POLICY BRIEF

CONSOLIDATED GUIDELINES ON HIV TESTING SERVICES FOR A CHANGING EPIDEMIC

NOVEMBER 2019

World Health Organization

People's knowledge of their own, and their partners', HIV status is essential to the success of the HIV response. The overarching goals of providing HIV testing services (HTS) are to deliver a diagnosis and to effectively facilitate access to and uptake of appropriate HIV prevention, treatment and care.

These consolidated guidelines bring together existing and new evidence-based guidance and recommendations for delivering high-impact HIV testing services, including linkage to HIV prevention and treatment, in diverse settings and populations. A key objective of these guidelines is to encourage greater national and global commitment to implementing effective and efficient HTS as a vital element of the national and global HIV response, essential to achieving and maintaining low HIV incidence.

Box 1 summarizes new WHO guidance on HTS. Table 1, at the end of this brief, presents the full list of WHO recommendations on HTS.

Definition: HIV testing services

The term "HIV testing services" embraces the full range of services that should be provided together with HIV testing. This includes counselling (brief pre-test information and post-test counselling); linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.

Progress has been made, but gaps remain

Globally, HTS and antiretroviral therapy (ART) have been scaled up substantially. In 2005 it was estimated that in Africa only 10% of people with HIV were aware of their HIV status and that, globally, only 12% of people who wanted to test for HIV were able to do so. Nearly 15 years later it is now estimated that 85% of all people with HIV in eastern and southern Africa, and nearly 80% of people with HIV worldwide, know their status.

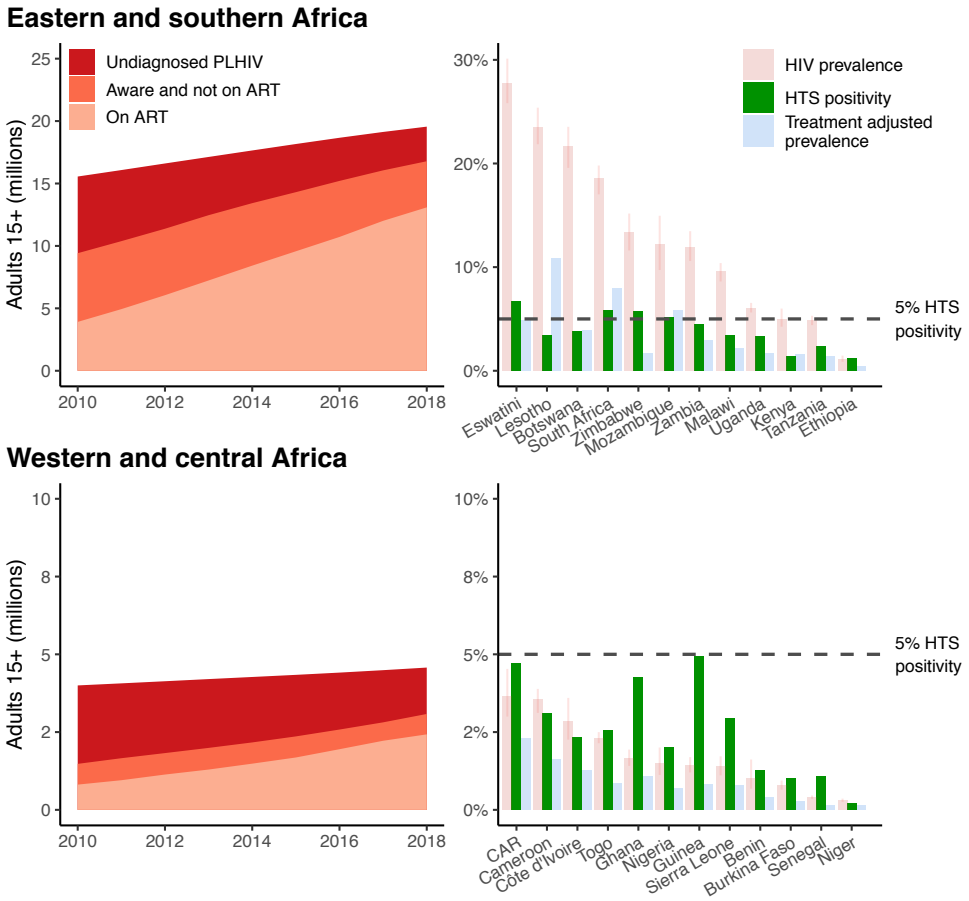
With the offer of immediate ART initiation and improved treatment options, access to and uptake of treatment has increased. Now, most people with HIV who know their status are accessing treatment and care. Fig. 1 shows how

Box. 1 Summary of new WHO guidance, recommendations and good practice statements

1. **Demand creation:** NEW **Good practice statement** highlighting evidence-based approaches and considerations for the use of incentives for HIV testing services, including linkage.
2. **Counselling message:** ✓ **Updated** messages and guidance on concise communications with emphasis on linkage and latest information on the benefits of treatment and prevention services.
3. **HIV self-testing:** ✓ **Updated** HIV self-testing should be offered as an approach to HIV testing services *(strong recommendation, moderate-quality evidence)*.
4. **Social network-based approaches:** NEW Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention *(conditional recommendation, very low-quality evidence)*.
5. **HIV testing strategies:** ✓ **Updated.** In response to changes in the HIV epidemic, WHO encourages countries to move toward using three consecutive reactive tests to provide an HIV-positive diagnosis.
6. **Western blotting:** NEW Western blotting and line immunoassays should not be used in national HIV testing strategies and algorithms *(strong recommendation, low-quality evidence)*.
7. **Dual HIV/syphilis rapid diagnostic tests:** All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)* at least once and as early as possible *(syphilis: strong recommendation, moderate-quality evidence; HBsAg*: strong recommendation, low-quality evidence)*.

   NEW Dual HIV/syphilis rapid diagnostic tests (RDTs) can be the first test in HIV testing strategies and algorithms in ANC settings.
8. **Optimal maternal retesting time points:** ✓ **Updated.** In high HIV burden settings, retesting is advised for all pregnant women with an unknown or HIV-negative status during late pregnancy (third trimester). Catch-up testing is needed if the first test or retest is missed or delayed. High HIV burden countries could consider an additional retest in the post-partum period for specific districts or regions with high HIV burden or incidence, women from key populations or who have a partner with HIV who is not virally suppressed.

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



Between 2010 and 2018…

…in eastern and southern Africa

- The number of adult PLHIV unaware of their HIV status decreased from 6.1 million to 2.8 million.
- Adult HIV prevalence decreased from 7.1% to 7.0%.
- The proportion of adults with undiagnosed HIV decreased from 2.8% to 1.0%.
- In countries with 20% HIV prevalence and above, in 2018, national HTS positivity was close to or below 5%.
- National HTS positivity was much closer to the treatment-adjusted prevalence (which excludes adults with HIV on ART) than national HIV prevalence.
- Countries where national HTS positivity is lower than the treatment-adjusted prevalence there may be a need to further optimize HTS.

…in western and central Africa

- The number of adult PLHIV unaware of their HIV status decreased from 2.5 million to 1.5 million.
- The prevalence of HIV among adults decreased from 1.6% to 1.5%.
- The proportion of adults with undiagnosed HIV infection decreased from 1.0% to 0.5%.
- National HTS positivity was below 5% in all countries.
- Countries where national HTS positivity exceeded overall HIV prevalence likely reflects highly focused HTS in key populations, priority locations and patients with HIV-related symptoms.

PLHIV: People living with HIV; ART: antiretroviral therapy; HTS: HIV testing services; CAR: Central African Republic.
HTS positivity presented in this figure is based on national programme data reported to 2018 UNAIDS Global AIDS Monitoring. National HTS positivity refers to the number of tests conducted where an HIV-positive result was returned to a person in the calendar year.
Treatment-adjusted prevalence refers to the estimated national HIV prevalence, adjusted to exclude people with HIV who are on ART from the numerator and the denominator. Treatment-adjusted prevalence includes: people with HIV who are undiagnosed, people with HIV who know their status but have not initiated treatment, and people with HIV who previously initiated treatment but have disengaged from care.
Source: Estimates shared in personal communication from K Giugere, M Maheu-Giroux, JW Eaton, October 2019; UNAIDS/WHO, 2019; Marsh K, Eaton JW, Mahy M, Sabin K, Autenrieth C, Wanyeki I, Daher J, Ghys PD. Global, regional and country-level 90-90-90 estimates for 2018: assessing progress towards the 2020 target. AIDS. 2019; 33 (Suppl 3): S213. doi: 10.1097/QAD.0000000000002355.

Fig. 1. Closing the gap in the number of undiagnosed people living with HIV (2010–2018)

successful HTS and ART scale-up is closing the testing gap and contributing to the decline in HIV positivity in HTS programmes, particularly in high HIV burden settings such as eastern and southern Africa.

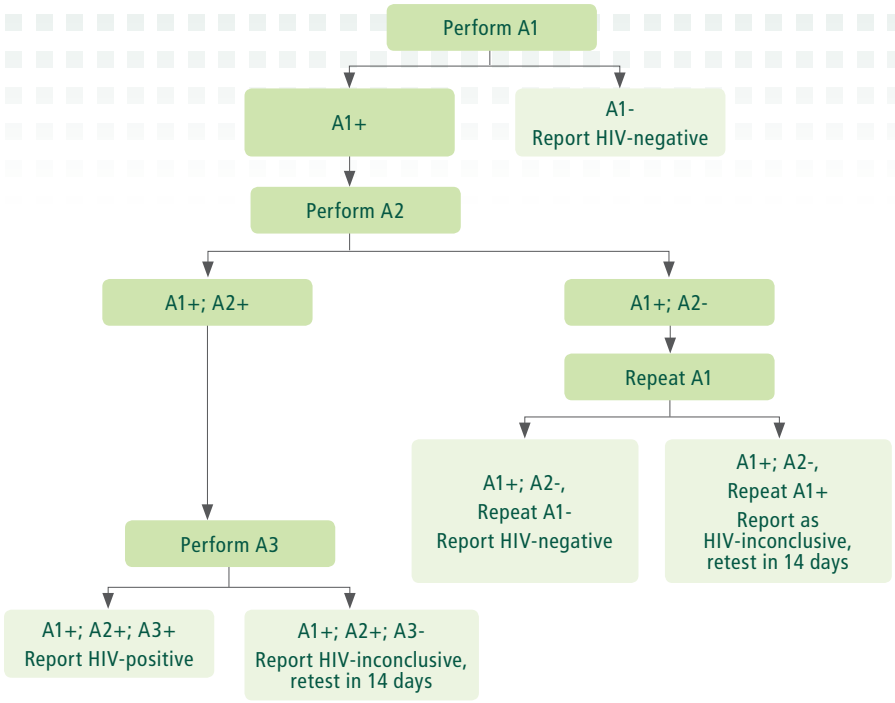
Despite these achievements, substantial gaps remain. Many of those at highest risk remain unreached. In high HIV burden settings, in southern Africa, this includes men and adolescents and young people (ages 15–24 years). Worldwide, key populations – men who have sex with men, people who inject drugs, people in prisons or other closed settings, sex workers and transgender people – are underserved despite being most affected by HIV and at high ongoing risk.

While there have been increases in the number of HIV tests conducted every year, in many settings HTS is not sufficiently focused. In many settings where treatment coverage rates are high, poorly targeted HTS continues to miss people with HIV who do not know their status. Further, people with HIV who learn their status without adequate support may not link to care or may be lost to follow-up.

These realities require new focus and new approaches to reach people with undiagnosed HIV early in their infection. WHO's updated HTS guidance responds to the changing face of the HIV epidemic. It supports development and scale-up of a strategic mix of evidence-based HTS approaches in facilities and in community settings for those in need of HIV testing, prevention and treatment services.

Accurate and reliable HIV testing services

Providing a correct HIV diagnosis, as quickly as possible, is critical to all HIV testing services and national programmes. To achieve accurate results, WHO recommends countries use an HIV testing strategy/algorithm that uses a combination of rapid diagnostic tests (RDTs) and/or enzyme immunoassays which, when used together, achieve at least a 99% positive predictive value. The positive predictive value is the measure that indicates the probability that an HIV-positive diagnosis is correct.



A1: Assay 1 (first test); A2: Assay 2 (second test); A3: Assay 3 (third test). Assay (tests) are HIV rapid diagnostic tests (RDTs) or enzyme immunoassays (EIAs).

Fig. 2. WHO HIV testing strategy using three consecutive reactive tests as basis for HIV-positive diagnosis

At a population level the number of people testing for HIV who receive an HIV-positive diagnosis affects the likelihood of a correct diagnosis. Specifically, when the proportion of people testing for HIV who receive an HIV-positive result drops below 5%, at least three consecutive reactive tests are needed to maintain a 99% positive predictive value and thus ensure that HIV-positive diagnoses are accurate. For this reason, since 1997 WHO has recommended that countries with lower HIV burden (less than 5% HIV prevalence) use three consecutive reactive tests to provide an HIV-positive diagnosis (Fig. 2). In contrast, in high burden countries with 5% HIV prevalence or greater, WHO recommended using two consecutive reactive tests to provide an HIV-positive diagnosis.

In response to declines in HIV prevalence among those untreated (also called treatment-adjusted prevalence) and in national HIV positivity in HTS programmes, WHO is now encouraging countries currently using two consecutive reactive tests to provide an HIV-positive diagnosis to move toward using three reactive tests as their treatment-adjusted prevalence and national HIV positivity in HTS programmes fall below 5%. Low HIV burden countries, with national HIV prevalence below 5%, are also reminded to continue to use three consecutive reactive tests to provide an HIV-positive diagnosis.

Programmes with particularly low national HIV positivity in HTS programmes and treatment-adjusted prevalence should prioritize this shift to prevent misdiagnosis and unnecessary initiation of lifelong treatment. Countries should consider using national HIV positivity in HTS programmes and treatment-adjusted prevalence to assess their needs and determine when to begin changing their testing strategy and algorithm.

Efforts to optimize delivery of HIV testing services are needed to support programmes making this transition, such as the use of HIV self-testing or test for triage approaches, whereby all those with a reactive first test are referred to a facility for further testing using the full national testing algorithm.

WHO still recommends that all programmes retest people diagnosed with HIV prior to initiating lifelong treatment. This retesting to verify an HIV-positive diagnosis is intended to catch human errors such as mislabeling of test results.

Move away from western blotting

Western blotting/line immunoassays methods rely on specimens collected in a health facility by venepuncture. These specimens are then processed and sent to a laboratory, where skilled staff perform the test. The laboratory then sends the test results to the referring facility, which contacts the client to deliver the result.

Conducting western blotting/line immunoassays, interpreting the results and returning the test results to clients takes valuable time and resources, from both a cost and human resource perspective. The result often can be delayed or hinder ART initiation, resulting in loss to follow-up. Newer testing technologies are faster, more acceptable, more accurate and less costly than western blotting.

To support scale-up of HIV testing, prevention and treatment, **WHO recommends countries move away from using western blotting and line immunoassays** in favour of simpler rapid diagnostic tests (RDTs) and enzyme immunoassays (EIAs).

Mobilizing demand creation and pre-test information

Demand creation refers to activities that directly improve an individual's knowledge, attitudes or motivations. Within HTS, demand creation activities complement broader efforts to increase HIV testing and linkage to onward HIV prevention and care services among those in greatest need.

Evidence reviewed suggests that peer-led and digital platforms, including short pre-recorded videos, are tools that can be considered for encouraging HTS uptake. Demand creation approaches that have showed evidence of impact on HTS uptake include:

1. advertisement of specific HTS attributes;

2. brief key messages (less than 15 minutes);

3. messages encouraging testing during couples counselling;

4. messages related to risk reduction and economic empowerment, particularly for people who inject drugs;

5. motivational messages.

Although incentives may be effective for demand creation in some situations, the benefits and risks should be carefully weighed.

Pre-test counselling is not recommended as part of HIV testing services. Instead, evidence supports the use of concise pre-test information and messages that offer and encourage testing.

Differentiated HIV testing service delivery approaches

It is essential for countries to provide a strategic mix of WHO-recommended differentiated HIV testing service delivery approaches (Box 2). These approaches need to be used to reach the remaining people with HIV who do not know their status as well as people who have previously been diagnosed with HIV but are not on ART. Programmes need to routinely review and use their data to optimize HTS implementation so that it reaches the populations and geographic settings where the proportion of people with HIV who do not know their status is greatest.

Box 2. WHO-recommended differentiated HTS delivery approaches

1. **Facility-based HIV testing services** should be considered and routinely offered in sexually transmitted infections (STIs), viral hepatitis, tuberculosis (TB) and ANC services, malnutrition clinics and health services for key populations in all settings.

   In high HIV burden settings HIV testing services should be routinely offered at clinical settings. Key entry points in high HIV burden settings also include contraception/family planning clinics and voluntary male medical circumcision (VMMC) clinics.

2. **Community-based HIV testing services** are recommended for key populations in addition to facility-based testing options in all settings. In high HIV burden settings, community-based HIV testing for all populations is recommended.

   All community-based HIV testing services should be complementary to facility-based services and focused on efficiently and effectively reaching those in greatest need of HIV testing services.

3. **HIV self-testing** (HIVST) is recommended as an HIV testing approach. There are many effective ways to deliver and support HIVST, depending on the population and setting. Communities need to be engaged in developing and adapting HIVST models.

4. **HIV partner services –** that is, offering voluntary HTS to sexual and/or drug injecting partners of people with HIV – is recommended as part of a comprehensive package of testing and care. Part of this package of services are various options, including: (1) provider-assisted referral, in which a trained provider directly assists people who have tested HIV-positive by contacting their partner(s) and offering them HTS and (2) patient referral, in which a trained provider encourages the client to disclose their HIV status to their partner(s).

   It is important for HIV partner services to offer **HIV testing for untested biological children of HIV-positive clients**.

   Programmes should consider offering **social network-based approaches**, which offer HIV testing to social contacts of key populations in addition to sexual and/or drug injecting partners.

   People with HIV should be provided options on how their partners can be contacted, as well as time to consider the best options, based on their needs. People who do not want their partners to be contacted or need time to consider should be supported in their decision. Where feasible and acceptable to the client, provider-assisted referral should be prioritized, as it is highly effective and provides the opportunity to offer comprehensive prevention interventions to partners who are HIV-negative but remain vulnerable to HIV acquisition.

To provide early HIV diagnosis, and as part of broader efforts to eliminate mother-to-child transmission of HIV, syphilis and hepatitis B virus, pregnant women should be tested as early as possible, ideally in first trimester. **Dual HIV/syphilis rapid diagnostic tests (RDTs) can be used as the first test in antenatal care (ANC).**

HIV retesting: considerations for prevention and diagnosis

The primary goal of retesting should be to enable those who have previously tested HIV-negative to stay HIV-negative and to identify those who have become HIV-positive as early as possible so that they can start treatment. Support for linkage to appropriate HIV prevention interventions for those who test HIV-negative should be considered and prioritized for people with ongoing HIV risk.

WHO recommends annual retesting for:

- sexually active individuals in high HIV burden settings and;
- people who have ongoing HIV-related risks in all settings.

More frequent retesting – that is, every 3–6 months – may be warranted based on individual risks and as part of broader HIV prevention interventions. Those retesting more often would include individuals taking pre-exposure prophylaxis (PrEP), who require quarterly HIV testing, and those from a key population group presenting with an STI.

Retesting in specific groups. In certain situations, individuals who have been tested for HIV in the past should be retested. These include:

- individuals presenting with a diagnosis or receiving treatment for STIs or viral hepatitis
- individuals with a confirmed or presumptive TB diagnosis
- outpatients presenting with clinical conditions or symptoms indicative of HIV
- individuals with recent HIV risk exposure or who are concerned that they may have been exposed.

Retesting of pregnant women with an HIV-negative or unknown status is advised in high HIV burden settings as part of efforts to prevent of mother-to-child transmission. The optimal time is in late pregnancy (during the third trimester). Catch-up testing at the next available visit is needed if the first test or retest are missed or delayed.

Maternal retesting is not cost-effective in low HIV burden settings. If implemented, it should address only members of key populations or women with a sexual partner with HIV who is not virally suppressed on ART or from a key population.

Linkage to care

Diagnosing individuals with HIV and facilitating their engagement in care and ART initiation as early as possible is the professional and ethical responsibility of testers and a primary goal of all testing services. The core package of post-test services needs to include: concise counselling messages and effective supportive interventions, approaches and tools to facilitate rapid ART initiation and additional linkages to HIV prevention, care, support and other relevant services.

Post-test counselling messages remain key. They should be concise, addressing the needs of the client and focused on supporting linkage to care. Messages need to provide clients with the latest information, including:

- the personal health benefits of early ART,
- that people with HIV on ART who achieve and maintain viral suppression cannot transmit HIV to their partners and
- the benefits of voluntary provider-assisted referral for people with HIV.

Messages should also include information on HIV prevention interventions and how to access them, such as male and female condoms, PrEP for those at high ongoing risk, VMMC for men and boys in eastern and southern Africa and harm reduction services for people who inject drugs.

All people with HIV-positive diagnoses should be offered a package of support interventions that ensure timely linkage to care. WHO recommends co-located and well-coordinated ART services and peer support and peer navigation to facilitate linkage. Several other approaches can be considered among specific groups whose linkage rates are low – for example, men, young people and key populations. These approaches could include home ART initiation, friendly and flexible services designed to suit these groups and digital platforms, such as linkage support via social media and videos.

It is also important to optimize the linkage of people who are HIV-negative but at ongoing risk to effective prevention. Once these people are engaged in prevention services, HTS will continue to be part of "prevention monitoring" – such as quarterly testing among people taking PrEP – to identify new infections so that people can be started on ART as soon as possible.

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

Approach and reference	Recommendations and good practice statements
Mobilization and pre-test services	
Demand creation for HIV testing services NEW **Good practice statement** WHO (2019). Consolidated guidelines on HIV testing services.	Demand creation to increase HTS uptake and engage those in greatest need of services is a valuable tool for mitigating stigma, discrimination and criminalization. Demand creation approaches may need to be prioritized, depending on the setting, focus population and available resources, as part of a strategy to reach people with HIV who do not know their status and who have high HIV-related risk. A wide range of demand creation strategies have been rigorously tested to assess impact on HIV testing uptake and the proportion of people with HIV diagnosed, but often later outcomes related to linkage to care or prevention have not been measured. Evidence-based platforms for delivering demand creation include: • peer-led demand creation interventions, including mobilization; • digital platforms, such as short pre-recorded videos encouraging testing. Approaches that have showed evidence of increasing demand include: • advertisement of specific HTS attributes; • brief key messages and counselling by providers (less than 15 minutes); • messages during couples counselling that encourage testing; • messages related to risk reduction and economic empowerment, particularly for people who inject drugs; • motivational messages. Evidence suggests that the following approaches may be less effective for demand creation: • personal invitation letters; • individualized content messaging; • counselling focused on building relationship between the client and counsellor; • general text messages, including SMS. Some studies report increases in HTS uptake when incentives are offered, however when considering the use of incentives for demand creation, benefits and risks should be carefully weighed, such as: • resource use and sustainability, especially for providing financial incentives, which may undermine the principles of universal health coverage; • longer-term behavioural changes associating HTS and other services with incentive against short-term increases in uptake; • negative effect on equity, due to prioritization of some populations and diseases; • potential to deprioritize systematic implementation of strategies that improve service delivery, reduce barriers and disincentives, such as patient costs associated with accessing health services more broadly.
Service delivery approaches	
Facility-based HTS **Updated guidance** WHO (2017). Syphilis testing and treatment guidelines. https://www.who.int/reproductivehealth/publications/rtis/syphilis-ANC-screenandtreat-guidelines/en/ WHO (2016). WHO recommendations on antenatal care for a positive pregnancy experience. https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/ WHO (2015). Consolidated guidelines on HIV testing services. https://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/ WHO (2017). WHO guidelines on hepatitis B and C testing. https://www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-testing/en/	All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg)* at least once and as early as possible *(syphilis: strong recommendation, moderate-quality evidence; HBsAg*: strong recommendation, low-quality evidence)*. *Particularly in settings with a ≥2% HBsAg seroprevalence in the general population. Dual HIV/syphilis rapid diagnostic tests (RDTs) can be the first test in HIV testing strategies and algorithms in ANC. **High HIV burden settings** HIV testing should be offered to all populations and in all services (for example, services for sexually transmitted infection (STI), hepatitis, tuberculosis (TB), children under five, immunization, malnutrition, ANC and all services for key populations) as an efficient and effective way to identify people with HIV. **Low HIV burden settings** HIV testing should be offered for : • adults, adolescents or children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection, including TB and STIs • HIV-exposed children and symptomatic infants and children • key populations and their partners • all pregnant women. In some resource-limited settings, particularly those with low HIV burden, programmes may need to prioritize resources by focusing HTS in pregnancy on geographical areas with higher prevalence or among women with high ongoing risk such as members of key populations.

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

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