for Standardization (ISO) (ISO 17043) or should be actively pursuing ISO accreditation. ISO accreditation provides assurance of the provider's competence to plan and implement proficiency testing programmes. It is important that EQA schemes include the follow-up unacceptable EQA results with appropriate corrective actions.

WHO does not recommend cross-checking with dried blood spot specimens.

Retesting is recommended for all individuals newly diagnosed as HIV-positive; this retesting should be performed before ART initiation. The objective is to identify errors in diagnosis before initiating long-life treatment. WHO does not recommend cross-checking with dried blood spot specimens, especially given the recommendation to retest all seropositive individuals prior to starting ART. See Chapter 8 for details on retesting.

Another form of external assessment is **accreditation** of testing sites (also called registration or certification) by an external certification body (see section 9.2.5).

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/PT**.
- 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** removes the root cause of a problem or reduces or eliminates the chances that it will recur. A **preventive action** avoids a possible future problem or reduces the likelihood that it will happen again, usually referring to the subject of the correction. Data from QC and EQA activities and process control can guide corrective and preventive actions under the mantle of continual process improvement.

Process management links closely with activities associated with occurrence management.

How to implement

- Site supervisors should **proactively identify and take opportunities** for improvement and, if appropriate, relay these ideas to a higher level of management for broader implementation.

9.3.11 Client service

Programmes need to ensure that clients are satisfied with the testing service. This includes both external clients, including people undergoing testing, civil society and regulatory agencies, and internal clients, such as doctors, nurses, counsellors and other health care workers. 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 all who request testing. 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 both complaints and encouragement.

9.3.12 Facilities and safety

It is important that testing sites are well-designed and maintained. The testing site, including where counselling may take 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 materials (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.

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, for example, separation of work areas according to risks, universal precautions (that is, working under the assumption that all specimens are potentially infectious), prevention of and/or response to needlestick injuries and other occupational exposures, chemical and biological safety, spill containment, waste disposal and use of personal protective equipment.

Facilities must be organized to protect the **confidentiality of clients**, including a separate waiting room for those requiring additional testing. Otherwise, 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.

As with facility-based services, 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 clients. 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, responsible for writing a biosafety manual with safety procedures, including post-exposure procedures, and ensuring that the staff is aware of the contents.

9.4 Quality improvement for HIV testing

Quality assurance is not a once-and-done activity. Providers and managers of testing must continually monitor and evaluate their programme to improve services. To maintain a functioning QMS that addresses national, subnational, facility and community concerns, all stakeholders must be involved at every level. Middle- and low-income countries have applied a range of QI 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.

WHO supports the implementation of high-quality HIV services and provides guidance for selecting measures of high-quality services (see Box 9.3). 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 (8)*.

Box 9.3. Further WHO reading on QA relevant for HIV testing services

- Guidance for procurement of in vitro diagnostics and related laboratory items and equipment; 2017. https://apps.who.int/iris/bitstream/handle/10665/255577/9789241512558-eng.pdf?sequence=1
- A handbook for improving HIV testing and counselling services. Field-test version; 2010. https://iris.who.int/bitstream/handle/10665/44446/9789241500463_eng.pdf
- Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results; 2015. https://www.who.int/publications/i/item/9789241508179
- Laboratory quality management system: handbook; 2011. https://www.who.int/publications/i/item/9789241548274
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- Post-market surveillance of in vitro diagnostics; 2020. https://iris.who.int/handle/10665/337551

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List of web annexes

Web Annex A. GRADE table and systematic review: should social network testing approaches be offered as an additional HIV testing approach?

Web Annex B. Grade table and systematic review: should HIV self-testing be offered as an additional testing option in health facilities?

Web Annex C. GRADE table and systematic review: should HIV self-testing be used to support PrEP delivery?

Web Annex D. Modelling HIV self-testing for oral PrEP scale-up in Kenya: impact on HIV drug resistance and HIV outcomes

Web Annex E. GRADE table and systematic review: should caregiver-assisted testing with HIV self-test kits be offered as an additional HIV testing approach for children 18 months and older?

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Web Annex G. Values and preferences of key population communities in the Asia-Pacific region regarding HIV recency testing

Web Annex H. Compiled case examples

Web Annex I. Summary table of declarations of interest

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