



World Health
Organization

GUIDELINES



CONSOLIDATED GUIDELINES ON
**HIV TESTING
SERVICES**

**5Cs: CONSENT, CONFIDENTIALITY, COUNSELLING,
CORRECT RESULTS AND CONNECTION**

JULY 2015

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#Test4HIV

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ABBREVIATIONS AND ACRONYMS

AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	anti-retroviral therapy
ARV	anti-retroviral drugs
CDC	United States Centers for Disease Control and Prevention
CLIA	chemiluminescence immunoassay
DBS	dried blood spot
DNA	deoxyribonucleic acid
ECL	electrochemiluminescence immunoassay
EIA	enzyme immunoassay
eMTCT	elimination of mother-to-child transmission
EQA	external quality assessment
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV testing services
IVD	in vitro diagnostic medical device
NASBA	nucleic acid sequence-based amplification
NAT	nucleic acid testing
NGO	nongovernmental organization
OST	opioid substitution therapy
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	United States President's Emergency Plan for AIDS Relief
PICO	population/intervention/comparison/outcome
PITC	provider-initiated testing and counselling
PMTCT	prevention of mother-to-child transmission
PrEP	pre-exposure prophylaxis

QA	quality assurance
QC	quality control
QI	quality improvement
RDT	rapid diagnostic test
RNA	ribonucleic acid
SOP	standard operating procedure
STI	sexually transmitted infection
TB	tuberculosis
TNA	total nucleic acid
UAT	unlinked anonymous testing
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VCT	voluntary counselling and testing
VMMC	voluntary medical male circumcision
WB	Western blot
WHO	World Health Organization

GLOSSARY

Acute infection: the period in which an individual becomes HIV-infected and before HIV antibodies can be detected by a serological assay (1).

Analyte: a substance or chemical constituent that is analysed, generally referring to a component of blood or another bodily fluid. In the context of HIV, analytes include HIV p24 antigen and HIV-1/2 antibodies.

Assay: a complete procedure for detecting the presence of or the concentration of an analyte, including all the components of a test kit used to identify HIV p24 antigen or HIV-1/2 antibodies.

Biological surveillance: the collection and use of biological markers to inform surveillance, in this context, HIV surveillance systems. This term is replacing the term *serosurveillance* because biological specimens other than serum are increasingly being collected routinely.

Concentrated epidemic: HIV has spread rapidly in a defined subpopulation (such as men who have sex with men, sex workers, transgender people, people who use drugs or people in prison or other closed settings) but is not well established in the general population. This type of epidemic suggests that there are active networks of people with high risk behaviours within the subpopulation. The future course of the epidemic is determined by the nature of the links between subpopulations with a high HIV prevalence and the general population. Numerical proxy: HIV prevalence is consistently over 5% in at least one defined subpopulation but is below 1% in pregnant women attending antenatal clinics.

Confirmed: to issue an HIV status, initially reactive test results need to be confirmed according to the national validated testing algorithm.

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

Early infant diagnosis: testing of infants to determine their HIV status, given that HIV can be acquired in utero (during pregnancy), peripartum (during delivery), postpartum (through breastfeeding) or via parenteral exposure (2).

Eclipse period: the period between HIV infection and detection of virological markers, such as HIV RNA/DNA or HIV p24 antigen (1).

External quality assessment (EQA): inter-laboratory comparison to determine if the HIV testing service can provide correct test results and diagnosis.

Generalized epidemic: HIV is firmly established in the general population. Although subpopulations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain the epidemic. Numerical

proxy: HIV prevalence is consistently over 1% in pregnant women attending antenatal clinics.

HIV status: a collection of results from one or more assays. An HIV status is similar to HIV diagnosis. It refers to reports of HIV-positive, HIV-negative or HIV-inconclusive, whereas HIV diagnosis generally refers to HIV-positive diagnoses and in some cases HIV-negative diagnoses.

HIV test result: the result from a single test on a given assay.

Index testing: a focused approach to HIV testing in which the household and family members (including children) of people diagnosed with HIV are offered HIV testing services; also referred to as index case HIV testing (3).

Indicator condition-guided HIV testing: a focused approach to test people more likely to be infected with HIV who are identified through indicator conditions, such as STIs, lymphoma, cervical or anal neoplasia, herpes zoster and hepatitis B/C. These conditions occur more frequently in HIV-infected people than in uninfected people, either because they share a common mode of transmission with HIV or because their occurrence is facilitated by the characteristic immune deficiency associated with HIV infection (4).

Integration: the co-location and sharing of services and resources across different disease areas. In the context of HIV, this may include the provision of HIV testing, prevention, treatment and care services alongside other health services, such as TB, STI or viral hepatitis services, antenatal care (ANC), contraceptive and other family planning services and screening and care for other conditions, including noncommunicable diseases.

In vitro diagnostic (IVD) medical device: a medical device, used alone or in combination, intended by the manufacturer for the examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. For example, IVDs can be used for the following test purposes: diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status. Examples of IVDs include reagents, calibrators, control materials and specimen receptacles (5).

Key populations: Defined groups who, due to specific higher-risk behaviours, are at increased risk for HIV *irrespective of the epidemic type or local context*. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people.

Lay provider: any person who performs functions related to health-care delivery and has been trained to deliver specific services but has not received a formal professional or paraprofessional certificate or tertiary education degree (6).

Multi-analyte testing: similar to multiplex testing (see “Multiplex testing”), the term refers to the use of the same platform to test for different analytes with different sets of reagents, typically using more than one specimen (7).

Multiplex testing: testing a single specimen with one test device for more than one analyte, for example, a single test device that detects HIV-1/2 antibodies and antibodies to *Treponema pallidum* (syphilis) (7).

Negative predictive value: the probability that a person with a negative test result is not infected with HIV, that is, “true negative” (8).

Non-reactive test result: a test result that *does* not show a reaction indicating the presence of analyte.

Nucleic acid testing (NAT): also referred to as molecular technology, for example, polymerase chain reaction (PCR) or nucleic acid sequence-based amplification (NASBA). This type of testing can detect very small quantities of viral nucleic acid, that is, RNA, DNA or TNA, qualitatively and quantitatively (9).

Pre-test information: a dialogue and the provision of accurate information by a trained lay provider or health worker before an HIV test is performed (10).

Positive predictive value: the probability that a person with a positive test result is infected with HIV, that is, “true positive” (8).

Quality assurance (QA): a part of quality management focused on providing confidence that quality requirements will be fulfilled (11).¹

Quality control (QC): a material or mechanism which, when used with or as part of a test system (assay), monitors the analytical performance of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it (11).¹

Quality improvement (QI): a part of quality management focused on increasing the ability to fulfil quality requirements (11).¹

Quality management system: a system to direct and control an organization with regard to quality.

Reactive test result: a test result that shows a reaction to indicate the presence of analyte.

Repeat testing: refers to a situation where additional testing is performed for an individual *immediately* following initial test results, within the same testing visit, using the same assays and, where possible, the same specimen (12).

Retesting: There are certain situations in which individuals should be retested after a defined period of time: (1) HIV-negative people with recent or on-going risk of exposure, (2) people with an HIV-inconclusive status and (3) HIV-positive people before they enrol in care or initiate treatment. Reasons for retesting before initiation of care or treatment include ruling out laboratory or transcription error and either ruling in or ruling out seroconversion (12, 13).

Rapid diagnostic test (RDT): in vitro diagnostic of immunochromatographic or immunofiltration format for, in the case of HIV diagnosis, the detection of HIV-1/2 antibodies and/or HIV p24 antigen (8, 9).

Self-testing (HIVST): a process in which an individual who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him- or herself, often in private. Reactive test results must be followed by additional HIV testing services (14).

¹ See also, ISO 9000:2005. Quality management systems – Fundamentals and vocabulary. Geneva: International Organization for Standardization; 2005 (<https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-3:v1:en>, accessed 30 June 2015).

Sensitivity: denotes the probability that an HIV assay will correctly identify all specimens that contain HIV-1/2 antibodies and/or HIV p24 antigen (12).

Sentinel surveillance: a type of surveillance that is conducted through selected sites among populations of particular interest or that may provide approximations of prevalence for a larger population, for example, in antenatal clinics (8, 15).

Seroconversion: when an individual first produces a quantity of HIV antibodies sufficient to be detectable on a given HIV serological assay (12).

Serodiscordant couple: a couple in which one partner is HIV-positive and one partner is HIV-negative (16).

Serological assay: an assay that detects the presence of antibodies in human specimens, typically serum or plasma but also capillary/venous whole blood and oral fluid. RDTs, immunoassays (including EIAs, CLIAs, ECLs) and certain supplemental HIV assays are examples of serological assays (9).

Specificity: denotes the probability that the assay will correctly detect specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

Supplemental assay: an assay that provides additional information for specimens that a first-line assay has found to be reactive but may not be able to definitively confirm that reactivity.

Task sharing: the rational redistribution of tasks between cadres of health-care providers with longer training and other cadres with shorter training, such as trained lay providers (6, 17).

Test for triage: a community-based HIV testing approach involving trained and supported lay providers conducting a single HIV RDT. The lay providers then promptly link individuals with reactive test results to a facility for further HIV testing and to an assessment for treatment. Individuals with non-reactive test results are informed of their results, referred and linked for appropriate HIV prevention services and recommended for retesting according to recent or on-going HIV risk and national guidelines (18).

Testing algorithm: the combination and sequence of specific assays used within HIV testing strategies (12).

Testing strategy: generically describes a testing sequence for a specific objective, taking into consideration the presumed HIV prevalence in the population being tested (19).

Throughput: the number of specimens per hour per operator that can be tested by an assay; the volume of clients that come through a facility, laboratory or other community-based settings.

Verified: people diagnosed HIV-positive are retested and their HIV diagnosis is verified before they initiate care or treatment.

Window period: the period between HIV infection and the detection of HIV-1/2 antibodies using serological assays, which signals the end of the seroconversion period.

EXECUTIVE SUMMARY

Purpose

Countries, programme managers, health workers and other stakeholders have indicated the importance of consolidating World Health Organization (WHO) guidance for HIV testing services (HTS). Thus, this guidance brings together existing guidance relevant to the provision of HTS and addresses issues and elements for effective delivery of HTS that are common in a variety of settings, contexts and diverse populations. In addition, this document provides a new recommendation to support HTS by trained lay providers, considers the potential of HIV self-testing to increase access to and coverage of HIV testing, and outlines focused and strategic approaches to HTS that are needed to support the new UN 90–90–90 global HIV targets – the first target being diagnosis of 90% of people with HIV (20). Moreover, this guidance will assist national programme managers and service providers, including those from community-based programmes, in planning for and implementing HTS.

These guidelines aim to:

- provide comprehensive evidence-based recommendations for HTS;
- support testing by trained lay providers to increase access to HTS through community-based approaches;
- offer guidance to countries to deliver a mix of HTS approaches appropriate to their epidemic context, focusing on HTS for groups most affected and currently undiagnosed and underserved;
- provide guidance to ensure the accuracy of test results and support improvement of the quality of HTS;
- catalyse greater national and global commitment to the provision of effective HTS as a key element of comprehensive HIV programmes, with better linkage to prevention, treatment and care, to reduce HIV incidence, morbidity and mortality.

These guidelines discuss issues relating to HTS and highlight the need for tailored HTS approaches to the following population groups:

- infants
- children
- adolescents (10–19 years old)
- pregnant and postpartum women
- couples and partners
- men
- key populations.¹

¹ In this document key populations are defined as the following groups: men who have sex with men, people in prison or other closed settings, people who inject drugs, sex workers and transgender people. For further guidance on key populations, see *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* (<http://www.who.int/hiv/pub/guidelines/keypopulations>).

During global meetings and consultations in 2015, stakeholders advised WHO to consider developing a term, in place of “HIV testing and counselling”, that encompasses the full range of services available. The Guideline Development Group discussed this and agreed that *HIV testing services* should be used.

Definition: HIV testing services

Throughout these guidelines the term **HIV testing services (HTS)** is used to embrace the full range of services that should be provided together with HIV testing – **counselling** (pre-test information and post-test counselling); **linkage** to appropriate HIV prevention, treatment and care services and other clinical and support services; and coordination with laboratory services to support **quality assurance** and the delivery of **correct results**. The WHO 5 Cs are principles that apply to all models of HTS and in all circumstances (see section 1.7).

Guideline development methodology

The WHO HIV Department led the development of these guidelines along with a WHO Guideline Steering Group and a Guideline Development Group of external experts.

The WHO Guideline Steering Group proposed that the consolidated HTS guidelines provide a synthesis of current recommendations on approaches to delivering HTS, including pre-test and post-test services and messaging, HIV diagnosis, quality assurance of HIV testing, HIV diagnosis in the context of surveillance and the monitoring and evaluation of HTS. The Group determined that guidelines on HTS developed prior to WHO's adoption of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) process were still valid, as these were supported by evidence and widely implemented. For example, although provider-initiated testing and counselling (PITC) was recommended in 2007, the Group determined that this widespread and evidence-based intervention (21, 22) did not require additional review or revisions. However, the Group did propose that the guidelines create a framework to assist countries in selecting a mix of HTS approaches and include a new recommendation for trained lay providers to conduct HIV testing services, using rapid diagnostic tests (RDTs).

In late 2014 the WHO Guideline Steering Group formed a Guideline Development Group comprising a geographically and gender-balanced group of academics, researchers, programme managers, implementers and people from community networks and organizations. From January through March 2015, WHO convened a series of virtual guideline development meetings to review the compilation of previous WHO guidelines related to HTS, to appraise the evidence for formulating a new recommendation on HIV testing by lay providers using RDTs and to review all sections of the consolidated guidelines. Following these meetings external peer reviewers, UN agency reviewers and WHO staff members from the Department of HIV as well as other WHO departments and regional teams reviewed the draft consolidated HTS guidelines.

Recommendations

Table 1 summarizes the recommendations presented in this document. All recommendations and guidance in the document derive from existing WHO guidance, with the exception of the new recommendation on HIV testing by trained lay providers.


The new recommendation on HIV testing by trained lay providers is in line with existing WHO recommendations that support task sharing in the health sector. The Guideline Development Group, using the GRADE process, assessed the quality of the available evidence as moderate. Based on this evidence the group made a strong recommendation that trained lay providers, using RDTs, can perform HIV testing.

New guidance from the WHO/UNAIDS Working Group on Global HIV/AIDS and STI Surveillance is included in this document (Chapter 9). This guidance suggests that countries and programmes use the currently recommended diagnostic testing strategy for HIV surveillance, make use of programmatic data for surveillance when possible – particularly in prevention of mother-to-child transmission programmes – and that programmes should encourage and move toward the return of test results to participants in surveillance studies.

Implications for programming

Public health considerations underlie the need to prioritize and improve access to accurate, high-quality HTS for diverse populations and settings. These guidelines aim to support countries to provide more effective and acceptable HTS as part of their HIV programmes. They also aim to expand coverage strategically in areas and among populations in greatest need, to increase access to services, to improve the quality of testing services and to help to achieve global targets – particularly the new UNAIDS target of diagnosing 90% of all people with HIV by 2020. To accomplish this, countries will need to assess their specific situations and take into account their epidemiological context and the populations most in need in their settings. It is also important to assess and, as much as possible, to address social and legal barriers to access as well as issues concerning the quality of health services.

Table 1. Summary of WHO recommendations on HIV testing services

Approach	Recommendations
Chapter 2 and Chapter 4: New recommendation	
 HIV testing by trained lay providers using rapid diagnostic tests (RDTs)	Lay providers who are trained and supervised can independently conduct safe and effective HIV testing using RDTs (<i>strong recommendation, moderate quality of evidence</i>).
Chapter 3: Pre-test and post-test services	
Disclosure WHO (2010). Guideline on HIV disclosure counselling for children up to 12 years of age (http://www.who.int/hiv/pub/hiv_disclosure/en/).	Initiatives should be put in place to enforce privacy protection and institute policy, laws and norms that prevent discrimination and promote tolerance and acceptance of people living with HIV. This can help create environments where disclosure of HIV status is easier (<i>strong recommendation, low quality of evidence</i>).
Retesting WHO (2010). Delivering HIV test results and messages for re-testing and counselling in adults (http://www.who.int/hiv/pub/vct/hiv_re_testing/en/index.htm).	All settings It is recommended to offer retesting at least annually to people from key populations and to HIV-negative partners in serodiscordant couples. Depending on client risk behaviours, more frequent voluntary retesting should be offered and available.
	Generalized HIV epidemic Retest all HIV-negative pregnant women in the 3rd trimester, postpartum or during labour because of the high risk of acquiring HIV infection during pregnancy.
	Concentrated HIV epidemic Retest HIV-negative pregnant women who are in a serodiscordant couple, or are from a key population group.
Retesting before ART initiation WHO (2014). WHO reminds national programmes to retest all newly diagnosed people with HIV (http://www.who.int/hiv/pub/vct/retest-newly-diagnosed-phiv-full/en/).	National programmes should retest all people newly and previously diagnosed with HIV before they enrol in care and initiate ART. Retesting people on ART is not recommended, as there are potential risks of incorrect diagnosis, particularly for in vitro diagnostics (IVDs) that use oral fluid specimens.
Chapter 4: Service delivery	
Provider-initiated testing and counselling (PITC) WHO (2007). Guidance on provider-initiated HIV testing and counselling in health facilities (http://www.who.int/hiv/pub/vct/pitc/en/index.html).	Generalized HIV epidemic PITC should be offered for: all clients and in all services (including services for sexually transmitted infection (STI), viral hepatitis, tuberculosis (TB), children under age five, immunization, malnutrition, antenatal care and all services for key populations) as an efficient and effective way to identify people with HIV.
	Concentrated HIV epidemic PITC should be offered for clients (adults, adolescents and children) in clinical settings who present with symptoms or medical conditions that could indicate HIV infection, including presumed and confirmed TB cases.

Approach	Recommendations
<p>Provider-initiated testing and counselling (continued)</p>	<p>Regardless of epidemic type PITC should be considered for malnutrition clinics, STI, hepatitis and TB services, ANC settings and health services for key populations.</p> <p>For TB settings: routine HIV testing should be offered to all clients with presumptive and diagnosed TB; partners of known HIV-positive TB patients should be offered HTS with mutual disclosure (<i>strong recommendation for all people with HIV in all general HIV epidemic settings</i>); and TB-control programmes should mainstream provision of HTS in their operations and routine services.</p>
<p>Community-based HIV testing services WHO (2013). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html).</p>	<p>Generalized HIV epidemic WHO recommends community-based HIV testing services, with linkage to prevention, treatment and care services, in addition to routinely offering PITC for all populations, particularly key populations (<i>strong recommendation, low quality of evidence</i>).</p> <p>Concentrated HIV epidemic WHO recommends community-based HIV testing services, with linkage to prevention, treatment and care, in addition to PITC, for key populations (<i>strong recommendation, low quality of evidence</i>).</p>
<p>Chapter 5: Priority populations</p>	
<p>Infants and children WHO (2010). WHO recommendations on the diagnosis of HIV infection in infants and children (http://www.who.int/hiv/pub/paediatric/diagnosis/en/).</p> <p>WHO (2011). Guideline on HIV disclosure counselling for children up to 12 years of age (http://www.who.int/hiv/pub/hiv_disclosure/en/).</p>	<ul style="list-style-type: none"> • HIV-exposed infants and children younger than 18 months with unknown or uncertain HIV exposure should be tested (with a virological assay) within 4–6 weeks of birth so that those presumptively diagnosed with HIV can start ART (<i>strong recommendation, high quality of evidence</i>). • HIV-exposed infants with non-detectable NAT at 4–6 weeks should undergo HIV serological testing at around nine months of age (or at the time of the last immunization visit) to rule out HIV infection. Infants whose serological assays are reactive at nine months should undergo virological testing to rule in HIV infection (<i>strong recommendation, low quality of evidence</i>). • Children of school age (6–12) should be told their HIV-positive status and their parent's or caregiver's status; younger children should be told their status incrementally to accommodate their cognitive skills and abilities (<i>strong recommendation, low quality of evidence</i>).
<p>Adolescents WHO (2013). Guidelines on HIV testing and counselling for adolescents and care for adolescents with HIV (http://www.who.int/hiv/pub/guidelines/adolescents/en/).</p>	<p>HIV testing services, with linkages to prevention, treatment and care, should be offered for adolescents from key populations in all settings (<i>strong recommendation, very low quality of evidence</i>).</p> <p>Adolescents with HIV should be counselled about the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine if, when, how and to whom to disclose (<i>conditional recommendation, very low quality of evidence</i>).</p>

Approach	Recommendations
<p>Adolescents (continued)</p>	<p>Generalized HIV epidemic HIV testing services, with linkage to prevention, treatment and care, should be <i>offered</i> to all adolescents in generalized epidemics (<i>strong recommendation, very low quality of evidence</i>).</p> <p>Concentrated HIV epidemic HIV testing services, with linkage to prevention, treatment and care, should be <i>accessible</i> to adolescents in low-level and concentrated epidemics (<i>conditional recommendation, very low quality of evidence</i>).</p>
<p>Pregnant and postpartum women WHO (2013). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html).</p>	<p>High prevalence settings PITC for women should be considered a routine component of the package of care in all antenatal, childbirth, postpartum and paediatric care settings. In such settings, where breastfeeding is the norm, lactating mothers who are HIV-negative should be retested periodically throughout the period of breastfeeding.</p> <p>Low prevalence settings PITC can be considered for pregnant women in antenatal care as a key component of the effort to:</p> <ul style="list-style-type: none"> • eliminate mother-to-child transmission of HIV • integrate HIV testing with testing for syphilis and viral or other key tests as relevant to the setting • strengthen the underlying maternal and child health systems. <p>Couples and partner testing services are recommended in antenatal care settings, facilitating provision of interventions, including ART for prevention in serodiscordant couples in all settings (<i>strong recommendation, very low quality of evidence</i>).</p>
<p>Couples and partner HIV testing and counselling WHO (2012). Guidance on couples HIV testing and counselling, including antiretroviral therapy for treatment and prevention in serodiscordant couples (http://www.who.int/hiv/pub/guidelines/9789241501972/en/index.html).</p>	<ul style="list-style-type: none"> • Couples and partners should be offered voluntary HIV testing services with support for mutual disclosure (<i>strong recommendation, low quality of evidence</i>). • In antenatal care settings couples and partners should be offered voluntary HIV testing services with support for mutual disclosure (<i>strong recommendation, low quality of evidence</i>). • HIV testing services for couples and partners, with support for mutual disclosure, should be offered to individuals with known HIV status and their partners (<i>strong recommendation, low quality of evidence for all people with HIV in all epidemic settings; conditional recommendation, low quality of evidence for HIV-negative people depending on the country-specific HIV prevalence</i>).
<p>Key populations WHO (2014). Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (http://www.who.int/hiv/pub/guidelines/keypopulations/en/).</p>	<ul style="list-style-type: none"> • HIV testing services should be routinely offered to all key populations in the community, in closed settings such as prisons and in facility-based settings. • Community-based HIV testing services for key populations linked to prevention, treatment and care services are recommended, in addition to routine facility-based HIV testing services, in all settings (<i>strong recommendation, low quality of evidence</i>). • Couples and partners should be offered HIV testing services with support for mutual disclosure. This applies also to couples and partners from key populations.

Approach	Recommendations
Chapter 7: Testing strategies	
<p>Testing strategies for high and low prevalence settings WHO (2012). Service delivery approaches to HIV testing and counselling (HTC): a strategic policy framework (http://www.who.int/hiv/pub/vct/htc_framework/en/).</p>	<p>High prevalence In settings with <i>greater than 5% HIV prevalence</i> in the population tested, a diagnosis of HIV-positive should be issued to people with two sequential reactive tests.</p> <ul style="list-style-type: none"> • For individuals with A1+; A2–; A3+, an HIV-inconclusive status is reported, and the client should be asked to return in 14 days for retesting. • For individuals with discrepant test results where the A1 is reactive, the A2 is non-reactive and the A3 is non-reactive (that is, A1+, then A2–, then A3–), the final result should be considered HIV-negative. <p>Low prevalence In settings with <i>less than 5% HIV prevalence</i> in the population tested, a diagnosis of HIV-positive should be issued to people with three sequential reactive tests.</p> <ul style="list-style-type: none"> • For individuals with A1+; A2–, the final result should be considered HIV-negative. However, if A1 is a fourth generation assay (Ab/Ag) and A2 is an Ab-only assay, when A1+; A2–, the result should be considered HIV-inconclusive and the person should be retested after 14 days. • For individuals with A1+; A2+; A3–, an HIV-inconclusive status is reported, and the client should be asked to return in 14 days for retesting. • HIV testing services may use combinations of RDTs or combinations of RDTs/EIAs/supplemental assays rather than EIA/Western blot combinations.
Chapter 9: HIV testing in the context of surveillance	
<p>HIV testing in the context of surveillance (http://www.who.int/hiv/strategic/surveillance/workinggroup/en/).</p>	<ul style="list-style-type: none"> • For surveillance, use a testing strategy and national validated testing algorithm that is suitable for HIV diagnosis. • Use programmatic data, when possible, for HIV surveillance; particularly for prevention of mother-to-child transmission programmes. • Routinely return HIV diagnoses to participants in the context of surveillance. • Use HIV incidence assays for population-level incidence estimates and not for individual disease staging; returning these test results to study participants is not recommended. • Use linked HIV testing for biological surveillance that is either confidential (using personally identifiable information) or anonymous (using unique study codes).

NEW

INTRODUCTION

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1 INTRODUCTION

1.1 Progress and challenges

HIV testing is the gateway to HIV prevention, treatment, care and other support services. People's knowledge of their HIV status through HIV testing services (HTS) is crucial to the success of the HIV response. The Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) have endorsed global goals to achieve "zero new HIV infections, zero discrimination and zero AIDS-related deaths". Because of the potential serious medical, social and psychological consequences of misdiagnosis of HIV (either false-positive or false-negative), all programmes and people providing HIV testing must strive also for **zero misdiagnoses**.

The overarching goals of HIV testing services are to:

- identify people with HIV through the provision of quality services for individuals, couples and families;
- effectively link individuals and their families to appropriate HIV treatment, care and support, as well as HIV prevention services, based upon their status; and
- support the scale-up of high impact interventions to reduce HIV transmission and HIV-related morbidity and mortality, that is, antiretroviral therapy (ART), voluntary medical male circumcision (VMMC), prevention of mother-to-child transmission (PMTCT), pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

The new global 90–90–90 targets call for 90% of all people with HIV to be diagnosed, 90% of people with HIV diagnosed to receive ART and 90% of those on ART to have a suppressed viral load by 2020 (20). The first 90 – diagnosis of HIV – is essential to the second 90 – initiation of ART among people with HIV – and the ultimate outcome of the third 90 – viral load suppression among people on ART, which improves client outcomes and prevents HIV-1 transmission (23).

The challenge is to increase access to and uptake of HTS for those who remain undiagnosed and for those at greatest ongoing risk for HIV infection.

Significant increases in access to HTS

Approximately 150 million children and adults in 129 low- and middle-income countries reportedly received HIV testing services in 2014.¹ In the 77 countries that reported for both years, 33% more

¹ Global AIDS Response Progress Reporting (WHO, UNAIDS, UNICEF), 6 July 2015.

people were tested in 2013 than in 2009 (24, 25). Much of this growth stems from the expansion of provider-initiated testing and counselling (PITC) in clinical settings, the introduction of more community-based HTS and the ability to provide same-day test results, and often diagnosis, using rapid diagnostic tests (RDTs). While significant progress has been made, in 2013 it was estimated that 55% of people with HIV remain unaware of their status, and testing continues to be delivered without specifically aiming to reach those most at risk and as yet undiagnosed (26).

In high prevalence settings men lag behind

In countries with high HIV prevalence, HIV testing rates for men are generally lower than for women, as Fig. 1.1 illustrates. Global reporting suggests that this is because in these settings HTS is conducted mainly in reproductive health services, including antenatal care (ANC), where the routine offer of HIV testing is generally the norm. Additional approaches are needed to increase uptake of HTS among men, including the provision of HTS in settings that are more appropriate and acceptable to men, and to devise ways to encourage testing of male partners in high prevalence settings and of couples and male partners of women with HIV in all settings (24).

Provider-initiated HIV testing services need to be expanded

PITC, often referred to as routine HIV testing, can be expanded in more settings and more regions. According to Global AIDS Response Progress Reporting (WHO, UNICEF, UNAIDS), at the end of 2014, 76% of 117 reporting low- and middle-income countries had a policy of recommending PITC during all client encounters, and 90% of 39 reporting countries in the WHO African region recommended PITC in ANC settings. However, in other African countries and in Asia, HIV testing coverage of pregnant women is less than 40% (24).

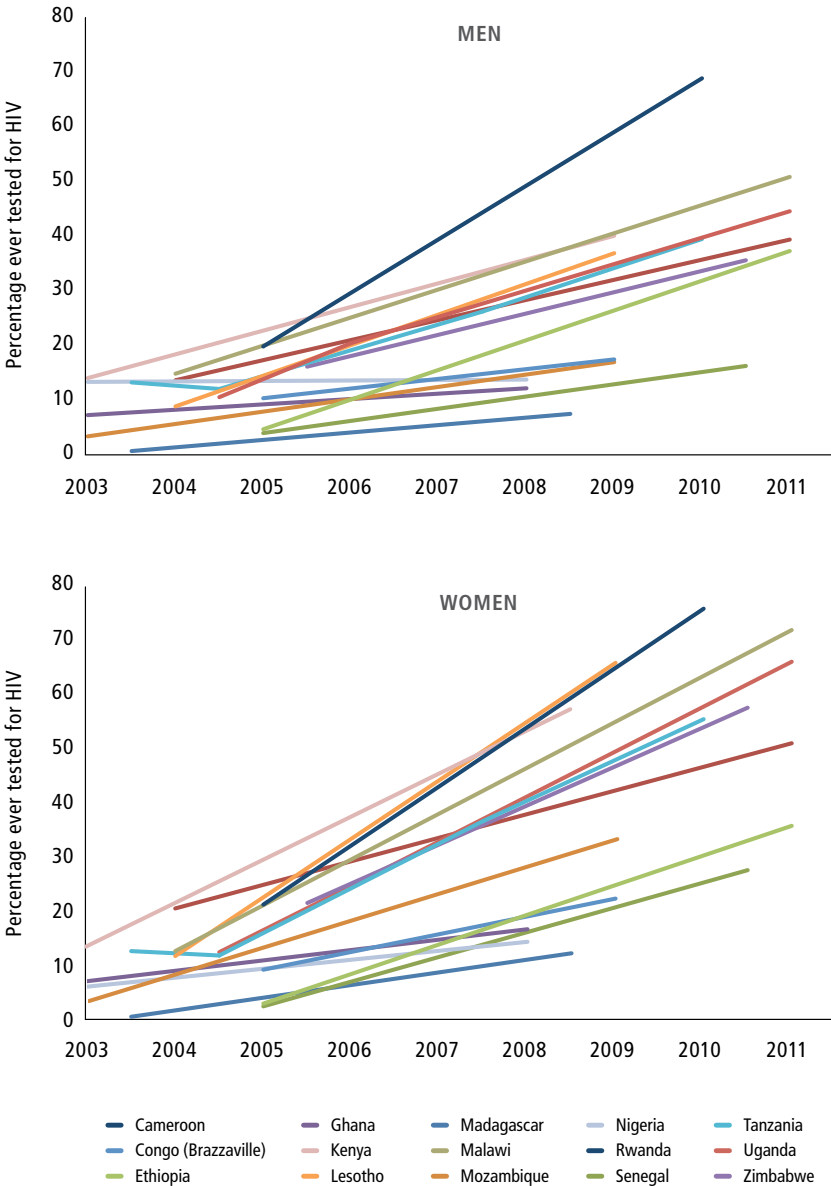
Approaches are needed to increase early infant diagnosis and timely referral of infants diagnosed as HIV-positive to treatment and care.

HIV testing coverage among children is low also. Although HIV testing coverage in PMTCT programmes has improved significantly over the past decade, rates of early infant diagnosis remain far from optimal. Among reporting countries in 2012, only one-third of infants born to HIV-infected mothers received a virological HIV test within the first two months of life

(24). Moreover, despite reports of a high proportion of HIV cases detected among children tested in clinical settings in countries with generalized epidemics (27–29), in many settings PITC is still rarely offered to children in TB and malnutrition clinics (30, 31). Such low HIV testing coverage for infants and children also is a missed opportunity to offer HTS to parents, caregivers and family members of children attending facility-based health services. Barriers to HIV testing among infants and children include mothers moving back to their home villages after delivery in a faraway facility, fear of disclosure of HIV status, fear of stigma and discrimination and parents' lack of knowledge of the need to enrol children in infant care, as well as impediments such as lack of transportation, inconvenient service hours and long waits at health facilities (30, 31).

Approaches are needed to increase early infant diagnosis and timely referral of infants diagnosed as HIV-positive to care and treatment. Both are key to improving health outcomes and child survival.

Fig. 1.1. Percentage of men and women ages 15–49 years who were ever tested for HIV and received their results in 15 selected countries in the WHO African Region, 2003–2011



Source: Staveteig, 2013 (22).

Adolescents, too, are underserved

While most infants with undiagnosed HIV infection will die before their fifth birthday, some long-term survivors will continue to remain unidentified as HIV-infected into adolescence. Adolescents, particularly girls, are also at risk for acquiring HIV through sexual transmission. In sub-Saharan Africa adolescents (10–19 years of age) are less likely than adults to be tested, to obtain care, to remain in care and to achieve viral suppression (13). Between 2005 and 2012 the number of HIV-related deaths among adolescents increased by 50% (32). Based on Demographic and Health Surveys and Multiple Indicator Cluster Surveys from 2008 to 2012 in the WHO African Region, fewer than one of every five girls ages 15–19 years were aware of their HIV status (24). Because uptake of HIV testing among adolescents is low and services for adolescents are of poor quality or in many settings have not yet been developed, there is often little support for adolescents to overcome barriers, adhere to treatment and stay in care. Therefore, high levels of HIV-related morbidity and mortality are becoming more common among adolescents (33).

Access for key populations should be prioritized

Key populations continue to be disproportionately affected by HIV in all settings. In 2013 there were an estimated 2 million new HIV infections worldwide. Of these, an estimated 40% occurred among key populations (10, 34). Within key populations adolescents (10–19 years old) and young people (15–24 years old) are at greater risk for acquiring HIV than older people (10). In countries with low HIV prevalence, HIV testing often takes place primarily in ANC services and does not reach key populations. The estimated HIV testing coverage among key populations in many countries remains low (34), and even these reports may be overestimates. In many countries data on HIV testing coverage collected for key populations are based on small samples from a limited number of settings and, therefore, may overestimate overall coverage in these populations.

Countries and programmes must prioritize and focus on tailored HTS approaches for key populations in all settings.

Also, in all settings people from key populations are less likely than the general population to link to HIV services in a timely manner because their behaviour is criminalized and they experience stigma and discrimination (10). For instance, in Bangkok 25% of drug users report that they avoid health services

because they are afraid of compulsory treatment (35), and uptake of HIV services remains low. Likewise, globally, men who have sex with men report that the experience of homophobia is the most important deterrent to their use of health services (36).

To reduce HIV burden, countries and programmes must prioritize and focus on tailored HTS approaches for key populations in all settings.

Late or delayed linkage to prevention, treatment, care and support is common

Globally, many people diagnosed with HIV infection are not linked to treatment and care (13). In resource-limited settings, primarily sub-Saharan Africa, it is estimated that as much as 40% of people who are diagnosed through HIV testing services are not linked to care (25, 37, 38). Barriers that hinder or delay linkage to HIV treatment and care

persist, including transportation costs and distance to the facility, stigma, fear of disclosure, staff shortages and long waiting times (37), as well as policy and legal barriers that may hinder access particularly for adolescents and key populations. Ultimately, many people with HIV are diagnosed late and start ART late, with CD4 counts below 200 cells/ μ L (39). Such late initiation has not decreased significantly over the past decade (39). A combination of interventions is needed to improve linkages to prevention, treatment and care and to reduce loss to follow-up between HIV testing and treatment and care, especially for key populations.

Challenges of quality HIV testing are evident

It is important that all clients who undergo HIV testing receive the correct HIV diagnosis.

In addition to strategically expanding HTS, it is equally important that all clients who undergo HIV testing receive the correct HIV diagnosis. Recent reports suggest that misdiagnosis of HIV status is occurring in resource-limited settings (40). Recent

policy analysis also suggests that only 20% of national HIV testing strategies align with WHO recommendations (41) (see Annex 2). An audit in three countries conducted by Médecins Sans Frontières found significant rates of false-positive diagnoses reported to individuals (2.6%–4.8%) (42). Retesting all individuals diagnosed HIV-positive found that 10.3% had been misdiagnosed HIV-positive in the Democratic Republic of Congo and 7.1% in Ethiopia (42). In Malawi, during a three-month period in 2014, 7% of people previously diagnosed HIV-positive who were retested did not have a concordant HIV-positive status and may have been misdiagnosed. Following quality improvement (QI) and re-training, during another three-month period in 2014, only 4% of the people previously diagnosed HIV-positive who were retested before ART initiation did not have concordant results (43). The rate of false-negative HIV statuses reported (people infected with HIV who are told they are not infected) remains unknown and is difficult to assess, as there is not routine follow-up for people who receive an HIV-negative status.

Poor quality HIV testing is multifaceted; it results from a number of factors, sometimes in combination, including poor product performance, improper storage of test kits and supplies, clerical or transcription errors, user errors in performing the test and/or interpreting the test result, lack of training, improper use of the testing strategy and/or algorithm, lack of supportive supervision and training, lack of standard operating procedures (SOPs) and poor documentation and record-keeping practices. To address these problems, effective quality assurance systems must expand along with the expanded delivery of HTS.

To close these various gaps in coverage and quality, more proactive, rights-based HIV testing approaches are needed. This includes more emphasis on quality assurance, more focused promotion of testing in geographical areas of high HIV prevalence and incidence and among key populations, and strategic investment in multiple efforts to increase demand for testing services. Also critical to closing gaps are use of a broader array of approaches to HIV testing, including couples and partner HIV testing, routine facility-based HTS in clinical settings beyond ANC and TB, community-based HTS and, potentially, HIV self-testing (HIVST) (14, 24).

1.2 Rationale

These guidelines aim to address gaps and limitations in current approaches to HTS. Countries and other programme managers and health workers have indicated the importance of consolidating WHO's guidance on HTS to aid national programme managers and service providers, including those from community-based and community-led programmes, in planning for and implementing services.

1.3 Scope of guidelines

These guidelines outline a public health approach to strengthening and expanding HTS. They present and discuss a new recommendation to allow trained lay providers to perform HTS, and they compile a range of existing WHO guidelines into one consolidated document.

Summary of chapters

Chapter 2 details the methodology for development of these guidelines.

Chapter 3 describes pre-test and post-test services, including linkage to prevention, treatment and care services.

Chapter 4 provides general service delivery recommendations.

Chapter 5 addresses HTS for specific populations – infants and children, adolescents, pregnant women, couples and partners (including serodiscordant couples), men, key populations and other vulnerable populations.

Chapter 6 presents and discusses a framework for focusing HTS approaches in different epidemic and population contexts.

Chapters 7 and 8 describe help with how to conduct and assure the quality of HIV testing.

Chapter 9 discusses HIV testing and diagnosis in the context of surveillance.

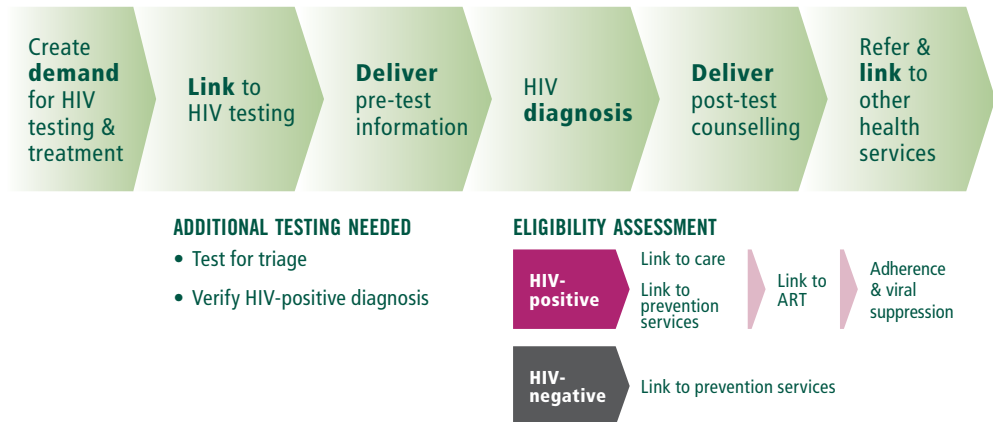
Chapter 10 outlines core monitoring and evaluation considerations for HIV testing.

1.4 Using these guidelines

Like the *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (13)* and the *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (10)*, these guidelines address issues across the continuum of HIV prevention, diagnosis, care, treatment and support (Fig. 1.2). These consolidated guidelines aim to cover all aspects of HTS. Each chapter contains information for specialists and includes information on specific HTS topics so

that sections and chapters can be read alone. Information from other chapters is included and cross-referenced where appropriate. In addition, some chapters will be particularly useful to specific audiences, for example, those responsible for developing HIV testing strategies and selecting HIV assays (Chapter 7), quality assurance (QA) (Chapter 8), surveillance (Chapter 9) and monitoring and evaluation of HTS (Chapter 10).

Fig. 1.2. Continuum of linkage to care and prevention



Background documents developed to support these guidelines and the systematic reviews and GRADE (Grading of Recommendations, Assessment, Development and Evaluation)¹ tables for new recommendations appear in Annex 1, published on the WHO website at <http://www.who.int/hiv/pub/guidelines/>.

1.5 Goal and objectives

The primary goal of these guidelines is to provide consolidated guidance for national programme managers and other decision-makers to consider in the design and management of their HIV response and particularly their approach to HIV testing services. Specific objectives in support of this goal include the following:

- **consolidate existing and new guidance** for HTS for all populations and settings and for various approaches so that it is **easily accessible and user-friendly**;
- present a new recommendation to support **trained lay health providers conducting HIV testing**, using RDTs, in order to increase access to testing, particularly through community-based HTS;
- consider issues relating to **HIVST**, including approaches to introducing and monitoring the acceptability, uptake and effectiveness of HIVST;
- **update** and clarify existing service delivery guidance as needed;

¹ Andrews JC, Schünemann HJ, Oxman AD, Pottie K, Meerpohl JJ, Coello PA et al. GRADE guidelines: 15. Going from evidence to recommendations: determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66:726–35.

- provide guidance to inform **strategic decision-making** regarding the mix of approaches to delivering HTS that will maximize impact;
- provide specific guidance on how to implement **WHO recommended testing strategies**, how to **validate testing algorithms**, and how to better select assays to **assure and improve the quality** of HIV testing;
- provide guidance on HIV testing and diagnosis in the context of surveillance, emphasizing the **routine return of HIV status to individuals**.

1.6 Target audience

These guidelines address national HIV programme managers and other decision-makers, particularly within ministries of health. Such managers are responsible for the national health sector response to HIV, including HIV testing, as well as prevention, treatment and care services for the entire populations of Member States. These managers also play a key role in ensuring the availability of a continuum of prevention, treatment and care services for key populations.

These guidelines will also be of use to officers at the national level responsible for other communicable diseases, especially other forms of sexually transmitted infections (STIs), tuberculosis (TB) and viral hepatitis (HBV and HCV). These guidelines also will assist national and subnational programme managers responsible for the provision of HTS and a comprehensive range of integrated services.

Finally, these guidelines will be helpful to other implementers of HTS, including international and national nongovernmental organizations and community-based organizations. They will serve as the normative guidance to support effective funding, planning, implementation, and monitoring and evaluation of HTS for donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria.

1.7 Guiding principles

A public health and human rights-based approach is important to delivering HTS. A human rights-based approach gives priority to such concerns as universal health coverage, gender equality and health-related rights such as accessibility, availability, acceptability and quality of services. For all HTS, regardless of approach, the actual public health benefits must always outweigh the potential harm or risk. Moreover, the chief reason for testing must always be both to benefit the individuals tested and to improve health outcomes at the population level. HTS should be expanded not merely to achieve high testing uptake or to meet HIV testing targets, but primarily to provide access for all people in need to appropriate, quality HTS that are linked to prevention, treatment, care and support services. Thus, HIV testing for diagnosis must always be voluntary, consent must be informed by pre-test information, and testing must be linked to prevention, treatment, care and support services to maximize both individual and public health benefits.

All forms of HIV testing should adhere to the WHO 5 Cs: **C**onsent, **C**onfidentiality, **C**ounseling, **C**orrect test results and **C**onnection (linkage to prevention, treatment and care services) (44). Coerced testing is never appropriate, whether that coercion comes from a health-care provider, an employer, authorities (such as immigration services) or a partner or family member.

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.
- **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. Confidentiality should be respected, but 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.
- **Counseling:** Pre-test information can be provided in a group setting, but all people should have the opportunity to ask questions in a private setting if they request it. All HIV testing must be accompanied by appropriate and high-quality post-test counselling, based on the specific HIV test result and HIV status reported. Quality assurance (QA) mechanisms as well as supportive supervision and mentoring systems should be in place to ensure the provision of high-quality counselling.
- **Correct:** Providers of HIV testing should strive to provide high-quality testing services, and QA mechanisms should ensure that people receive a correct diagnosis. QA may include both internal and external measures and should receive support from the national reference laboratory. All people who receive a positive HIV diagnosis should be retested to **verify** their diagnosis before initiation of HIV care or treatment.
- **Connection:** Linkage to prevention, treatment and care services should include effective and appropriate follow-up, including long-term prevention and treatment support. **Providing HTS where there is no access to care, or poor linkage to care, including ART, has limited benefit for those with HIV.**

METHODOLOGY

2

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2 METHODOLOGY

2.1 Overview

The WHO HIV Department led the development of these guidelines in accordance with procedures and reporting standards laid out in the *WHO handbook for guideline development (45)*, using the GRADE process. These consolidated guidelines on HTS combine existing WHO recommendations which had previously been developed through the GRADE process, guidance published by WHO together with UN partners and one new WHO recommendation. All current WHO recommendations that pertain to HTS are included.

2.2 Establishing the Guideline Development Group

The WHO HIV Department set up three groups to perform specific guideline development functions: (1) an internal **WHO HTS Guideline Steering Group** to lead the process, (2) a **Guideline Development Group** comprising 19 external experts responsible for the formulation of the new WHO recommendation, service delivery guidance and selection of case examples and for review and approval of the final content of the guidelines document, and (3) 120 **external peer reviewers**. Members of the groups were selected so as to ensure a range of expertise and experience, including appropriate geographical, gender and community representation. (See Acknowledgements for lists of participants.)

Involvement of key stakeholders

An important element of this work was engaging with a diverse set of stakeholders to update and synthesize key messages across existing WHO guidance on HTS. These stakeholders included countries (ministries of health and laboratory services), researchers, international and national implementing agencies, community networks and implementers, WHO regional and country offices and other UN agencies. Also, to maximize stakeholder engagement and ensure the relevance of the guidelines to countries, WHO solicited case examples from civil society, community-based organizations and networks, including key populations and people living with HIV, and additional experts in the field.

Declarations of interest

All Guideline Development Group participants and external peer reviewers submitted declarations of interest to the WHO secretariat. The WHO secretariat and the Guidelines Development Group reviewed all declarations and found no conflicts of interest sufficient to preclude anyone from participating in the development of the guidelines. A full compilation and summary of the declarations are available in Annex 15; see <http://www.who.int/hiv/pub/guidelines/>.

2.3 Defining the scope of the guidelines

To develop these guidelines, the WHO Guideline Steering Group mapped all existing WHO guidance specifically concerned with HTS (see Table 1, page xix). Then, the Group reviewed these and other materials to identify areas requiring updating, gaps, overlaps and inconsistencies. The outcome of the mapping exercise was presented to the Guidelines Development Group at several virtual scoping meetings during November and December 2014. The group reviewed the mapping, advised on the scope of the guidelines and noted areas that did not need updating and areas requiring new guidance – specifically, HIV testing, using RDTs, by trained lay providers.

2.4 Review of the evidence

These guidelines include one new recommendation, on HIV testing by trained lay providers, as well as existing recommendations. Development of the new recommendation began with a systematic review of the evidence. The Guidelines Development Group recommended commissioning new literature reviews and appraisal of existing reviews to investigate values and preferences, along with reviews of the costs and feasibility of implementation (see Annex 1). Also, WHO commissioned a new descriptive review of current national policies on trained lay providers' involvement in HIV testing to inform consideration of the feasibility of the new recommendation (see Annex 2).

2.5 Development of the recommendation on HIV testing, using RDTs, by trained lay providers

As noted, the scoping exercise identified a need for evidence-based recommendations concerning trained lay providers performing HIV testing with RDTs. The question was framed in the PICO (Population, Intervention, Comparator, Outcome) format. The WHO Guideline Steering Group drafted the PICO question. The question was circulated to the members of the Guideline Development Group, who selected and ranked the importance of a range of outcomes and gave comments. Once the PICO question was completed and agreed, external researchers used it to develop search protocols and perform a systematic review of the available scientific evidence, as described below. See Annex 1 for details.

PICO question: Should trained lay providers, using HIV rapid diagnostic tests (RDTs), perform HIV testing?

P: People who receive HTS

I: HIV testing, using HIV RDTs, performed by trained lay providers

C: HIV testing, using HIV RDTs, performed by trained health professionals (for example, nurses or doctors), or no intervention

O: Primary: (1) Measures of testing quality (quality assurance) (for example, lost or damaged/uninterpretable specimens); (2) accurate test results (sensitivity and specificity); (3) adverse events (for example, coercion, inter-partner violence, psychosocial events and/or self-harm, stigma, discrimination); (4) uptake of HTS. **Secondary:** (5) Rate of CD4 measurement (among all participants found to have HIV, the percentage who reach this next stage of triage); (6) linkage to medical visit after diagnosis; and (7) initiation of ART (among participants eligible per national guidelines).

2.5.1 Systematic review of values and preferences

Researchers used the same search strategies to identify studies presenting information on end-users' values and preferences related to the PICO question. Researchers included studies in the values and preferences review if the studies presented primary data examining people's preferences regarding different cadres of health providers and HIV testing. These studies could be qualitative or quantitative in nature but had to present primary data; opinion pieces and review articles were not included. Researchers qualitatively summarized the values and preferences literature; this summary is presented in Annex 1.

2.5.2 Policy analysis

WHO conducted a separate analysis of national HIV testing policies to assess the overall feasibility of HIV testing provided by trained lay providers. Two researchers searched, reviewed and analysed national HIV testing policies from the Americas, Africa, Asia and Europe. From 1 November 2014 through 21 December 2014, the researchers conducted electronic searches for national HIV testing policies, using Google, governmental and nongovernmental websites and WHO databases. They also contacted WHO and UNAIDS regional technical advisors and key experts in the field. This report is presented in Annex 2.

2.6 Developing the recommendation

From January through March 2015, WHO convened 12 virtual guideline development meetings (two parallel morning and afternoon meetings on six separate occasions to allow participation from all time zones) and nine WHO Steering Group meetings. During these meetings participants considered the evidence for formulating a new recommendation and reviewed all relevant sections of the consolidated guidelines.

2.7 Review of service delivery, implementation approaches and case examples

In addition to the systematic review on trained lay providers conducting HIV testing and the review of 48 countries' policies on HIV testing (see Annex 2), two other literature reviews were conducted. Both were on community-based HTS: one among key populations and the other among the general population. Both inform the discussion of HTS approaches described in Chapter 4 and strategic decision-making described in Chapter 6.

WHO also identified examples of HTS practices in the field. These case examples offer insights into implementation of HTS, including services for key population groups. They explain why and how programmes have worked and the types of challenges faced during implementation. Case examples were solicited and collected specifically to illustrate effective and acceptable ways to deliver community-based HTS among key populations. The WHO Steering Group and Guideline Development Group then reviewed the case examples and selected the most relevant for inclusion in the guidelines. See Annex 3 for all case examples collected and more details.

2.8 Additional background work

As part of the guideline development process, WHO commissioned three other literature searches and mathematical modelling to provide the most up-to-date information. They include:

- **Attitudes, values and preferences on HIV self-testing among key populations.** This review informs Chapter 4 and discussion on HIV self-testing (see Annex 4).
- **Review of the cost of different HIV testing approaches.** The review informs Chapter 6 on the strategic selection of HTS approaches (see Annex 5).
- **Mathematical model on the cost of testing pregnant women in high and very low prevalence settings.** This model informs Chapter 6 on the strategic selection of HTS approaches (see Annex 6).
- **Review of misdiagnosis of HIV status.** This review informs Chapters 7 and 8 on HIV diagnosis and the quality of services (see Annex 14).



PRE-TEST AND POST-TEST SERVICES

3

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KEY POINTS

- The 5 Cs are essential for all HTS: **consent, confidentiality, counselling, correct test results and connection** to HIV prevention, treatment and care (see section 1.7).
- HTS should be **prioritized for and promoted to those who are at high risk** and have not been tested recently.
- Verbal consent is usually adequate, but all individuals should have a private opportunity to refuse testing. **Mandatory testing is never warranted.**
- HTS must ensure that all test results and client information are **confidential**. Although disclosure to sexual partners, supportive family members and health workers is often beneficial, this must be done only by or with the consent of the person being tested.
- **Retesting for individuals thought to be in the window period** is needed only for those who report specific recent risk.
- It is the ethical and professional responsibility of the person providing HIV test results to adhere to international and national guidelines to ensure **correct test results**.
- **People who test HIV-negative** will usually need only brief health information about their HIV status report, how to prevent acquisition of HIV in the future and where and how to link to HIV prevention services, as appropriate. People with significant ongoing risk may need more active support and linkage to HIV prevention services. Everyone who is diagnosed HIV-positive should receive post-test counselling, including couples where one or both are diagnosed HIV-positive.
- **People** whose test results are not yet confirmed or whose HIV status is reported as **inconclusive** need follow-up services to ensure that they receive an HIV diagnosis.
- **Key populations** need tailored approaches and messages.
- **Connection** to prevention, treatment and care is an essential component of HTS.

3 PRE-TEST AND POST-TEST SERVICES

3.1 Introduction

Linkage to appropriate services following diagnosis should be regarded as a key component of effective and comprehensive HTS.

Attaining the UN 90–90–90 targets depends on the first 90 – diagnosing 90% of people with an HIV infection. Many people with HIV have already been diagnosed, as evidenced by such achievements as the estimated 13 million people on ART worldwide. Many people needing care and treatment remain

undiagnosed, however. Successful linkage from diagnosis to prevention, treatment and care services is also essential to reach the second and third 90s – that 90% of HIV-positive people who have been diagnosed are on ART and that 90% of people with HIV receiving ART have achieved viral suppression (20).

Receipt of an HIV diagnosis empowers individuals to make informed decisions about HIV prevention, treatment and care that will affect both HIV transmission and an individual's health and survival. Therefore, linkage to appropriate services following diagnosis should be regarded as a key component of effective and comprehensive HTS (see Fig. 1.2, page 8).

This chapter discusses essential services prior to HIV testing as well as post-test messages and counselling services. Post-test services are described specifically for individuals who test HIV-negative, individuals who are diagnosed HIV-positive, individuals who receive a reactive test result but need further testing and individuals who have an inconclusive HIV status. The importance of linkages to prevention, treatment and care is explained, and innovative approaches to improve successful linkages are explored.

3.2 Services prior to HIV testing

Certain basic services should be provided prior to testing *in all settings*, regardless of the approach used to deliver HTS (see Chapter 4 for description of various approaches). These services apply to all adults, couples or partners, and adolescents. Specific pre-test services for testing of children are described in *Operational guidelines on HIV testing and counselling of infants, children and adolescents for service providers in the African region* (<http://tinyurl.com/hivtestguideafro>) (46).

3.2.1 Promoting HTS

Many countries and programmes have vigorously promoted HTS through mass media, including radio, television, billboards and posters, the Internet and electronic social media. The use of the mass media has been shown to increase the uptake of HTS in the short term (47). In both high and low HIV prevalence countries, as a result of campaigns and promotional activities, there is widespread knowledge that HTS are available and where

they are available. For example, among countries with generalized epidemics, recent Demographic and Health Surveys indicate that in Zambia (2014) 96% and in Tanzania (2011–2012) 91% of both men and women know where to receive an HIV test. Knowledge of where to receive HIV testing in countries with concentrated epidemics is lower but still widespread. For example, among both men and women, 69% in Cambodia (2010) and 71% in Sierra Leone (2013), know where to receive a test. Some countries report gender differences. For example, in the Dominican Republic (2010) 96% of women and 85% of men knew where to receive a test, and in Ethiopia (2011) 66% of women and 82% of men knew where to receive one.

Since knowledge of HIV testing and of where it is available is widespread, the continued need for promotion addressing the general population should be assessed. Depending on the goals of the HTS programme, general promotion and awareness campaigns for HTS may no longer be necessary. Even in countries with generally widespread knowledge of HIV testing, however, promotional activities may need to focus on populations where HIV testing rates remain suboptimal, including key populations and adolescent groups, which will likely require tailored messages and approaches – for example, via social media.

Case examples: Promoting HIV testing services

- In China a 24-hour online HIV test scheduler and “Easy Tell”, an anonymous partner notification system, supported HIV self-testing.
- In Macedonia members of parliament received HIV testing through mobile services; this event publicized the benefits of HIV testing.
- In Kenya a professionally designed four-phase mass media campaign significantly increased testing when it directly mentioned HIV and the personal, family and prevention benefits of testing (48).
- In Lebanon activities including word-of-mouth, outreach campaigns, referrals from health-care providers and social media promoted a specialized medical centre offering sexual health services for men who have sex with men, sex workers and transgender people.
- In Lithuania an association of women affected by HIV and their families organized a mobile HIV testing tour. To promote uptake, city mayors, other municipal leaders, public health and prison authorities, and local media were informed about the programme, and newspapers, radio and television presented over 80 communications about the mobile services.

Sources: Marum et al., 2008 (48); Annex 3.

In addition to outreach and promotion, clear signs that direct prospective clients to testing are important. This applies to testing in health facilities, in the community and through mobile services. In certain clinic settings, where HIV testing is routinely offered, such as ANC, STI clinics and TB services, signs, printed information and posters and group health education sessions can efficiently inform pregnant women, other clients and family members that testing is offered.

3.2.2 Creating an enabling environment

Critical enablers are elements outside of health sector interventions that allow health interventions and services to be provided effectively and safely. Examples range from tolerance among the larger population toward people from key populations to laws and policies that enable young people to be tested without parental consent. While these factors are not directly the responsibility of the health sector, health-care providers and organizations delivering HTS should work with community-based organizations, legal authorities and advocacy organizations to ensure that the environment supports and enables people to learn their HIV status. For a description of critical enablers, see Chapter 4 and the *Consolidated guidelines on diagnosis, prevention, care and treatment for key populations* (<http://www.who.int/hiv/pub/guidelines/keypopulations/en/>) (10).

WHO recommendation

Initiatives should be put in place to enforce privacy protection and institute policy, laws and norms that prevent discrimination and promote tolerance and acceptance of people living with HIV. This can help create environments where disclosure of HIV status is easier (*strong recommendation, low quality of evidence*).

Source: WHO, 2011 (49).

3.2.3 Ensuring a confidential setting and preserving confidentiality

All HTS providers must remain committed to preserving confidentiality, one of the 5 Cs of HTS (see Section 1.7). Confidentiality applies not only to the test results and reports of HIV status but also to any personal information, such as information concerning sexual behaviour and the use of illegal drugs. HTS should avoid practices that can inadvertently reveal a client's test results, or HIV status, to others in the waiting room or in the health facility. Such practices might include counselling all people diagnosed HIV-positive in a special room or by a specific provider or making it obvious to others which clients will need or is receiving additional testing or lengthy post-test counselling. Lack of confidentiality discourages people from using HTS. For example, in Cambodia some sex workers refused HIV testing because the outreach setting where peer educators were providing counselling was not perceived as private (50). Health workers and others who provide HIV testing may need special training and sensitization regarding the confidentiality of medical records, particularly where key populations are concerned.

3.2.4 Providing pre-test information

Historically, HIV counselling has been provided both before and after HIV testing. Before the introduction of RDTs, same-day results were not feasible, so counsellors included comprehensive information in the pre-test session in case the client did not return for their test results. Moreover, in the pre-treatment era pre-test counselling often focused on

providing a risk assessment, preparing clients to cope with an HIV-positive diagnosis in the absence of treatment and encouraging clients to return to receive their test results.

With the widespread use of HIV RDTs, most people receive their HIV test results – at least results of the first test – and often a diagnosis on the same day. Therefore, intensive pre-test counselling is no longer needed and may create barriers to service delivery (51, 52).

Individual risk assessment and individualized counselling during the pre-test information session is no longer recommended. Depending on local conditions and resources, programmes may provide pre-test information through individual or group information sessions and through media such as posters, brochures, websites and short video clips shown in waiting rooms. When children and adolescents are receiving HTS, information should be presented in an age-appropriate way to ensure comprehension.

Offering or recommending HIV testing to a client or a group of clients includes providing clear and concise information on:

- the benefits of HIV testing
- the meaning of an HIV-positive and an HIV-negative diagnosis
- the services available in the case of an HIV-positive diagnosis, including where ART is provided
- the potential for incorrect results if a person already on ART is tested
- a brief description of prevention options and encouragement of partner testing
- the fact that the test result and any information shared by the client is confidential
- the fact that the client has the right to refuse to be tested and that declining testing will not affect the client's access to HIV-related services or general medical care
- potential risks of testing to the client in settings where there are legal implications for those who test positive and/or for those whose sexual or other behaviour is stigmatized
- an opportunity to ask the provider questions.

Special considerations for pregnant or postpartum women

Pre-test information or health education for women who are or may become pregnant or are postpartum should also include:

- the potential risk of transmitting HIV to the infant
- measures that can be taken to reduce mother-to-child transmission, including the provision of ART to benefit the mother and prevent HIV transmission to the infant
- counselling on infant feeding practices to reduce the risk of HIV transmission
- the benefits of early HIV diagnosis for mothers and infants
- encouragement for partner testing.

Supporting intensified tuberculosis case finding at HIV testing facilities

Tuberculosis (TB) is the most common presenting illness among people with HIV. It is fatal if undetected or untreated and is the leading cause of death among people with HIV, responsible for about one of every four HIV-associated deaths. Early detection of TB and

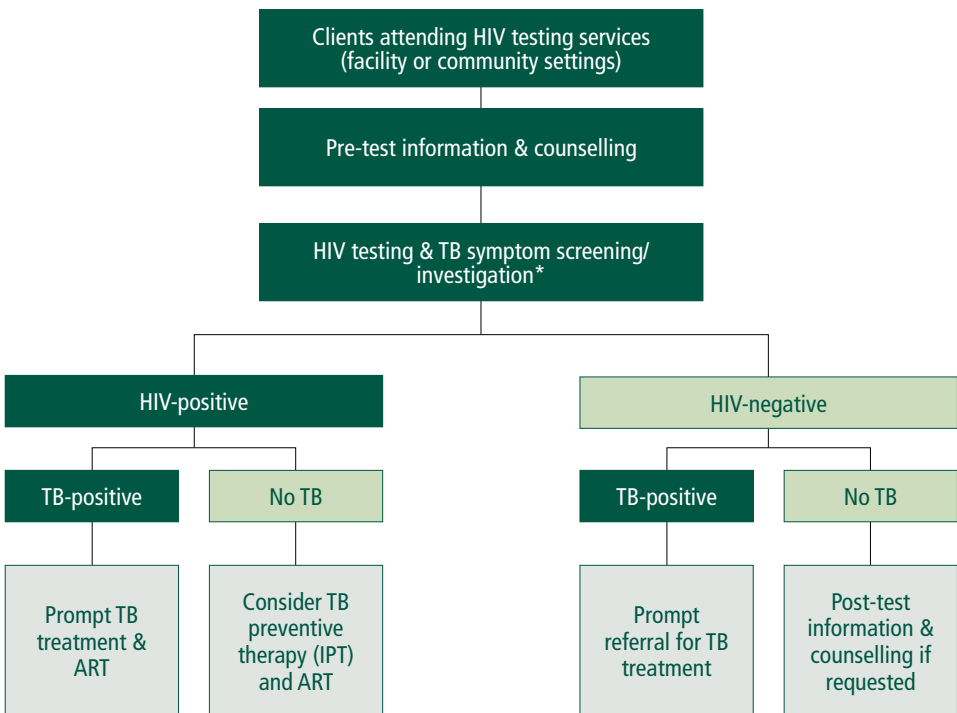
prompt linkage to TB treatment along with ART can prevent these deaths. HTS provides an important opportunity for intensified TB case finding and, thus, early detection and treatment of TB.

HTS should integrate screening for TB symptoms into the information session before HIV testing, both at health facilities and in community-based testing.

HTS should integrate screening for TB symptoms into the information session before HIV testing, both at health facilities and in community-based testing. All clients with TB symptoms should be thoroughly investigated, and post-test counselling should discuss the outcome of this investigation. All clients diagnosed with TB should be promptly registered

with the national TB programme and started on anti-TB treatment. HIV-positive clients diagnosed with active TB should be urgently started on ART, regardless of CD4 count, while those not having TB should consider TB preventive therapy (for example, isoniazid preventive therapy) as indicated in the schema in Fig. 3.1.

Fig. 3.1. HIV/TB testing and screening algorithm to increase TB case finding in HTS



*Per national guidelines.

Case example: In India intensified TB case finding is systematic at all HIV testing facilities

Health workers or trained lay providers at HIV testing facilities screen each client for the presence of cough for two weeks, fever, weight loss and night sweats or other symptoms suggestive of pulmonary or extra-pulmonary TB. This screening is an integral part of pre-test information. All symptomatic clients are systematically referred and enrolled for investigations in the same facility. This activity is routinely reported to the district, state and national levels. The following table summarizes the data for four recent years.

Year	Total clients attending HIV testing centres (excluding pregnant women)	Presumptive TB cases identified	Total TB cases diagnosed among presumptive	Proportion of HIV-positive TB patients started on ART
2010	7 678 746	484 617	51 412	57%
2011	9 774 581	580 695	55 572	59%
2012	9 193 113	552 350	46 863	59%
2013	7 264 722	620 539	64 506	88%

Source: TB India, 2014 (53).

Special considerations for couples or partners who ask to be tested together

An increasing number of countries offer couples counselling and partner testing, which promotes mutual disclosure of HIV status and increases adoption of prevention measures, especially in the case of discordant couples (one HIV-positive partner and one HIV-negative partner). The pre-test information session for couples should not ask about past sexual behaviour or risks, as this is unnecessary and may create problems for the couple. The person conducting a pre-test information session should make clear that both testing and post-test counselling can be provided individually, if either partner prefers, and that disclosure of HIV status to the other person is not required. For more information on couples testing, see *Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples* (http://apps.who.int/iris/bitstream/10665/44646/1/9789241501972_eng.pdf) (16).

Special considerations for key populations

There are many reports of discrimination and stigma against people from key populations in health-care settings. In many settings health workers lack experience, knowledge or training on how to provide inclusive and non-judgemental HTS for key populations. Countries should prioritize the training of health workers so that they can provide acceptable services, better understand the needs of key populations and be familiar with local support and prevention services (10). Links with key population networks and community-based organizations to support or provide HTS, including services delivered by peers, may increase reach, uptake and acceptability.

Consent by adults

Informed consent remains one of the essential 5Cs of testing services. It should always be obtained individually and in private by an HTS provider. In most settings verbal consent for HIV testing is sufficient. The provider must ensure that the client has learned enough about testing to give informed consent. HTS may provide information about testing and the need for consent in a group setting, such as group health education, but clients should give consent in an individual and private manner. In settings such as ANC or TB clinics, where HIV testing is routine, health workers should carefully explain how a client can decline testing and ensure that each person has a private opportunity to opt out of testing. People who are under the influence of drugs or alcohol or otherwise mentally impaired should not be tested, as they are not able to give informed consent. HTS should ensure that no one coerces clients into being tested.

Consent by adolescents

Policies related to age of consent for testing can pose barriers to adolescents' access to HIV testing and other health services. While policies on age of consent for HIV testing vary among countries, ministries of health are encouraged to review these policies in light of the need to uphold adolescents' rights to make choices about their own health and well-being (with consideration for different levels of maturity and understanding). All training materials should address applicable laws and regulations regarding age of consent for HIV testing and situations in which minors may consent for themselves. All staff involved in HTS should be aware of their countries' laws and regulations. For more information see *HIV and adolescents: guidance for HIV testing and counselling and care for adolescents living with HIV* (<http://www.who.int/hiv/pub/guidelines/adolescents/en/>) (54) and *Adolescent HIV testing, counselling and care: implementation for health providers and planners* (http://apps.who.int/adolescent/hiv-testing-treatment/page/Informed_consent_and_HIV_testing) (55).

3.3 Services for those who test HIV-negative

Individuals who test HIV-negative should receive brief health information about their test results. Research to date has not demonstrated that a lengthy counselling session is needed or is beneficial. Further, lengthy post-test counselling for people testing negative may divert counselling resources that are needed by those who test HIV-positive, those whose results are inconclusive and those who are found to be in a serodiscordant relationship (52, 56).

Counselling for those who test HIV-negative should include the following:

- an explanation of the test result and reported HIV status;
- education on methods to prevent HIV acquisition and provision of male or female condoms, lubricant and guidance on their use;
- emphasis on the importance of knowing the status of sexual partner(s) and information about the availability of partner and couples testing services;
- referral and linkage to relevant HIV prevention services, including voluntary male medical circumcision (VMMC) for HIV-negative men, PEP, PrEP for people at substantial ongoing HIV risk;

- a recommendation on retesting based on the client's level of recent exposure and/or ongoing risk of exposure (see next section);
- an opportunity for the client to ask questions and request counselling.

3.3.1 Retesting during the window period

In many settings post-test counselling messages recommend that all people who have a non-reactive (HIV-negative) test result should return for retesting to rule out acute infection that is too early for the test to detect – in other words, in the window period. However, **retesting is needed only for HIV-negative individuals who report recent or ongoing risk of exposure. For most people who test HIV-negative, additional retesting to rule out being in the window period is not necessary** and may waste resources.

For most people who test HIV-negative, additional retesting to rule out being in the window period is not necessary.

The routine and widely reiterated advice to everyone with a negative test result to retest after a “three-month window period” is not appropriate. This is because most people who receive HIV testing and test HIV-negative, particularly where HIV testing is offered routinely in clinical settings, will not be at

risk from recent infection. For a small minority who identify a specific recent suspected exposure, retesting after four to six weeks can be advised.

See Table 3.1, page 31, and *Delivering HIV test results and messages for retesting and counselling in adults* (http://www.who.int/hiv/pub/vct/hiv_re_testing/en/) (12) for detailed and specific guidance on messages concerning retesting.

3.3.2 Retesting for those who remain at high risk of HIV acquisition

People who are diagnosed HIV-negative but remain at high risk, such as some people from key populations, may benefit from regular retesting. Retesting gives these people both the opportunity to ensure early HIV diagnosis and to receive ongoing health education on HIV prevention. **WHO recommends that people in high-risk categories retest at least annually** (12).

3.3.3 Services for adolescents who test HIV-negative

Particularly in high prevalence settings, adolescents who test HIV-negative need information and education about healthy behaviours, such as correct and consistent condom use, reduction of risk-associated behaviours and prevention of HIV and unwanted pregnancy and about the need for retesting if they have new sexual partners. Those testing negative also need referral to appropriate prevention services, such as VMMC, contraception and harm reduction (54). For more information see *HIV and adolescents: guidance for HIV testing and counselling and care for adolescents living with HIV* (http://apps.who.int/iris/bitstream/10665/94334/1/9789241506168_eng.pdf) (55).

3.3.4 Services for partners who both test HIV-negative

Particularly in high prevalence settings, couples and others who test for HIV with a sexual partner and are both diagnosed HIV-negative can benefit from the standard health information and prevention education given to individuals who test negative. In addition, the counsellor or health worker may offer further counselling at the couple's or a partner's request.

3.4 Services for those whose HIV status is inconclusive or test results are not yet confirmed

An **HIV-inconclusive status** means, in high prevalence settings, that **the first reactive test result was not confirmed** by additional testing using subsequent HIV assays or that, in low prevalence settings, the first two test results were reactive but the third assay was non-reactive (see Chapter 7). All clients with an HIV-inconclusive status should be encouraged to **return in 14 days for additional testing to confirm their diagnosis**.

Receiving an HIV-inconclusive status may be confusing and stressful for the individual or couple and may be difficult for the provider to explain. As with many other tests for medical conditions, resolving the discrepancy with a third test is not useful, given the high probability that it may equally produce a false-reactive result. Most, if not all, HIV-inconclusive statuses can be resolved with retesting 14 days later. (For a full discussion of discrepant test results and resolving an HIV-inconclusive status, see Chapter 7.) Clients with an HIV-inconclusive status should be told that a definitive diagnosis cannot be provided that day and that immediate referral to HIV care or ART initiation is not appropriate. They should be given a clear plan for follow-up testing.

Unconfirmed results occur when clients who have an initially reactive HIV test result do not receive additional testing in the same visit to confirm their HIV diagnosis. This may occur in community settings where only one assay is performed, an approach known as test for triage (see Chapter 4). It is the responsibility of providers and counsellors to explain that **this initial result is not an HIV diagnosis** and needs confirmation and to refer clients with a reactive test result to a site where they can receive an HIV diagnosis. These providers should encourage clients to go *as soon as possible* to a facility, such as a clinic or laboratory, for additional HIV testing and a diagnosis. It is not necessary for these clients to wait 14 days to go to the facility. After the test result is confirmed and an HIV diagnosis is given, HIV-positive clients should receive post-test counselling. In particular, **every effort is needed to reduce loss to follow-up between a test for triage and additional testing and HIV diagnosis**.

3.5 Services for those whose test results are HIV-positive

An HIV-positive diagnosis is a life-changing event. Before giving HIV-positive test results, the health worker, trained lay provider, or counsellor should keep in mind the 5 Cs of HTS, as recommended by WHO and UNAIDS, in particular **correct test results** (see section 1.7). It is the professional and ethical duty of the person providing the HIV diagnosis to ensure that testing procedures follow WHO-recommended testing strategies as described in Chapter 7.

A diagnosis of HIV infection is a life-changing event. Before giving these results, the provider should keep in mind the 5 Cs of HTS.

Once health workers or lay providers are confident of adherence to all measures to ensure **correct test results**, they should provide post-test health education and counselling. All post-test **counselling** should be “**client-centred**”, which means avoiding formulaic messages that are the same for everyone

regardless of their personal needs and circumstances. Instead, counselling should **always be responsive** to and tailored to the unique situation of each individual or couple. Health workers, professional counsellors, social workers and trained lay providers can provide counselling. People with HIV who are trained in counselling may be particularly understanding of the needs and concerns of those who receive an HIV-positive diagnosis.

WHO good practice recommendation

To ensure that clients who are misdiagnosed are not needlessly placed on life-long ART (with potential side-effects, waste of resources and psychosocial and emotional implications), WHO recommends that all clients be retested to verify their HIV diagnosis prior to enrolling in care and/or starting ART.

Source: WHO, 2012 (44); WHO, 2014 (57).

The information and counselling that health workers, or others, should provide to **HIV-positive clients** is listed below. Absorbing all of this information in one session may be very challenging, and a follow-up counselling session may be required. Indeed, the shock of learning of an HIV-positive diagnosis may make it difficult for a person to take in further information immediately.

- **Explain** the test results and diagnosis.
- **Give the client time** to consider the results and help the client cope with emotions arising from the diagnosis of HIV infection.
- Discuss **immediate concerns** and help the client decide who in her or his social network may be available to provide immediate support.
- Provide clear **information on ART** and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to obtain ART.
- Make an **active referral** for a specific time and date. (An active referral is one in which the tester makes an appointment for the client or accompanies the client to an appointment, including an appointment for co-located services, and enrolment into HIV clinical care.) Discuss barriers to linkage to care, same-day enrolment and ART eligibility assessment. Arrange for follow-up of clients who are unable to enrol in HIV care on the day of diagnosis.
- Provide information on how to **prevent transmission of HIV**, including information of the reduced transmission risk when virally suppressed on ART; provide male or female condoms and lubricants and guidance on their use.

- Discuss possible disclosure of the result and **the risks and benefits of disclosure**, particularly among couples and partners. Offer couples counselling to support mutual disclosure.
- Encourage and offer HIV **testing for sexual partners, children and other family members** of the client. This can be done individually, through couples testing, index testing or partner notification.
- Assess the risk of **intimate partner violence** and discuss possible steps to ensure the physical safety of clients, particularly women, who are diagnosed HIV-positive.¹
- Assess the risk of suicide, depression and other **mental health** consequences of a diagnosis of HIV infection.
- Provide **additional referrals for prevention, counselling, support and other services** as appropriate (for example, TB diagnosis and treatment, prophylaxis for opportunistic infections, STI screening and treatment, contraception, ANC, opioid substitution therapy (OST), and access to sterile needles and syringes, and brief sexuality counselling (58)).
- Encourage and provide time for the client to ask additional questions.

Case example: Adhara HIV/AIDS Association, Spain

In Seville a community-based outreach programme of the Adhara HIV/AIDS Association (<http://www.adharasevilla.org>) makes sure that the partner of someone testing HIV-positive is promptly linked to a consultation with an HIV specialist. They have compared this strategy with voluntary HIV testing at community centres and found that the number of newly diagnosed HIV-positive cases at the detached community centre was lower compared with using the index partner testing strategy.

Source: Annex 3.

3.5.1 Special considerations concerning disclosure

People who test HIV-negative rarely need assistance or support with disclosing their HIV status to others. In contrast, maintaining privacy about testing HIV-positive and deciding about disclosure are serious concerns for many who are diagnosed HIV-positive.

There are three forms of disclosure relevant and appropriate to HIV testing:

- **Disclosure by the individual to a sexual partner, family member or friend.** Such disclosure can have considerable benefits, particularly for couples and sexual partners. However, many clients who learn that they are HIV-positive need time to absorb the diagnosis before they are ready to disclose and may benefit from additional counselling. Research findings on the consequences of disclosure, especially disclosure by women to their male partners, are mixed. Women who have experienced intimate partner violence

¹ Training in assessment of intimate partner violence and knowledge of referral sources is helpful.

prior to testing may experience violence from their partner after disclosing their HIV status. Providers and counsellors should assess the risk of intimate partner violence in the individuals they serve (59, 60) and make referrals as needed.

- **Disclosure by a health worker to a sexual partner of the individual.** In some settings laws or regulations require the disclosure of HIV-positive status to sexual and/or drug-injecting partners. Where this is the case, providers should discuss this with clients before asking for informed consent for testing. Providers need to be sensitive to clients who may be more susceptible to adverse outcomes of disclosure, such as discrimination, violence, abandonment or incarceration and to adapt counselling accordingly. Such clients may need additional counselling both before and after testing.
- **Disclosure by a health worker to other health workers** involved in the client's care. Providers need to inform people who test positive that, in order to assure appropriate medical care, the diagnosis will be shared with other medical workers as needed. Such disclosure should respect the client's basic right to privacy and confidentiality of all medical information.

Disclosure by a health worker to the police or other legal authorities is not considered ethical in the context of HTS unless the client has consented to this disclosure. In this case HTS providers should obtain written consent to disclose a client's HIV status to legal authorities.

3.5.2 Post-test counselling for special populations

Key populations. Intensified post-test counselling combined with follow-up counselling by community health workers significantly increases the proportion of people with HIV from key populations who enrol in HIV care (61). Also, people who inject drugs are more likely to start and stay in HIV treatment if they are participating in OST programmes (62). Therefore, referral to community health workers and to other services such as OST should be included in post-test counselling for people from key populations. Some people from key populations who test HIV-positive may lack social networks and/or a supportive family to help them deal with their diagnosis. These people may need additional counselling as well as peer support services to cope with this diagnosis. A peer counsellor may particularly help people understand and cope with the diagnosis and support linkage to care and treatment by serving as a "peer navigator", who assists with finding, choosing and obtaining a full range of services.

The 2014 WHO *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* (<http://www.who.int/hiv/pub/guidelines/keypopulations/en/>) (10) describes essential services for key populations. In terms of HTS these guidelines describe interventions to reduce barriers to testing and to linkage to care after testing.

Couples and partner HIV testing services. Couples counselling requires additional training and enhanced counselling skills. Post-test counselling for serodiscordant couples may be especially challenging, as these results may be hard for the provider to explain and difficult for the couple to accept. For more guidance on post-test counselling and services for discordant couples, see *Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples* (http://apps.who.int/iris/bitstream/10665/44646/1/9789241501972_eng.pdf) (16).

Pregnant women. Post-test counselling for pregnant women who are diagnosed with an HIV infection should include the following, in addition to the standard messages described above for all people diagnosed with HIV infection:

- **childbirth plans:** providers should encourage HIV-positive pregnant women to deliver in a health facility for their own well-being as well as to ensure access to PMTCT services;
- **use of ARVs for the client's health,** when indicated and available, as well as the use of **ARVs to prevent transmission to the infant;**
- the importance of **partner testing** and information on the availability of couples testing services;
- ensuring **screening for TB** and testing for other infections such as syphilis;
- **counselling on adequate maternal nutrition,** including iron and folic acid;
- advice on **infant feeding** options and support to carry out the mother's infant feeding choice;
- **HIV testing for the infant** and needed follow-up for HIV-exposed infants.

Adolescents. Along with standard messages for all those diagnosed with an HIV infection, post-test counselling for adolescents with HIV should include (54):

- **tailored help** with linkage to HIV care and treatment;
- counselling, referral and linkage to specific **psychosocial and mental health services** tailored to both the situation in which infection happened and the developmental age of the individual;
- information on adolescents' **rights and responsibilities,** especially their **right to confidentiality;**
- an opportunity to ask questions and discuss **issues related to sexuality** and the challenges they may encounter in relationships, marriage and childbearing;
- individualized planning on **how, when and to whom to disclose** HIV status and engage families and peers in providing support;¹
- referral for **small-group counselling and structured peer support groups,** which may particularly benefit adolescents with HIV.

Children. Informing children of their HIV diagnosis is complex, and the approach depends on the child's age and the counselling skills of the health-care provider. For information on disclosure to children, see *Guidance on HIV disclosure counselling for children 12 years of age and younger* (http://www.who.int/hiv/pub/hiv_disclosure/en/) (49).

3.6 Linkage to care

Without linkage to treatment and care, testing and learning one's HIV-positive status have limited value. Also, those who test HIV-negative, if at continuing high risk, as well as those who test HIV-positive, need linkage to prevention services. Table 3.1 classifies the variety of services that may be appropriate links for people with HIV and for people who test HIV-negative. WHO provides guidance on the HIV care and prevention services that may be offered according to client needs and overall context (13).

¹ Additional WHO guidance on disclosure to and by adolescents appears at: <http://apps.who.int/adolescent/hiv-testing-treatment/page/disclosure>.

Table 3.1. HIV care and prevention services by test status

	HIV-positive	HIV-negative
Treatment	Antiretroviral therapy	
Prevention	Male and female condoms and condom-compatible lubricants	
		PrEP for people at substantial ongoing risk of HIV-infection
		PEP following suspected exposure
		VMMC (in 14 priority countries)
	Harm reduction for people who use drugs (needle and syringe programmes, OST, other drug-dependence treatment and opioid overdose prevention and management)	
	Behavioural interventions to support risk reduction, particularly for people with HIV and key populations	
Sexual and reproductive health	Contraception	
	Brief sexuality counselling	
	PMTCT	
	Cervical cancer screening	
	Anal cancer screening (for men who have sex with men)	
	STI screening	STI screening for those with ongoing risk, including key populations
HIV testing for partners and family members	For all partners and family members (includes partner notification and index case testing)	For partners of people from key populations, where appropriate
Retesting and confirmatory testing	Retest before ART initiation or when linked to care from community-based testing	Retest at least every 12 months if at high ongoing risk, particularly key populations
Other clinical services	Assessment and provision of vaccinations, such as HBV for key populations, pregnant women and infants, tetanus vaccination for adolescent boys and men receiving VMMC where appropriate	
	HBV and HCV testing and treatment	HBV and HCV testing particularly for key populations, according to epidemiology, and treatment
	Co-trimoxazole chemoprophylaxis	
	Intensified TB case finding and linkage to TB treatment	
	Provision of isoniazid preventive therapy if person does not have TB	
	Malaria prevention (such as bed nets and prophylaxis), depending on epidemiology	
Other support services	Mental health services	
	Psychosocial counselling, support and treatment adherence counselling	
	Support for disclosure and partner notification	
	Legal services	

Sources: WHO, 2013 (13); WHO, 2012 (41); WHO, 2008 (59).

Key messages about linkages and connections to prevention, treatment and care

- There appear to be good practices that support linkage to prevention, treatment and care (see box, next page). However, evidence is limited.
- All people who test HIV-positive need immediate linkage to care to maximize the benefits of ART.
- Special efforts will be needed to link people who have a reactive test result in a community setting to facility-based services for additional testing and an HIV diagnosis. For those diagnosed HIV-positive, retesting to verify diagnosis is critical before care or treatment is initiated.
- People diagnosed HIV-positive and those testing HIV-negative with ongoing HIV risk need to be linked to prevention services.
- National policies and strategic planning are needed to improve access to and uptake of HIV testing as well as linkage from testing to prevention, treatment and care.

3.6.1 Linkage to treatment and care

Linkage is defined as a process of actions and activities that support people testing for HIV and people diagnosed with HIV to engage with prevention, treatment and care services as appropriate for their HIV status. For people with HIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in care or treatment (64).

Linkage to care after receiving an HIV-positive diagnosis remains challenging. In resource-limited settings, primarily sub-Saharan Africa, it is estimated that as much as 40% of people who are diagnosed through HTS are not linked to care (25, 37, 38), and late initiation of ART continues to be common (39). Factors that may contribute to poor linkage and particularly to poor rates of enrolment in care and treatment following HIV testing range from **client factors**, such as feeling healthy, depression, lack of social or family support and fear of disclosure, to **social or cultural factors**, such

as stigma and discrimination, **structural or economic factors**, including legal issues and lack of transportation, and **health system barriers**, such as poor referrals, stigmatizing or unfriendly services and long waiting times in facilities (65, 66).

Good practices to increase linkage

Providers of HTS have a crucial role in ensuring linkage to care for people diagnosed with an HIV infection, whether that linkage is quick or delayed. Prompt linkage to HIV care and treatment is ideal and should be encouraged. However, many people do not link to care and treatment immediately. Often, people need time to accept the diagnosis and seek support from partners and families before linking to care (67), and others cycle in and out of care (37). Systematic reviews and several studies describe practices, listed below, that may improve linkage to care and treatment of people who have received an HIV-positive diagnosis.

Good practices include:

- **Comprehensive home-based HIV testing**, which includes offering home assessment and home-based ART initiation (52, 68–70);
- **Integrated services**, where HIV testing, HIV prevention, treatment and care, TB and STI screening and other relevant services are provided together at a single facility or site (34);
- Providing **on-site or immediate CD4 testing with same-day results** (37, 70–74);
- Providing assistance with transport, such as **transportation vouchers**, if the ART site is far from the HTS site (37, 75);
- **Decentralized ART provision** and community-based distribution of ART (76);
- Support and involvement of **trained lay providers** who are peers and act as peer navigators, expert patients/clients and community outreach workers to provide support and to identify and reach people lost to follow-up (76–78);
- **Intensified post-test counselling** by community health workers (79);
- Using communication technologies, such as **mobile phones and text messaging**, which may help with disclosure, adherence and retention (80–82), particularly for adolescents and young people (54);
- Providing **brief strengths-based case management**, which emphasizes people's self-determination and strengths, is client-led and focuses on future outcomes, helps clients set and accomplish goals, establishes good working relationships among the client, the health worker and other sources of support in the community, and provides services outside of office settings (52, 83, 84);
- **Promoting partner testing** may increase rates of HIV testing and linkage to care, as may approaches in PMTCT settings that encourage male involvement (85, 86).
- **Intimate partner notification** by the provider, with permission, is feasible in some settings; it identifies more HIV-positive people and promotes their early referral to care (87–90).

Case examples: “Test, treat and retain” – continuum of care and assessment tool in the Eastern Mediterranean

In an effort to improve linkage to services, the WHO Regional Office for the Eastern Mediterranean developed a tool to assess the barriers to HIV testing, treatment and care. As a result of this assessment, Egypt, Iran, Pakistan and Sudan all were able to identify programmatic weaknesses that caused poor linkage rates.

- In Egypt the assessment identified client factors as the key barriers to linking to HIV treatment. Clients fear disclosure and lack of confidentiality along the continuum of care.
- In Iran the assessment showed that loss to follow-up is highest among people who inject drugs; 62% of people who inject drugs who had an initial reactive RDT did not link to laboratory-based confirmatory testing.
- In Pakistan also, it was difficult to link people who inject drugs to confirmatory testing and, as appropriate, to HIV care and treatment. In fact, many people who inject drugs in Pakistan refused services, often due to fear of stigma and discrimination.
- In Sudan efforts are underway to improve linkage to care from outreach mobile testing, which has had poor linkage rates, by introducing peer navigators to help and support clients in linking to services.

Sources: EMRO, 2014 (91); Annex 3.

3.6.2 Linkage to HIV prevention services

A range of HIV prevention services should be available for those with HIV, in addition to timely initiation of ART (92), and for those who are HIV-negative, (see Table 3.1).

Linkage to prevention services for people who test HIV-negative is not well-documented or studied. It is important to support linkage to prevention services for those with the greatest ongoing risk, for example, people in settings of high HIV incidence, people from key populations and others at high risk of HIV, such as serodiscordant couples. In VMMC-priority countries, linking HIV-negative men to VMMC services is important. Although linkage of men and boys eligible for VMMC from HIV testing to VMMC services can be challenging, it can succeed when linkage is prioritized. For example, in a Mozambique programme where lay providers' HTS was performed, 68% of HIV-negative males were linked to VMMC services (93).

Case example: Government of Mozambique and Jhpiego VMMC programme

The Government of Mozambique and Jhpiego provide a voluntary medical male circumcision (VMMC) programme and a related home- and community-based HTS programme. The HTS programme uses lay providers employed by local community and faith-based groups; they are known as community counsellors. Home-based HTS has been very acceptable to Mozambican communities, with more than one million clients tested between 2007 and 2014. Over the years the role of the community counsellors has expanded to include additional health screening and education.

The Mozambican VMMC programme began in November 2009 and had reached 322 129 men as of February 2015. In 2012, as the number and capacity of VMMC sites expanded, a decision was taken to train the community counsellors to refer men testing HIV-negative at home or at other community settings to VMMC services. Considerable effort was made to ensure that the community counsellors would be perceived as credible sources of information about VMMC. First, they attended a VMMC counselling training, followed by a two-week internship at a VMMC site. During their internship, they provided HTS for VMMC clients and had the opportunity to observe client flow from group education to post-operative follow-up. Two-thirds of men linked to the VMMC site received circumcisions.

Source: Annex 3.

3.6.3 Linkage policy

Countries should consider policies and strategies to improve and prioritize linkage between HTS and prevention, treatment and care services.

For example, in 2009 the Ethiopia Ministry of Health developed its National Referral and Linkage Strategy (94). Key aspects of this strategy include activities to:

- strengthen the community environment to reduce stigma and increase community-based support for treatment adherence and retention
- improve service delivery, reporting and feedback mechanisms
- reduce barriers to care, such as administrative processes and the requirement for identification cards for enrolment in HIV care (94).

Monitoring people's linkage following HIV testing is critical to strengthening treatment and prevention cascades. For additional guidance on the monitoring and evaluation of linkage to prevention, treatment and care services, see:

- *Consolidated strategic information guide for HIV in the health sector* (<http://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en/>) (95).
- *Metrics for monitoring the cascade of HIV testing, care and treatment services in Asia and the Pacific* (http://www.wpro.who.int/hiv/documents/Metrics_to_Monitor_and_evaluate_the_Impact_of_ART/en/) (96).

SERVICE DELIVERY APPROACHES

4

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KEY POINTS

- There are **many facility-based and community-based approaches to delivering HTS**. Selecting approaches strategically and applying effective programming practices are critical.
- There are **many advantages to integrating HIV testing with testing for HBV and HCV and with screening and testing for TB and STIs**.
- **Trained lay providers using RDTs should be authorized to perform HIV testing and provide pre-test information and post-test counselling**. This will increase access to HTS, particularly to community-based services.
- The **routine offer of HTS in clinical settings (PITC)** has been widely implemented in antenatal and TB clinics in high HIV burden settings but **often not in other facility settings, including paediatric clinics; this is a missed opportunity**.
- WHO proposes a **new approach for testing in community settings – “test for triage”**, in which a single RDT is offered in the community with linkage to further testing in a facility to confirm an HIV-positive diagnosis and start clinical care when needed.
- **HIV self-testing (HIVST)** is increasingly available, both informally and in a regulated manner, in some countries. The potential benefits of HIVST, related issues and potential cautions should be weighed and considered.

4 SERVICE DELIVERY APPROACHES

4.1 Principles and approaches to service delivery

HTS can be delivered in different ways and to different people. Services can be offered in a variety of settings, both in health facilities and in the community. HTS can be offered in facilities such as primary care clinics, inpatient wards and outpatient clinics, including specialist clinics such as STI and TB clinics, in district and provincial or regional hospitals and their laboratories and in private clinical services. In the community HTS can be offered through home-based index testing or door-to-door outreach, in schools and other educational establishments and in workplaces, places of worship, parks, bars and other venues. In addition, HIV self-testing (HIVST), a process in which an individual who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him or herself, often in private, is an emerging approach that can extend HTS to people who may be unable or reluctant to attend existing HTS as well as to people who frequently retest (14).

Assess the situation

To identify approaches with the greatest public health benefit and impact, a situational assessment should be undertaken. This assessment should consider HTS coverage, gaps in coverage in geographic areas with high levels of undiagnosed HIV infection and among populations at high risk of HIV infection, the social and epidemiological context and the available financial and human resources.

A strategic mix of HTS approaches

A strategic mix of HTS approaches facilitates diagnosis of as many people as early as possible, with linkage to prevention, treatment, care and support for those testing HIV-positive and to prevention services for those who test HIV-negative.

Countries need to consider a strategic mix of approaches to deliver HTS. The mix should facilitate the diagnosis of as many people with HIV as early as possible. In diagnosing as many people as possible, the mix should aim to maximize yield, efficiency, cost-effectiveness and equity. Equity does not mean that HTS should be provided equally across a country or population; rather it should focus HTS on populations at greatest risk for HIV and who are undeserved. Also, the mix should support timely and

complete linkage to prevention, treatment, care and support services for those testing HIV-positive. Those who test HIV-negative, particularly those at ongoing risk, need linkage to prevention services as well as to learn where and when to retest. The organization of the health system, local context, epidemiology, current testing coverage and available financial and human resources and what the intended clients want, will determine the appropriate mix of HTS approaches to reach populations at high risk and geographic areas with largely undiagnosed HIV infection (44).

Provide a supportive environment with critical enablers

Critical enablers are key to the success of health sector HIV interventions. Critical enablers are conditions, to some extent outside the purview of the health sector, that facilitate the accessibility, acceptability, uptake, equitable coverage, quality, effectiveness and efficiency of HIV interventions and services. These critical enablers support the uptake of HIV testing and linkages to prevention, treatment and care, especially for groups that are reluctant to use or have limited access to current HTS, such as men, adolescents, key populations and other vulnerable groups. Collaborating with other ministries, NGOs and faith-based organizations is crucial to develop the necessary strategies, activities and approaches that address critical enablers (Fig. 4.1).

Fig. 4.1. Addressing critical enablers for HTS programmes



* Includes decriminalization and age of consent.

Source: WHO, 2014 (10).

All HTS must meet standards

HTS must emphasize the WHO 5 Cs (see section 1.7). All people being tested for HIV must give **informed verbal consent to be tested** and be made **aware of their right to refuse testing**. Mandatory, compulsory or coercive HIV testing is never appropriate (44). HTS should always be provided in a respectful, non-discriminatory and ethical manner, reflecting the professional integrity of the provider and respecting the human rights of the person being tested.

All sites that provide HTS should have SOPs and ethical codes of conduct. They should protect client information and confidentiality and should employ appropriately trained and supervised health workers (including lay providers) (97).

All HIV testing should follow a validated national **testing algorithm** and WHO-recommended testing strategies.¹ **This approach should include retesting all people previously diagnosed HIV-positive before they enrol in care or initiate treatment** (57).

All HTS should have appropriate quality assurance (QA) and quality improvement (QI) mechanisms in place (44, 95).

¹ A **testing strategy** refers to the sequence in which diagnostic tests are used for a specific objective, taking into consideration the presumed HIV prevalence in the population tested. A **testing algorithm** refers to a defined combination of specific assays within a testing strategy.

4.2 Good practices for effective HTS programming

Several WHO-recommended effective health programming practices can improve the quality and efficiency of HTS in some settings. These practices include:

- integration of HTS with other health services
- decentralization of HTS to primary health-care facilities and outside the health system (for example, workplaces, schools, places of worship)
- task sharing of HTS responsibilities to increase the role of trained lay providers (10, 13).

Definitions

Integration: the co-location and sharing of services and resources across different disease areas. In the context of HIV, this may include the provision of HIV testing, prevention, treatment and care services alongside other health services, such as TB, STI, HBV and HCV services, antenatal care, contraceptive and other family planning services, and screening and care for other conditions, including noncommunicable diseases.

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

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

4.2.1 Integration of HIV testing with other services

Integration involves not only providing related services in a single setting, but also linking recording and reporting systems to share information, with the consent of the client, and to provide referrals between settings and providers. **WHO recommends the integration of HIV services, including HTS, with a range of other relevant clinical services**, such as those for TB, maternal and child health, sexual and reproductive health, harm reduction programmes for people who inject drugs and, in priority countries, VMMC programmes (13). The primary purpose of such integration is to make HTS more convenient for people coming to health facilities largely for other reasons, and to increase the uptake of HIV testing. Also, certain other services, such as TB, STI and harm-reduction services, attract a clientele that is generally at high risk for HIV infection. Thus, integration with HTS and other HIV services creates the opportunity to diagnose coinfections and to start care and treatment services for all conditions at the same time and in the same place. Integration is appropriate in all epidemic settings and particularly important where HIV prevalence is high.

For clients the integration of HTS into other health services may facilitate taking care of various health needs at the same time and in the same location, saving time and money. It

will likely facilitate linkage to complementary prevention or treatment and care services and expand the reach of HIV testing to people seeking other health services. For the health system, integration may reduce duplication of services and improve coordination – for example, in stock management (98).

The goal of programme collaboration should be to create integrated delivery systems that best facilitate access and increase impact.

Collaboration among programmes at every level of the health system is important to the success of HIV services and related health and social services. Aspects of coordination that need consideration include mobilizing, allocating and sharing resources (including multi-tasking and task sharing; see section 4.2.3); training, mentoring and supervising health workers;

procuring and managing medicines, test kits and other medical supplies; maintaining the quality of HIV testing; and reducing stigma and discrimination in health-care settings. The goal of programme collaboration should be to create integrated delivery systems that best facilitate access to and increase the impact of HTS, HIV treatment and other health services.

Case example: Integration of services

In Myanmar, in an effort to reduce harm associated with unsafe sexual practices among female sex workers, men who have sex with men and transgender people, Médecins du Monde provides HIV and sexual health services and psychosocial support in a friendly setting that offers various activities. Users are free to access medical care or just relax, with social activities and services offered such as meditation in dedicated areas, games, hair dressing or manicures.

Source: Annex 3.

4.2.2 Decentralization of services

In HTS *decentralization* refers to providing HTS in peripheral health facilities, community-based venues and other locations other than sites performing confirmatory HIV testing and related services. **Decentralization of services may be appropriate in both high prevalence and low prevalence settings.** For example, providing HIV testing in places closer to people's homes may reduce transportation costs and waiting times experienced in central hospitals and, therefore, increase uptake. Task sharing, and particularly the greater involvement of trained lay providers, can facilitate efforts to decentralize health services, including HTS.

Decentralization of services, however, may not always be appropriate or acceptable to potential users. In some settings centralized HIV services may provide greater anonymity than neighbourhood services for key populations or others who fear stigma and discrimination. Also, in some low prevalence settings, decentralizing HTS may be inefficient and costly. Context, needs, service gaps and overall costs and benefits should be weighed to decide where HTS should be decentralized.

4.2.3 Task sharing of HTS: increasing the scope of work of lay providers

Task sharing: background and rationale

Many countries continue to face shortages of trained health workers. Task sharing – that is, the rational redistribution of tasks between cadres of health-care providers with longer training with cadres with shorter training – is a pragmatic response to health workforce shortages. It seeks to increase the effectiveness and efficiency of available personnel and so to enable the existing workforce to provide HTS to more people.

Task sharing to trained lay providers seeks to enable the existing workforce to provide HTS to more people.

In particular, task sharing to staff that works in the community may help to address the needs of key populations and other priority groups that may be reluctant or unable to access HTS in health facilities, including linking them to services and providing ongoing care and support. Services led by trained lay

providers, including peer-based interventions, can be a welcome and thus important means of delivering services, providing information and teaching skills that promote safer behaviours. Beyond providing services, lay workers who are their clients' peers can act as role models and offer non-judgemental and respectful support that can help reduce stigma, facilitate access to services and improving their uptake (10, 99).

By itself, increasing task sharing and broadening the scope of responsibilities of trained lay providers will not fully rectify staff shortages and poor quality services. Task sharing is not simply a means to save resources but rather one potentially valuable tool to improve both access to and coverage of services and the quality of services.

WHO has previously recommended the use of lay providers to perform certain clinical services, including counselling and referrals, and has particularly recommended task sharing in the delivery of some HIV clinical services (17, 151), including in mother, newborn and child health services and promotion of HIV testing in pregnancy and prescription of ART by nurses (6). Task sharing to expand HTS has taken place for over a decade in many countries across the Americas (100), Europe (101, 102), sub-Saharan Africa (103–109) and Asia (110). Several systematic reviews, from various domains of health care, support the general conclusion that good health outcomes can be achieved by devolving tasks to nurses and lay or community health workers (111–114).

Definition

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

Source: WHO, 2014 (6).

Review of the evidence regarding task shifting to lay providers

In this guideline WHO issues a new recommendation endorsing the provision of HTS by lay providers (see definition in box) using RDTs. A summary of the results of a systematic review of the relevant evidence and a discussion of the guidance follow. Annexes 1 and 2 provide details.

The uptake of HTS can increase when trained lay providers deliver services. In a randomized trial in an emergency department in the United States of America, the rate of uptake of HTS was higher in the trained lay providers arm than in the trained health-care professionals arm – 57% (1382/2446) versus 27% (643/2409; $p < .001$) (100). Similarly, a pre/post study in rural Malawi reported that, after HTS was delegated from health workers with longer training to lay providers with shorter training, the uptake of HIV testing increased from 1300 to 6500 tests per month (104).

HIV testing conducted by trained lay providers is accurate and equivalent to testing by laboratory staff and health-care providers with longer training, as three studies have shown (103, 105, 110). In the Sisonke District of South Africa, of 3986 samples tested both by trained lay providers and by laboratory staff, all but 23 results matched (105). Of these 23, only two cases were deemed “critical errors”: the trained lay providers found HIV-positive test results whereas the laboratory reported HIV-negative test results. The remainder were cases in which at least one result was inconclusive. Most of these were considered cases in which a trained lay provider was extra cautious and waiting for laboratory confirmation before providing the client with an HIV status. Overall, sensitivity was calculated at 98.0% (95% CI: 96.3–98.9%) and specificity at 99.6% (95% CI: 99.4–99.7%). In Malawi HIV testing performed by trained lay providers had a sensitivity of 99.6% and a specificity of 100%. Of 2911 specimens sent for laboratory confirmation, only four results did not match the results found by lay providers. Three of these four were classified as “sample peculiarities” because the results from several parallel testing strategies continued to be discordant (103). In Cambodia, of 563 specimens, trained lay providers’ and laboratory staff’s test results matched in all but four cases (110). Further investigation found that all test results reported by trained lay providers were correct; errors in writing reports in the laboratory explained the discrepant findings.

Values and preference

Six additional studies reported on some aspect of the values and preferences of clients concerning trained lay providers conducting HTS (two in the USA (115, 116) and four in sub-Saharan Africa (108, 117–119)). In a randomized controlled trial in the USA that included a client satisfaction survey, clients reported greater overall satisfaction with the HTS provided by trained lay providers than with HTS provided by trained health professionals (OR: 1.50; 95% CI: 1.00–2.24) (115). In Botswana 46 of 47 clients who received HTS from a trained lay provider and participated in exit interviews expressed a high level of satisfaction with services and felt comfortable about returning for services in the future (119). Overall, studies found support among clients for trained lay providers performing HTS, particularly in the most rigorous study, the randomized controlled trial in the USA (100).

The systematic review and the values and preference search identified other benefits of trained lay providers offering testing and counselling. These include:

- **Opportunities for delivering a range of services.** Trained lay providers can deliver various health services within and beyond HIV prevention, treatment and care, including vaccination, TB and STI screening and testing and bed net distribution for malaria prevention.
- **Cost-saving.** Task sharing involving lay providers with shorter training may cost less than using health workers with longer training to perform the same tasks. Trained lay providers generally receive lower wages than health professionals. However, full programme costs, cost-effectiveness and affordability vary across settings.
- **Feasible and currently supported by national policy.** An analysis of national HIV testing policies in 48 countries found that trained lay providers are permitted to perform HIV testing with RDTs in 40% of countries overall and in over 60% of the 25 countries in the WHO African region. Even greater numbers of countries allow lay providers to perform pre-test information and post-test counselling (60% of the 48 countries and 80% in the WHO African region) (41) (see Annex 2). A number of countries, however, still limit these functions to health professionals with longer training.
- **Social and cultural context.** Task sharing with trained lay providers may increase the likelihood that services will be sensitive to the culture of the community (120, 121). In particular, trained lay providers may reach more people because they often are culturally competent at talking with their peers, particularly people from key populations and adolescents (10, 54, 122).

WHO recommendation



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

Additional considerations

Selection. Selection of lay providers is important. For example, in Zambia clients wanted providers they could trust; such trust was based on providers' professional conduct, knowledge, politeness, adeptness in dealing with sensitive issues and ability to listen (108).

Training, mentoring and ongoing support. Like other health-care providers and laboratory technicians, lay providers need training, mentoring and supervision by on-site supervisors, ideally including someone trained in laboratory procedures. National competency standards can help to ensure that lay providers are offering high quality HTS. Standardized training should cover how to conduct full HTS procedures, including collecting specimens, performing RDTs following the validated national testing algorithm and testing strategy, providing counselling and issuing test reports as well as record-

keeping and reporting. Lay providers also should be trained in medical ethics so that they are fully aware of their duties to obtain consent and to maintain confidentiality regarding the client and the client's test results and HIV status. As with any other health workers providing HTS, ongoing supportive supervision and mentoring of lay providers should cover both the testing and counselling aspects of their work, provide up-to-date job aides and SOPs, and involve regular external quality assessment (EQA). **A system for quality assurances (QA) will need to be in place for HTS provided by trained lay providers, as it should be for HTS conducted by health professionals.** See Chapter 8 for additional information on QA systems.

Remuneration. Trained lay providers may cost less than health workers with longer training. However, it is important that programmes compensate trained lay providers appropriately for their work. Otherwise, high turnover is likely. These workers should receive adequate wages and/or other appropriate incentives. The main reason for involving lay workers is to increase access to HTS and not to reduce costs.

Policy and regulations. Task sharing requires government leadership, to emphasize its importance, to give priority to its implementation and to ensure an enabling regulatory framework. National policies need to establish a role for trained lay providers with special skills to perform HTS and include their terms of reference in the national salary grid (see box). Some countries may need to change regulations and policies so as to enable nurses, other non-physician health professionals and trained lay providers to offer HTS. Support from the national medical, nursing and medical technologist councils will facilitate the necessary policy changes.

Key steps for introducing HTS by lay providers

Countries should review and revise national policies to:

- permit trained lay providers to provide all testing services, including collecting specimens, performing HIV rapid diagnostic tests, interpreting test results and reporting HIV status; to give pre-test information and post-test counselling; and to support linkages to prevention, treatment and care services;
- acknowledge and adequately remunerate trained lay providers for performing HTS, in keeping with their specialized skills;
- address the roles of trained lay providers in national policies and regulatory frameworks, such as human resource for health and HIV testing policies.

4.3 HIV testing service approaches

WHO recommends making HTS available through a wide range of approaches, both in facilities and in the community, as appropriate to local epidemiology and context.

4.3.1 Facility-based HIV testing services

Facility-based HIV testing services refers to HTS provided in a health facility or laboratory setting.

Voluntary counselling and testing

Developed before treatment became available, voluntary counselling and testing (VCT) was an early model for delivering HTS in dedicated, standalone facilities. It is now recognized that HIV testing in clinical sites may be more effective when it is offered as part of general medical care. Therefore, in many settings HTS has been integrated with other health services so that it can be either offered routinely to all those attending services or offered in particular clinical settings to those with indicator conditions. However, despite limitations due to higher costs and the need for the client to initiate the process of testing, standalone HTS may still be a way to reach people that complements other approaches in some high burden settings (123–125).

Provider-initiated testing and counselling

Provider-initiated testing and counselling (PITC) denotes HTS that is routinely offered in a health facility. It includes providing pre-test information and obtaining consent, with the option for individuals to decline testing. PITC has proved highly acceptable and has increased the uptake of HIV testing in low- and middle-income countries. Its outcomes in terms of uptake of post-test services are similar to those of other testing approaches (22).

Although it involves the routine offering of HTS, **PITC should not develop into mandatory testing or testing people without first informing them that they can decline**. PITC seeks to increase HTS coverage, to provide diagnosis earlier for those attending health facilities, to normalize HIV testing and to remove the need for personal motivation to seek HTS. It saves clients the possible embarrassment of asking for an HIV test, and it saves time for clients attending clinical services for other reasons (126). In low prevalence settings routine PITC will most likely not be cost-effective. However, HIV testing should still be made available for people who request testing or who exhibit clinical signs and symptoms indicative of HIV (126–129).

Since WHO first recommended PITC in 2007, this approach has been implemented in many clinical settings, particularly those with a high HIV burden:

- **PITC offered routinely in ANC** has proved highly acceptable in many countries (21). It has been responsible for the high level of knowledge of HIV status among women in many countries, particularly high-burden countries, allowing women to benefit from PMTCT and ART. However, rates of PITC coverage in ANC vary; the rate remains low in some settings. (See section 5.3 for recommendations on testing in ANC settings.)

- **PITC offered routinely in TB clinics**, to all TB patients, both active and presumptive cases (130), has proved highly acceptable (131). In 2014, 185 countries reported data on HIV testing for TB patients to WHO; 83 countries reported coverage of more than 75% among TB patients (132). In some countries, however, HIV testing is not standard practice in TB clinics, and the level of coverage remains low (130, 132).

WHO recommendations

1. Routine HIV testing should be offered to all patients with presumptive and diagnosed TB.
2. Partners of known HIV-positive TB patients should be offered HTS with mutual disclosure (*strong recommendation for all people with HIV in all generalized HIV epidemic settings*);
3. TB-control programmes should mainstream provision of HTS in their operations and routine services.

Source: WHO, 2012 (64).

- **PITC is less often offered in clinical settings**, even in high burden countries. This is a major missed opportunity. In general clinical settings PITC can have high rates of uptake and of new diagnoses (133–137). (See Annex 12 for guidance on strategically selecting PITC approaches for a specific setting.) Opportunities include:
 - **PITC offered in clinical settings** likely to be associated with higher rates of HIV infection, including STI clinics and services for key populations, including harm reduction services for people who inject drugs (126).
 - **PITC offered to people presenting in inpatient and outpatient hospital settings with symptoms and clinical conditions** indicative or related to HIV infection, particularly in low-level or concentrated epidemic settings; this approach has proved effective in Europe (126–129).
 - **PITC offered in paediatric clinics**. This approach has been effective in finding cases among previously undiagnosed children (138). PITC offered to adolescents has also proved to be efficient in high prevalence areas (54) (see Chapter 5, section 5.2 on adolescents). But PITC services for children and for adolescents are not common. In 2012 Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS) reported that only 55% of 84 countries said that they had a national policy requiring the routine offer of HTS for children (24). In many countries policy barriers, such as age of consent laws, hinder children and adolescents from obtaining HTS (54, 55). Even where favourable policies do exist, health-care providers are often uncomfortable testing children for HIV. A recent study in Zimbabwe reported that, although health workers in a primary care setting were asked to offer HIV testing to all children of unknown status, one-third of children were not offered HIV testing. Providers reported that they did not offer HIV testing because they perceived children to be at low risk of HIV and that they had greater discomfort counselling male caregivers than female caregivers (139).

In some low prevalence settings, PITC in paediatric general clinics and inpatient settings will not be cost-effective. However, offering HIV testing to all children whose parents have HIV or to all children with conditions indicative of HIV and in malnutrition clinics may identify many infections.

- **PITC offered in VMMC services** in the 14 priority VMMC countries,¹ as part of the package of services. There is generally high uptake of PITC among VMMC clients (140, 141). According to reports from Kenya, in 2011 86% of VMMC clients accepted PITC (2% of those tested were HIV-infected and referred to care and treatment services) (139, 140). This marks an increase in HIV testing among VMMC clients in Kenya, from 60% in 2008 (140). Stock-outs of HIV test kits and long waits for HIV testing can pose challenges for sites providing HTS in the context of VMMC services, particularly in countries with high uptake such as the United Republic of Tanzania and Zimbabwe (141).

Testing for TB through HIV services

Tuberculosis is the leading cause of death among people infected with HIV (132). However, only an estimated 48% of TB patients with HIV receive an HIV test. HIV testing in TB settings needs scaling up (132). WHO recommends intensified TB case finding among people with HIV to facilitate early TB detection and treatment (142). HTS offer an opportunity to screen for TB and detect it early (see section 3.2.4). **Systematic TB screening should be integrated into HTS and offered wherever HIV testing is carried out and to all populations receiving HIV testing, irrespective of their test results.** Intensified TB case finding in clinical and outreach settings will facilitate early detection of HIV-associated TB and linkage to treatment. Particularly in settings with a high burden of both TB and HIV, TB case finding in HTS might also contribute appreciably to the detection and treatment of TB in general (143, 144) and so reduce morbidity and mortality associated with TB.

Pre-test information for all clients willing to undergo HIV testing should include information on systematic assessment of TB. Screening findings should be returned promptly so that the results can be shared with the client along with post-test HIV information. All people with TB symptoms should be promptly referred for a TB diagnostic workup that includes investigations such as sputum smear microscopy, chest X-ray, histopathology and molecular testing, depending on country context and national guidelines (130). If a person is found to have TB, he or she should start TB treatment promptly.

Testing for both HIV and other STIs

HIV and STI coinfection is common (145). Services providing care for STIs are one of the key entry points for HIV prevention and referral services. **WHO recommends routinely offering HIV testing to clients diagnosed with other STIs** (146). Several studies have shown that HIV testing in STI clinics is feasible and uptake of testing is high (120, 147). Treatable STIs, such as gonorrhoea and syphilis, indicate recent condomless sex and, thus, identify people at a heightened risk of HIV acquisition. People receiving STI treatment may also have primary HIV infection and, therefore, a high HIV viral load. Thus, diagnosing individuals with coinfection is important both as a prevention strategy and to improve the quality of care for people with HIV.

¹ Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, United Republic of Tanzania, Uganda, Zambia and Zimbabwe.

Both syphilis testing and HIV testing should be routinely offered to women attending ANC (146, 148). Given their common mode of sexual transmission, HIV and syphilis coinfection is common. Syphilis infection is a recognized cofactor for HIV transmission and acquisition, and maternal syphilis infection has been associated with increased risk of mother-to-child transmission of HIV (149). In general, syphilis screening and treatment for pregnant women is one of the most cost-effective antenatal interventions, even in settings with a low prevalence of syphilis (148, 150).

Chapter 6 offers additional guidance on selecting effective approaches to HTS.

WHO recommendations

- **In generalized epidemics settings** routine HIV testing should be offered to all clients (adults, adolescents and children) in all clinical settings.
- **In low-level or concentrated epidemic settings**, HIV testing should be offered to clients (adults, adolescents and children) in clinical settings who present with symptoms or medical conditions that could indicate HIV infection, including presumed and confirmed TB cases.
- **Regardless of epidemic type** routine HIV testing should be considered for malnutrition clinics, STI, viral hepatitis and TB services, and ANC settings and for health services for key populations.

Source: WHO, 2004 (146); WHO, 2007 (126); WHO 2013 (130).

4.3.2 Community-based HIV testing services

Community-based HTS include a number of approaches – door-to-door/home-based testing and mobile outreach campaigns and testing in workplaces, parks, bars, places of worship and educational establishments. It is an important approach for increasing early diagnosis, reaching first-time testers and people who seldom use clinical services, including men and adolescents in high prevalence settings and people from key populations in all settings (3, 13).

Community-based HTS are now widespread, with 93 of 124 countries reporting in 2014 that their national policies support community-based HTS.¹ However, some studies find that linkage to prevention, treatment and care services following community-based HTS is suboptimal (152). Linkage to prevention and treatment services is critical and should be emphasized in all community-based HTS.

Mobile/outreach HTS include outreach to community sites through mobile vans or tents, in community sites such as churches, mosques or other faith settings, in places of entertainment such as bars and clubs, at cruising sites and sauna or in schools or workplaces. Such services may be offered continuously, on a regular schedule or as a one-time or occasional promoted event. Also, outreach can be linked to public events, such as sports

¹ Global AIDS Response Progress Reporting (WHO, UNAIDS, UNICEF), 1 July 2015.

events, music performances, theatre, agricultural fairs and holiday festivals. Outreach services may be designed to serve key populations, such as “moonlight HTS”, in which services are offered in the evening. HTS outreach may also be designed to serve rural populations, including pregnant women in remote areas, who may have limited access to facility-based HTS. Men in high prevalence settings can be reached through testing in market places and at transport hubs. Mobile approaches complement facility-based approaches, which often do not reach key populations because of stigma or cannot serve those in remote areas that lack health facilities.

Home-based HTS follow two main models: (1) testing that is offered door-to-door and provided to all consenting individuals, couples or families in a geographic area and (2) testing that is offered to households with a person known to have HIV (index clients) or an active or suspected TB patient, with consent obtained from the index client before the home visit. Door-to-door testing during the daytime may reach only women who are not working and younger children. Services during the evening or on weekends may increase uptake among others, including men.

National HTS campaigns are nationwide efforts to increase access to and uptake of HTS. Campaigns have been implemented in many different ways, some focusing on testing in facilities, others using a community-based approach, and some combining the two. Widespread knowledge of where to get tested makes large-scale campaigns less useful at this point. Objectives of and outcomes from national campaigns have varied with regards to coverage of different population groups, linkage and cost-effectiveness. A national HTS campaign can affect the entire population, both those at risk and those not at risk for HIV infection, by normalizing HIV testing. National campaigns can increase the number of people tested (153), but they can be expensive, a substantial number of people with HIV remain undiagnosed despite such campaigns, and linkage to care and treatment from campaigns has been problematic (152). Campaigns should not be considered in low prevalence settings unless special efforts are made to reach key populations and to support effective referral and linkage.

HTS and multi-disease campaigns offer HIV testing in addition to other health services. Depending on the context, these often include providing insecticide-treated bed nets, water filters, or screening for STIs, hepatitis, cardiovascular risk factors such as diabetes or hypertension and even depression (154, 155). However, these campaigns, too, can be costly and need to be evaluated. Linkage and the long-term impact of the other interventions provided have not been adequately assessed.

Workplace HTS seeks to provide formally employed men and women with access to testing. These people may have limited access to outside clinical services and may lose wages if they must leave work to seek health care. Workplace testing has been implemented with high levels of uptake and linkage to HIV and TB services, particularly in high burden settings (156–158).¹ Confidentiality, coercion and weak linkages to services are concerns with this approach. In the Middle East and North Africa, over 60% of HIV testing is carried out in relation to the workplace and work visa procedures and is generally mandatory (159). This often results in adverse outcomes for those testing HIV-positive. Workplace testing should be confidential. It should not be promoted where it is likely to be abused.

¹ Examples of workplace programmes include the International Labour Organization's VCT @ Work Programme (http://ilo.org/aids/WCMS_215899/lang-en/index.htm) and the Anglo American HIV Testing Programme (<http://southafrica.angloamerican.com/media/press-releases/2012/03-12-2012.aspx>).

Case example: PharmAccess, Rwanda

In 2001, to offer better services to employees, Heineken Breweries partnered with PharmAccess International Foundation (<http://www.pharmaccess.org/>) to launch a workplace HIV programme, called “the Heineken Access to HAART Programme”, at its facilities in Gisenyi and Kigali, Rwanda. The programme offers all employees and their dependents, including children, medical care services that include HIV testing services (HTS) and access to ART. Once started on ART, the worker retains the right to care until the end of life, even if he or she is laid off from work at the company.

As of 31 May 2015, the programme has performed 2951 HIV tests for a total of 2808 eligible individuals. As a result, between 2001 and 2015, 139 HIV-positive individuals have been diagnosed. Of the individuals diagnosed with HIV, 13% (18/139) have died; 6% (8/139) were lost to follow-up; another 13% (18/139) were referred to other HIV programmes. Overall, the programme retained 68% (95/139) of individuals with HIV in the programme; 90% (86/95) are on ART and 84% of these (72/86) have an undetectable viral load. Heineken has adopted the 90–90–90 UN targets and is committed to not discriminating against individuals living with HIV.

Source: Annex 3.

HTS in educational establishments can address sexually active youth in the context of sexual health education and behaviour change interventions. In South Africa, for example, a national campaign provides HTS to students ages 12 and older (160). Other examples include providing HTS for children under age five in locations such as play centres (161–164).

School-based HTS is often controversial, however, and currently there are few programmes in schools and few studies of the approach. The rationale for offering testing in schools is that it can be challenging for a young person to seek HTS at a health facility during school hours and in a school uniform, whereas school-based testing brings services to the students. Students are very difficult to reach otherwise, as they do not use health services or community services that are used mainly by older adults. As part of a well-resourced intervention that also provides post-test counselling on risk reduction, HTS in educational establishments may be a valuable tool to turn the rising tide of infection rates among adolescent women and young men who have sex with men. More research is needed to better understand issues of confidentiality, linkages to care and adolescents’ experiences with and expectations of school-based testing.

Case example: Organization for Public Health Interventions and Development (OPHID), Zimbabwe

Early diagnosis of children living with HIV is necessary for timely access to HIV care and treatment services, which optimizes outcomes. In 2008 OPHID (<http://www.ophid.co.zw>) developed a play centre project, as an addition to ongoing PMTCT programmes, to provide care and education to vulnerable children in three rural districts of Zimbabwe. By 2011, 176 community volunteers staffed 16 play centres serving 697 children three to five years old. As part of the programme, 59% of children enrolled in the play centre had received HIV testing services. HIV testing was offered and performed with the consent of the caregiver or guardian. All children diagnosed HIV-positive were successfully linked to ART; the use of standardized registers prevented loss to follow-up. When caretakers of children in care did not pick up their children's medications, community mobilizers visited them to offer help and support.

Source: Annex 3.

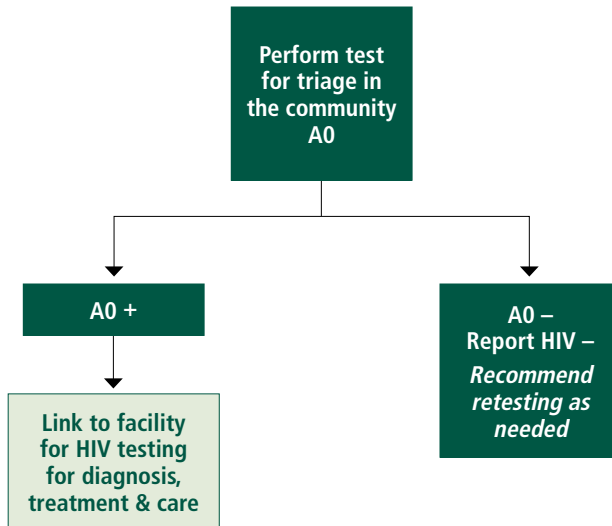
4.3.3 Test for triage: a strategy to support expanding community-based HTS

A simple approach to expanding community-based HTS is needed, particularly to reach higher risk populations who may not otherwise test for HIV and link to prevention, treatment and care.

Test for triage is an approach to support community-based HTS provided by lay providers. In this approach trained and supported lay providers conduct a single HIV RDT, referred to in Fig. 4.2 as A0. Note that A0 does not replace A1 in the national testing algorithm. If this single RDT is reactive (A0 +), the individual is promptly linked to a facility for further HIV testing, where the validated national testing algorithm is performed, beginning with A1 (see Chapter 7). If the reactive test result (A0 +) is confirmed and an individual is thus diagnosed HIV-positive, that person is then linked to clinical assessment and, if eligible, treatment. Individuals with a non-reactive test result (A0 –) are diagnosed HIV-negative, referred for and linked to appropriate HIV prevention services, and advised to retest if they have had recent or have on-going HIV risk (see section 3.4)(12).

Many community-based services, particularly those offered by NGOs and other community-based organizations, already use this "test for triage" approach. Although it may be ideal to provide a definitive diagnosis in a community setting, correctly conducting two or three RDTs for each individual with a reactive result on the initial test may be challenging. Particularly for lay providers, test for triage can reduce the complexity of testing procedures in outreach or home settings. Thus, test for triage may be particularly suited for countries without policies and infrastructure that enable lay providers or community-based organizations to perform HIV testing and issue test reports. Additionally, the "test for triage" approach can enhance access to other health services, using simple tools such as screening for cough of more than two weeks' duration and referral for TB diagnosis. Other health interventions and referrals could be included, such as blood pressure checks and referrals to reproductive health or harm-reduction services. The success of this approach

Fig. 4.2. The “test for triage” strategy



will require partnership between the trained lay providers who perform the test for triage and other health workers who conduct the additional testing required to make a diagnosis and to provide clinical assessment for ART initiation. Such a programme must have a system to support clients and minimize loss to care between initial testing in the community (the test for triage) and diagnosis in a facility.

Key advantages of the “test for triage” approach are that it:

- simplifies the scope of work for lay providers and task sharing arrangements;
- can reduce logistics, supply chain and training constraints, as a single RDT is used;
- improves access for those at highest risk and not currently testing for HIV;
- takes a first step toward introducing full community-based HTS, where a definitive diagnosis using the complete testing algorithm can be made;
- facilitates quick scale-up of HTS where HIV prevalence is high.

Potential challenges of the “test for triage” approach are that:

- in low prevalence settings, the rate of false reactive test results is higher than in high prevalence settings, which, without proper messaging, could lead to mistrust of services;
- it may be challenging to maintain an uninterrupted supply of test kits to community sites;
- lay providers may not correctly communicate the meaning of a reactive “test for triage” result, and clients may then mistake a reactive test result for an HIV-positive diagnosis;
- linkage to additional testing to confirm the HIV diagnosis may be poor;
- it may be difficult to track and monitor clients who have a reactive “test for triage” and, if confirmed HIV-positive, are then linked to HIV treatment and care.

Case example: Test for triage for community-based HTS

Although “test for triage” may be a new term, conducting one test in a community setting and then, for those with reactive results, conduct additional testing to confirm HIV status in a health facility or laboratory is routine practice in many countries.

- In Brazil collaboration between the Ministry of Health and NGOs reaches key populations (men who have sex with men, sex workers, people who inject drugs and transgender people) in venues convenient for these groups, including bars, clubs, saunas and city streets. One RDT using oral fluid is performed; all those with reactive results are referred for additional testing to confirm their HIV status. Between May 2014 and March 2015, 28 400 tests were performed in such community outreach settings.
- In Chengdu, China, a programme focused on men who have sex with men has provided testing for triage in outreach settings since 2007. By the end of 2014 it had served 18 683 men. Government-supported health facilities conducted additional testing to confirm HIV-positive status. In 2007 about 40% of men with a reactive test result went for testing to learn their HIV status. With careful follow-up, that rate improved to over 90% in 2014.

Rates of confirmed HIV-positive results after test for triage

Not all people who have a reactive test result will link to additional testing and learn their HIV status, and not all who do link are confirmed and diagnosed HIV-positive. Programmes in various countries report somewhat different rates of reactive HIV test results and HIV-positive diagnosis resulting from additional testing following test for triage.

- An NGO in Portugal has provided testing since 2011 in a community centre for men who have sex with men. Tests were reactive for 296 men (4% of those tested). Of these men, 82% underwent additional testing for confirmation of their HIV status at the National Health Service. Data on the first clinical assessment are available for 127 of those who underwent additional testing; almost all that were confirmed HIV-positive (98%) enrolled in ART immediately.
- A community-based programme in Greece reports providing free HIV testing to 13 438 people, of whom 303 had reactive RDT results. All of these people were linked to additional testing and received a diagnosis. Those diagnosed HIV-positive were referred for care and treatment.
- In Bolivia a mobile unit working during evening hours has offered HIV testing for two years to key populations including men who have sex with men, transgender people, sex workers and the homeless. Of 3371 people tested for HIV, 117 had reactive results and were referred for additional testing to confirm their HIV status. However, 51 (44%) did not undergo additional testing and did not confirm their HIV status.

Sources: Annex 3.

WHO recommendations

- **In generalized epidemics settings** a strategic combination of community-based HIV testing and counselling is recommended, with linkage to prevention, treatment and care services, in addition to provider-initiated testing and counselling (*strong recommendation, low quality of evidence*).
- **In all epidemic settings** community-based HIV testing and counselling is recommended for key populations, with linkage to prevention, treatment and care services, in addition to provider-initiated testing and counselling (*strong recommendation, low quality of evidence*).

Source: WHO, 2013 (13); WHO, 2014 (10).

4.3.4 HIV self-testing

By giving people the opportunity to test discreetly and conveniently, HIVST may increase uptake of HIV testing among people not reached by other HIV testing services.

HIV self-testing (HIVST) is a process in which an individual who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by him or herself, often in private. **HIVST does not provide a definitive diagnosis.** Instead, it is an initial test (A0), as in the “test for triage” approach (see previous section). HIVST does not

replace the need for the first HIV test in the validated national testing algorithm. A reactive self-test result always requires additional testing according to the validated national diagnostic testing algorithm. Therefore, a person distributing test kits for HIVST should advise anyone who has a nonreactive self-test result to retest if he or she has had recent or has ongoing HIV risk. Also, if a person has any uncertainty about correctly conducting the test procedure and reading the test result, he or she should go for facility-based or community-based HTS instead (14).

By giving people the opportunity to test discreetly and conveniently, HIVST may increase uptake of HIV testing among people not reached by other HIV testing services (69), many of whom are first-time testers (165). As early as 2005 it was reported that health workers in sub-Saharan Africa were self-testing for HIV, particularly where they were concerned about confidentiality (166–169). In general, studies report that HIVST is highly acceptable among a variety of populations (170–172).

User values and preferences for accessing HIVST vary. Potential users from key population groups, particularly men who have sex with men in high-income settings, want access to test kits for HIVST over the counter or through the Internet (172) (see Annex 4). In particular, in the USA men who have sex with men reported that they preferred online vouchers as a way to access test kits for HIVST, which could be mailed to them (173). Among the general population in Malawi, people preferred to obtain test kits for HIVST from a neighbourhood volunteer (165, 174). In Kenya people preferred access to test kits for HIVST in health facilities (175).

Studies generally report that HIV self-test results can be accurate (170, 176) when appropriately regulated test kits are used and instructions for use are followed (170). HIV self-test results have been less accurate, however, when inappropriate test kits were used or instructions were unclear (177–179) or when the individuals self-testing have been recently infected with HIV or are living with HIV and already on ART (180). Mathematical modelling suggests that HIVST is cost-effective in identifying people with HIV in certain settings (181). With support, linkage to care can be good. For example, a cluster randomized trial of a community-based HIVST programme in Blantyre, Malawi, reported that, among adults who self-tested for HIV, the offer of optional home initiation of care resulted in a three-fold increase in the proportion of adults initiating ART compared with standard facility-based HIV care (69). To date there are no reports of serious adverse events or harm as a result of HIVST (165, 182). Still, where HIVST is used, this should be monitored, as experience is limited. Some countries, for example, Kenya, have already introduced questions on use of HIVST into national population-based surveys (183). A question regarding HIVST has been added to the Demographic and Health Surveys.

There are several ways in which test kits for HIVST could be delivered or distributed (see Fig. 4.3). Programmes may offer more or less support along a continuum, combining different levels of access and distribution sites.

Fig. 4.3. Continuum of HIVST approaches

Open access	Semi-restricted	Clinically restricted
SUPERVISED HIV SELF-TESTING		
	Distribution by community health workers with supervision	Supervised by a health worker in a facility
UNSUPERVISED HIV SELF-TESTING		
Over-the-counter, such as pharmacies, markets or groceries	Distribution by community-based organization, NGO or health department through community health workers without supervision	Clinics distribute without supervision
Kiosks or vending machines		
Internet sales		

Globally, policy development regarding HIVST is at varying stages. The United States Food and Drug Administration approved over-the-counter sale and use of an HIV-1/2 RDT using oral fluid in the USA in 2012 (184–186), and approved two HIV-1/2 RDTs based on finger-stick whole blood in 2015 (185, 186). Several countries (Australia, China, France, Kenya and the United Kingdom) have introduced national HIV testing policies that include HIV self-testing. Several other countries (Malawi, Zambia and Zimbabwe) are considering such policies. WHO has not issued recommendations on HIVST due to gaps in the current evidence but has developed a technical update describing the potential benefits and challenges of this approach (14). WHO is working with collaborators to generate the evidence needed to issue recommendations and additional guidance on this topic.

Case example: Guangzhou Tongzhi, Guangdong Province, China

Guangzhou Tongzhi (GZTZ)¹, with support from the Guangzhou Centre for Disease Control and Prevention, operates HIV testing services in five cities in southern China. GZTZ also runs the website GZTZ.org. It is China's first and best-known website for men who have sex with men and transgender people and the most widely used to provide health education and to conduct surveys among men who have sex with men and transgender populations. Beginning in 2014, GZTZ has provided online support for HIV self-testing by sending HIV self-test kits to clients and providing online support and information, pre-test information and post-test counselling, referrals for further HIV testing and diagnosis and information on where and how to seek additional support services.

In five months GZTZ sold 199 HIV self-test kits to users in Guangdong province for US\$ 23, including a US\$ 16 deposit refundable following submission of feedback after self-testing. Of the 199 purchasers, 174 submitted feedback online. Of these, four reported having a reactive test result and six individuals, who might not have done so otherwise, sought follow-up care at a GZTZ facility.

Sources: Annex 3.

1 GZTZ is adopting a new name, Lingnan Partners Community Support Center.

PRIORITY POPULATIONS

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KEY POINTS

This chapter considers HIV testing services for specific populations.

- **Infants.** Diagnosing HIV-exposed infants as early as possible through virological testing is critical to starting ART as soon as possible and thus preventing early morbidity and mortality.
- **Adolescents.** In high prevalence settings programmes should prioritize testing children and adolescents to diagnose and link to treatment and care those who were not reached through infant testing programmes.
- **Pregnant women.** In many countries offering HIV testing in ANC as part of PMTCT has led to substantial decreases in new paediatric HIV infections and increased ART coverage for women. Testing of partners and retesting of pregnant women in late pregnancy or during breastfeeding has been less widely implemented and should be prioritized in high incidence settings.
- **Men.** In most high prevalence countries, men have less access to HIV testing, and they are tested, diagnosed and started on ART later than women. Programmes need to find ways to increase men's access to HTS and overcome this gender gap.
- **Key populations.** In almost all countries and settings, HTS for key populations are inadequate, and their access to HIV prevention, treatment and care services remains limited. Countries should prioritize, fund and support acceptable services for key populations and recognize and address health system, social and legal barriers that currently prevent equitable access to HTS by key populations.

5 PRIORITY POPULATIONS

5.1 Infants and children

Mortality is very high in the first year of life among infants infected with HIV who go untreated. In this period early HIV testing, prompt return of results and rapid initiation of treatment are vital. HIV testing for infants should be implemented with the aim of identifying as many HIV-infected infants as possible as early as possible. See the glossary and Chapter 7 (particularly section 7.1.4) for details on terminology and testing strategies, including for infants.

For infants and children under 18 months, HIV infection can be diagnosed only by virological testing; maternal HIV antibodies remain in the infant's bloodstream until 18 months of age, making test results from serological assays ambiguous. Virological testing using nucleic acid testing (NAT) technologies can be conducted using dried blood spot (DBS) specimens, which are collected at local sites and sent to centralized laboratories for testing. While early testing is increasing, there are ongoing challenges of access, such as prompt return of test results and initiation of early ART among infants who test HIV-positive.

Several approaches can increase infant testing. Scaling up early infant diagnosis (EID) through task sharing with lay providers is one promising approach (78). Development, now underway, of virological assays for use at the point of care is expected to greatly improve access to early diagnosis and treatment. HIV testing at the time of birth may improve linkage to treatment and reduce loss to follow-up; however, it is likely to be an effective public health strategy only in settings with a high proportion of deliveries taking place in facilities. In any case, this approach would miss infant infections that take place during breastfeeding.

For children 18 months of age and older (who were not breastfed or who have stopped breastfeeding at least six weeks earlier), standard HIV serological assays such as RDTs and EIAs can reliably determine HIV status. A negative serological test result for an infant does not completely exclude HIV exposure and infection, particularly when certain RDTs are used to test infants between four and 18 months of age, due to imperfect sensitivity during seroconversion for infection acquired postpartum through breastfeeding. During this time virological tests may be used to determine HIV infection.

WHO recommendations¹

- It is recommended that **all HIV-exposed infants** have HIV virological testing at four to six weeks of age or at the earliest opportunity thereafter (*strong recommendation, high quality of evidence*).
- It is recommended that well **HIV-exposed infants** undergo HIV serological testing at around nine months of age (or at the time of the last immunization visit). Infants who have reactive serological assays at nine months should have a virological test to identify HIV-infected infants who need ART (*strong recommendation, low quality of evidence*).
- It is recommended that **children 18 months of age or older with suspected HIV infection** or HIV exposure have HIV serological testing performed according to the validated national testing algorithm used in adults (*strong recommendation, high quality of evidence*).
- It is recommended that **infants with signs or symptoms** suggestive of HIV infection undergo HIV serological testing and, if reactive, should be referred for virological testing (*strong recommendation, low quality of evidence*).
- **Children of school age** (6–12 years old) should be told their HIV-positive status and their parent's or caregiver's status; younger children should be told their status incrementally to accommodate their cognitive skills and emotional maturity, in preparation for full disclosure (*strong recommendation, low quality of evidence*).

Source: WHO, 2010 (187); WHO, 2010 (2); WHO, 2013 (13).

5.1.1 Approaches for delivering HIV testing to infants and children

All infants whose mothers have received PMTCT services should be followed up and routinely offered EID, and those diagnosed with HIV should be started on ART. However, some infants are lost to follow-up, and some mothers with HIV may not have received PMTCT services. Prioritizing additional paediatric case finding is important. This can be achieved through the routine offer of PITC in health facilities, particularly in high prevalence settings, and also through testing the family members of index clients (see box next page).

Integration of HIV testing into child health programmes

In high prevalence settings HIV testing should be routinely available to all mothers and children through a variety of services – child health services, immunization clinics, under-5 clinics, malnutrition services, well-child services and services for hospitalized and all sick children, TB clinics, and services for orphans and vulnerable children. In Malawi, for instance, integrating testing for HIV-exposed infants at six weeks of age into routine postnatal, under-5 and immunization clinics has improved case finding and has proved acceptable and feasible (78).

¹ WHO is reviewing the evidence and plans to update recommendations on infant diagnosis in late 2015.

In low prevalence settings immunization and under-5 clinics should test HIV-exposed infants who were not tested for HIV as part of PMTCT services. HIV testing for children and other family members of anyone known to be living with HIV should be prioritized. Such testing requires systems to track mother–infant pairs – for example, by using child health and immunization records to identify HIV-exposed infants.

Testing the family members of index clients

In all settings all **children with an HIV-positive parent should be tested for HIV as a priority**. Gaps in HTS and in documenting the HIV status of children of HIV-positive parents constitute significant missed opportunities. These gaps can be closed by following up the families of cases identified in facility-based HTS and through improved case finding via ART clinics. In particular, HTS for orphans and vulnerable children in high prevalence settings, where one or both parents may have died from HIV, requires additional support (188).

Potential HIV testing approaches to improve HIV case finding among infants, children and adolescents

In all settings

- Offer early infant diagnosis for HIV-exposed infants.
- Offer testing to all children and adolescents presenting with indicator conditions or signs and symptoms that suggest HIV, including oral candidiasis, failure to thrive, chronic cough and skin conditions.
- Offer HIV testing to all children and adolescents attending TB clinics and malnutrition services.

In high prevalence settings also

- Offer HIV testing or retesting to mothers or infants in immunization clinics or under-5 clinics. If mothers are not available for testing or refuse testing, infant testing is an acceptable alternative. A negative serological test result for an infant does not completely exclude HIV exposure and infection, particularly when certain RDTs are used to test infants between four and 18 months of age, due to imperfect sensitivity during seroconversion for infection acquired postpartum through breastfeeding. During this time virological tests may be used to determine HIV infection.
- Offer testing to all children with parents or siblings receiving any HIV service (for example, PMTCT, ART) through home-based or facility-based HTS.
- Offer HIV testing to all children and adolescents attending paediatric inpatient health services.
- Offer HIV testing to all children and adolescents receiving orphan and vulnerable children (OVC) services.

5.2 Adolescents

In high prevalence settings there are two groups of adolescents (that is, people 10–19 years of age) who need access to HIV testing: (1) perinatally HIV-infected adolescents who were not diagnosed in infancy and (2) adolescents who acquire HIV through early sex or injecting drug use, particularly adolescents from key populations.

Perinatally infected adolescents urgently need to be diagnosed so that they can be linked to HIV care and start ART. In sub-Saharan Africa there are a significant number of undiagnosed adolescents who were infected perinatally or through transmission in health-care settings (for example, through transfusions or unsafe injections).

Particularly in high prevalence settings, adolescence may be a period of high risk of HIV infection. In such settings adolescent girls are generally at higher risk than males in their age group. In all regions adolescents from key population groups are at especially high risk for HIV infection (10).

Engaging adolescents in HIV testing, as well as in prevention, treatment and care, requires specific strategies. All HTS for adolescents, either in health services or in the community, should be based on adolescent-friendly principles to ensure that psychological as well as physical needs are addressed (54). Adolescents may need support particularly with issues of disclosure – when and to whom to disclose HIV-positive status (54) (see Chapter 3).

Involving adolescents in the design, delivery and evaluation of HIV services is necessary to ensure that these programmes address their needs (54). Services need to be convenient and available, through flexible opening hours and/or walk-in or same-day appointments. Separate hours and special events exclusively for adolescents may help overcome adolescents' concerns that older relatives, neighbours or family friends will see them attending HIV services, including HTS.

HTS for adolescents should be based on a human rights and public health approach (54). As with all HTS, HTS for adolescents should offer protection from stigma and discrimination related to HIV-positive status and risk behaviours and should also be confidential, respectful, inclusive and non-judgemental. It should provide strong referrals and linkages to HIV prevention, treatment, care and support services. When appropriate, and only with the adolescent's specific permission, health-care personnel should engage the support of adults – family members, teachers, community members – as adolescents learn to manage living with HIV.

Services for adolescents need to be tailored to different epidemiological contexts and different adolescent populations. For example, in high burden, priority countries, adolescent boys can be linked to VMMC and adolescent girls to reproductive health services. Special considerations are needed for adolescents from key populations and vulnerable adolescents, including those living on the streets, orphans, adolescents in child-headed households, girls engaged in sex with older men or in multiple or concurrent sexual partnerships and adolescents who are sexually exploited (10). In some settings specific campaigns and use of social media or web-based approaches, involving adolescents in identifying communication channels and appropriate language, may help reach adolescents, including those from key populations. In low-level or concentrated

epidemic settings, however, adolescent-focused HTS for the general population usually are not prioritized due to the very low prevalence of HIV in adolescents.

Policies related to age of consent to testing can pose barriers to adolescents' access to HTS and other health services, particularly for adolescents from key populations (55). Age of consent for HTS varies from country to country. WHO recommends that children and adolescents themselves be involved in the testing decision as much as possible (55). **Governments should revisit age of consent policies in light of adolescents' rights to make choices about their own health and well-being** (with consideration for different levels of maturity and understanding). Authorities also should consider the role of surrogate decision-makers in HTS for adolescents without parents or for those unwilling to involve parents. In any case providers of HTS should be aware of laws and policies governing the age of consent and develop appropriate procedures based on this legal framework to ensure that children and adolescents have access to HTS.

WHO recommendations

- **In all settings** HIV testing services, with linkages to prevention, treatment and care, are recommended for adolescents from key populations (*strong recommendation, very low quality of evidence*).
- **In generalized epidemic settings** HIV testing services, with linkage to prevention, treatment and care, are recommended for all adolescents (*strong recommendation, very low quality of evidence*).
- **In low-level and concentrated epidemic settings**, we suggest that HIV testing services, with linkage to prevention, treatment and care, be accessible to all adolescents (*conditional recommendation, very low quality of evidence*).
- **In all settings we suggest that adolescents** be counselled about the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine if, when, how and to whom to disclose (*conditional recommendation, very low quality of evidence*).

Source: WHO, 2013 (55).

WHO good practice recommendation

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

Source: WHO, 2013 (55).

5.3 Pregnant women

HTS as early as possible during pregnancy enables pregnant women with HIV to obtain and benefit most from prevention, treatment and care and to reduce the risk of HIV transmission to their infants. **WHO recommends offering HTS to pregnant women through a PITC approach** (126). Globally, this approach has been widely adopted and has proved acceptable to pregnant women. It is an essential component of all PMTCT programmes (21, 189).

Many countries prioritize PITC in ANC as a key component of their effort to eliminate mother-to-child transmission of HIV (eMTCT). HIV testing is also being effectively combined with screening for syphilis and hepatitis B, hepatitis B vaccination for infants and other testing.

PITC in ANC settings has considerable public health benefits. Still, measures must be taken to prevent unintentionally or intentionally coercive testing (21). These measures include regular mentoring and supervision of staff, retraining where necessary and monitoring of PITC procedures to ensure their acceptability to pregnant women.

HTS for pregnant women is an entry point into couples or partner HTS. **In high prevalence settings WHO recommends couples and partner HIV testing for all pregnant women and their partners** (16) (see section 5.4). Particularly for women from migrant or key populations, HIV testing may also be a point of entry to a broad range of pregnancy care services (190). **In low prevalence settings WHO recommends couples and partner HIV testing for pregnant women from key populations and for the partners of women diagnosed with HIV** (16).

The package of care for pregnant women with HIV should include systematic screening for TB symptoms and referral and treatment as necessary. The presence of undetected TB among HIV-positive pregnant women doubles the rate of vertical HIV transmission (191).

Pregnant women testing HIV-positive must be linked to ART for PMTCT and HIV services for their own health. **WHO recommends Option B+, which involves initiation of ART as soon as possible, regardless of CD4 count, and continuation of treatment for life for the mother's infection** (192).

Retesting in pregnancy

Although ART prevents vertical transmission of HIV most effectively when given early in pregnancy, it has some efficacy (especially when combined with infant ARV prophylaxis) even when started late in pregnancy, at the time of delivery or during the breastfeeding period. Therefore, in high prevalence settings HTS should be recommended to all women of unknown HIV status late in pregnancy, in labour or, if that is not feasible, as soon as possible after delivery. **In all settings pregnant woman who are diagnosed HIV-positive should be retested to verify their HIV status prior to enrolling in care and/or treatment.**

In settings of high HIV incidence, follow-up through the breastfeeding period is important to determine the HIV status of the infant and to identify possible seroconversion of the mother. Also, retesting of pregnant and postpartum women who have tested HIV-negative is important. For example, a recent study in communities in Malawi, Kenya

and South Africa found that an average of 4.1% of breastfeeding women had become infected during pregnancy or breastfeeding (193). In contrast, **in low prevalence settings, retesting all pregnant women in ANC or in the breastfeeding period is not warranted, as the incidence of HIV infection will be extremely low.**

WHO recommendations

In high prevalence settings

- **PITC** is recommended for women as a routine component of the package of care in all antenatal, childbirth, postpartum and paediatric care settings.
- **Retesting** is recommended in the third trimester, or during labour or shortly after delivery, because of the high risk of acquiring HIV infection during pregnancy.
- **In settings where breastfeeding is the norm**, lactating mothers who are HIV-negative should be retested periodically throughout the period of breastfeeding, as there is a risk of acquiring HIV at this time and a resulting high likelihood of transmission through breast milk. Early identification of such mothers enables immediate interventions to prevent transmission to the child.

In low prevalence settings

- PITC can be considered for all pregnant women.
- HIV testing is recommended for all pregnant women from key populations or who have partners with HIV or from a key population group.

Source: WHO, 2012 (16); WHO, 2013 (13).

5.4 Couples and partners

Testing the partners of people with HIV is an efficient and effective way of identifying additional people with HIV, who also can benefit from treatment.

Participating in couples and partner HTS has a number of benefits. These include adoption of prevention strategies by the couple (for example, condom use, immediate ART, PrEP), safer conception, improved uptake of and adherence to practices for PMTCT as well as to one's own ART (thus reducing transmission risk as well as morbidity and mortality) (16). Partner testing is an efficient and effective way of identifying additional people with HIV, who also can benefit from treatment. Couples and partner HTS help more people know their HIV status, particularly men, who in generalized epidemic settings are substantially less likely to test than women. Couples and partner HTS for the partners of women attending ANC, in particular, is a focus in the 21 priority eMTCT countries¹ (194).

¹ Angola, Botswana, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Ethiopia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, United Republic of Tanzania, Uganda, Zambia and Zimbabwe.

Couples and partner HTS can be conducted in various settings, including ANC and community-based TB services, through home-based HTS, during premarital health visits and in couples' HIVST (169, 195–197). People attending ART services can be encouraged to bring their partners to be tested. Couple and partner testing should also be a priority for people in key populations, including men who have sex with men. Programmes that particularly serve key populations should provide and encourage partner testing.

As with all HTS approaches, couples and partner HTS should be voluntary. Informed consent should be obtained from all individuals receiving HIV testing. Providers must be aware of the potential for intimate partner violence and should support people's decisions not to test with their partners.

Currently, the prevalence of serodiscordance is estimated at one-half to two-thirds of cohabitating couples or partners where one partner has HIV (198–201). Nonetheless, many people do not know their partner's HIV status. With the exception of a few countries such as Rwanda and Zambia, in most countries the proportion of couples and partners who test together is less than 20% (24). According to the WHO HIV Country Intelligence database, as of April 2014 only half (28/58) of WHO HIV focus countries made it a policy to offer ART to the HIV-positive partner in a serodiscordant couple, irrespective of CD4 count, as WHO recommends. A recent desk review of national policies in 21 priority countries found that most did not have specific targets or indicators to monitor their progress in couples and partner HTS or to measure its uptake or coverage.¹ In an associated online survey of field experts from these priority countries, less than half judged that most people would find couples and partner HTS acceptable, accessible or both.

In low-level and concentrated epidemics, couples and partner HTS should be made available for partners of people with HIV and people from key populations.

WHO recommendations

- Couples and partners should be offered HIV testing services with support for mutual disclosure (*strong recommendation, low quality of evidence*).
- Couples and partners in antenatal care settings should be offered HIV testing services with support for mutual disclosure (*strong recommendation, low quality of evidence*).
- In all epidemic settings couples and partner HIV testing services with support for mutual disclosure should be offered to **all individuals whose partners have HIV**.
- Partner testing for **HIV-negative people** should be offered only in high prevalence settings (*conditional recommendation, low quality of evidence*).

Source: WHO, 2012 (16).

1 Unpublished review, Darbes L et al., 2015.

5.5 Men

In high prevalence settings fewer men than women report ever testing for HIV (24). As a consequence men are more likely to start ART at later stages of HIV infection and thus experience higher morbidity and mortality after starting ART (202, 203). There are a number of barriers to men's access to available HTS, including fear, stigma, the perception that health facilities are "female" spaces and both the direct costs and the opportunity costs of accessing services.

Greater emphasis on reaching men with HIV testing services is required in many high prevalence settings.

Despite these barriers current approaches to delivering HTS can reach men. Successful approaches include PITC in ANC and other clinical settings and home-based and mobile HTS (106, 204–206). As reported in section 4.3.2, on-site

HTS at the workplace reaches men in formal employment (156–158). The availability of HTS services in VMMC clinics in the 14 VMMC priority countries has provided adolescent and adult males seeking circumcision with an opportunity to learn their HIV status. Those testing HIV-positive can be referred to prevention, treatment and care services. Although they will not have the benefit of HIV prevention from circumcision, they should not be denied circumcision if they want it nonetheless. Although these approaches do reach men, in many settings rates of men's use of available HTS remain low. This low uptake compromises the impact of proven HIV prevention interventions, including VMMC and treatment for prevention. Greater emphasis on reaching men is required in many high prevalence settings.

To increase men's uptake of ANC-based PITC, a letter to male partners of ANC clients can invite them to test at ANC (207, 208) or in a community-based setting (209). A trial in Malawi found that provider-initiated notification increased uptake of HTS among partners of those attending STI services, including male partners (204). A high proportion of these partners tested HIV-positive for the first time. This notification was undertaken with consent from the HIV-positive client who had attended STI services (87).

Men are less likely than women to use clinical health services. Therefore, community-based approaches to reaching men, including home-based and mobile HTS, may be helpful. Mobile HTS can reach many men (206). In high prevalence settings in sub-Saharan Africa, men were as likely as women to accept an offer of home-based HIV-testing, provided services were delivered when men were at home, for example, in the evenings or during weekends (210). Home-based HTS has also been shown to reach couples and partners (106).

Maximizing men's uptake of HTS requires a strategic combination of facility- and community-based approaches. As discussed in section 4.3, selecting a strategic combination of service delivery approaches for men requires considering men's preferences, local context, epidemiology and available resources. In addition, services should be delivered at times and in locations suitable to men who are not being reached by existing services. Support for HIVST may also increase men's uptake of HIV testing (165, 174).

5.6 Key populations

In many high prevalence settings, the HIV response has focused largely on the general population and not adequately appreciated the role of key populations in the dynamics of the epidemic.

Key populations – men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and transgender people – continue to have limited access to health services, including HTS. In many settings these groups experience particularly high HIV incidence (10). In many high prevalence settings, however, the HIV response has focused largely on the general

population and not adequately appreciated the role of key populations in the dynamics of the epidemic. Even in countries with concentrated epidemics, efforts to reach people from each key population group often remain inadequate.

For key populations, especially those whose behaviour is criminalized, HTS services are sometimes misused in punitive or coercive ways (26). As a result, people from key populations avoid health services that they need. Stigma, discrimination, lack of confidentiality, coercion and fear of repercussions, as well as lack of appropriate health services, resources and supplies, prevent people from testing and, if HIV-positive, linking to care (211, 212). Like all HTS, programmes for key populations need to emphasize WHO's "5 Cs" – particularly consent, confidentiality and connection to comprehensive prevention, treatment and care (see section 1.7).

Community-based HTS is a critical approach for reaching people from key populations who are unlikely to go to a facility for HIV testing, particularly those who are asymptomatic. To improve access to and uptake of HIV testing, community-based HTS should be made available in locations and settings acceptable and convenient to people from key populations (213). Also, HIVST may prove to be another important way to increase access to HIV testing among key populations and, hence, to prevention, treatment and care services (14, 172). PITC among key populations is recommended, so long as it is not compulsory or coercive and it is linked to treatment and care (10). In addition to HTS, testing and screening for STIs, TB and viral hepatitis should be offered to key populations (10). Intensified TB case finding, along with HTS, also is particularly beneficial among key populations. These populations are highly vulnerable to TB, particularly in countries with high burdens of both TB and HIV (214).

In prisons and other closed settings, offering voluntary HIV testing as part of a package of care is a critical approach (see box next page). HIV testing using RDTs could improve uptake of HTS and increase the speed with which clients receive test results and learn their HIV status. Particular attention should go to providing accurate information, obtaining informed consent and maintaining confidentiality. Also, there are often major challenges to continuity of care within closed settings and between prisons and the community (215); these need to be addressed.

Retesting at least annually is recommended for all people from key populations. More frequent voluntary retesting may be beneficial, depending on risk behaviours (see sections 3.3 and 7.4).

WHO recommendations

- HIV testing services should be routinely offered to all key populations in the community, closed settings such as prisons, and clinical settings.
- Community-based HIV testing services for key populations, with linkage to prevention, treatment and care services, is recommended in addition to provider-initiated testing and counselling (*strong recommendation, low quality of evidence*).
- Couples and partners should be offered HIV testing services with support for mutual disclosure. This applies also to couples and partners from key populations.

Special considerations for people in prisons and other closed settings

- It is important to guard against negative consequences of testing in prisons – for example, segregation of prisoners – and to respect confidentiality. It is also important that people who test positive have access and are linked to HIV care and treatment services.
- HTS should be voluntary in all settings.
- The use of “on-site” HIV testing using RDTs can increase the likelihood that prisoners will receive their results.
- Testing in conjunction with other risk-reduction services can increase the benefits of HIV testing. Such services include provision of condoms with lubricants; STI, TB and viral hepatitis screening; and provision of sterile injection equipment and opioid substitution therapy.

Source: WHO, 2014 (10).

5.7 Other vulnerable populations

Depending on context, there are a number of other groups, in addition to key populations, that are particularly vulnerable to HIV infection. These include, in high prevalence settings, migrant workers, refugees and other displaced populations, and other country-specific populations that may be at increased risk, for example, fisherfolk and long-distance truck drivers, all of whom can be hard to reach and, typically, seldom use HIV services.

Migrant workers, refugees and people who are displaced have difficulty accessing health-care services because of stigma, language differences, lack of required documentation, lack of transportation and long distances to services, discrimination and legal barriers. Some jurisdictions mandate HIV testing of immigrants; this requirement is not justified and can exacerbate the challenges of providing voluntary health services, including voluntary HIV testing. Displacement of key populations and others through human trafficking may further complicate the provision of HTS (216).

To address the needs of vulnerable populations, countries need to evaluate their epidemic and its social context and identify the 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 and deploy them so as to increase access to testing and uptake. Special policies and practices to protect vulnerable populations from mandatory or compulsory testing may be needed.



STRATEGIC PLANNING FOR HIV TESTING SERVICES

6

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KEY POINTS

- **Selection and programming of HIV testing services** must focus on identifying and testing people who are unaware of their HIV infection and diagnosing people earlier in the course of their infection. HIV-negative people at high ongoing risk should be linked to effective prevention services.
- **Linkage to and enrolment in care and treatment following an HIV-positive test is essential to reduce HIV transmission and prevent HIV-related morbidity and mortality.**
- A **mix of facility-based and community-based HTS approaches** is needed to reach different populations.
- All available epidemiologic data from surveillance, surveys, programmes and research should be used to determine **geographic, population, facility and service prioritization.**
- The selection of HTS approaches should be **based on patterns of HIV prevalence, current HTS coverage, uptake, available resources and programme cost-effectiveness** at national and subnational levels, as well as the **preferences of the populations** to be served.
- Programmes should monitor HTS data and in general favour the HIV testing approaches that result in the **highest proportion of HIV-positive diagnoses in priority populations.**

6 STRATEGIC PLANNING FOR HIV TESTING SERVICES

6.1 Introduction

When HIV testing was first introduced and few people had been diagnosed, HIV testing in almost any setting in a generalized epidemic would find a high proportion of HIV-positive cases. Thus, there seemed little need to focus services on specific populations with unmet need for HIV testing. Countries with low HIV prevalence and concentrated epidemics also often had much unmet need for HIV testing, and few data were available to inform decisions about where to strategically introduce testing services. HTS in many countries was often initially implemented in clinical settings, either widely through ANC services or as diagnostic testing offered to people with symptoms suggestive of HIV infection.

Over the past 30 years, much has changed in terms of HTS coverage and the availability of treatment and in terms of the data and tools available for informed and strategic decision-making. Between 2010 and 2014 nearly 600 million adults (ages 15+) reportedly received HIV testing services in 122 low- and middle-income countries reporting in this period.¹ The percentage of people with HIV who know their HIV status has increased substantially. UNAIDS estimates that 45% of people with HIV have been diagnosed (20). The focus of HTS must now shift to **identifying and testing the remaining 55% who are unaware of their HIV infection** and to **diagnosing people earlier in their infection**. Benefits of identifying people earlier in their infection and linking them to ART sooner include reduced morbidity, mortality and HIV transmission.

In addition, **the role of retesting** is much clearer today. Offering retesting to HIV-negative people at low ongoing risk is now considered unnecessary and a waste of human and financial resources. However, this practice persists in some settings. Retesting to rule out acute infection is recommended for people with recent known exposures, and routine retesting is recommended for people at high ongoing risk of exposure (12). See sections 5.3 and 7.4 for more information on retesting.

Considering variations in prevalence when planning HTS

Currently, guidance on how to implement HTS is often based on the broad definitions of a generalized or a concentrated epidemic in a country, based on the prevalence threshold of >1% in the “general population” to define a generalized epidemic and of <1% in the “general population” and >5% in at least one defined subpopulation to define a concentrated epidemic. These categories are not always helpful in determining how and where to best deliver HTS among populations and locations. In most countries HIV prevalence varies greatly across the country and even within districts, metropolitan areas and service delivery settings and among sociodemographic groups. Also, within the generalized epidemics there are

1 Global AIDS Response Progress Reporting (WHO, UNAIDS, UNICEF), 6 July 2015.

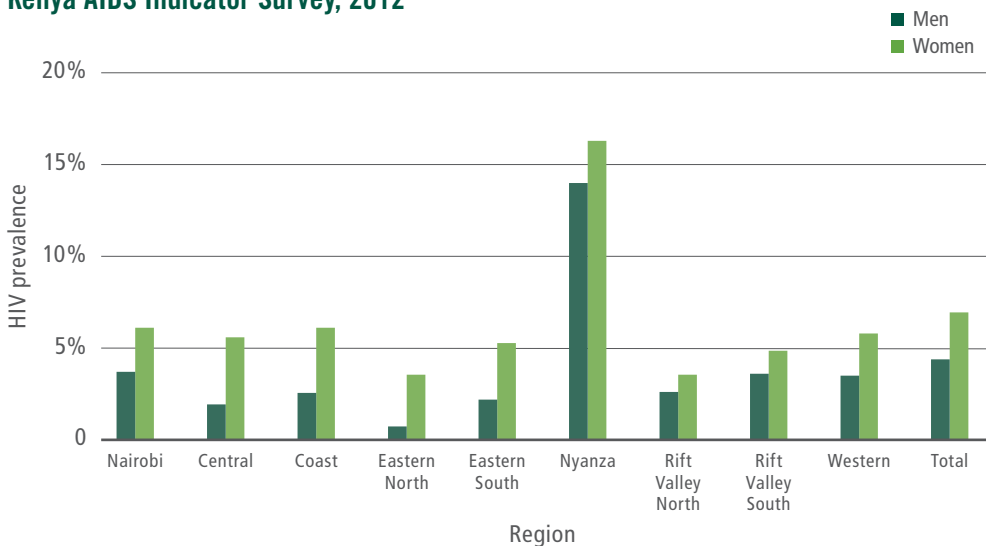
The broad categories of “generalized” and “concentrated” epidemic are not always helpful in determining how best to distribute HTS among populations and locations. A closer look is needed.

subpopulations that have significantly higher HIV prevalence and incidence than the general population. The choice among HTS approaches will be different in a generalized epidemic with prevalence between 1% and 2% from that in an epidemic with prevalence greater than 10%.

South Africa is an example. HIV prevalence differs greatly among the provinces, with rates from above 13% in KwaZulu-Natal, Mpumalanga, Free State and the North West to 5% in Western Cape (217). Within provinces there are substantial differences among metropolitan areas. Residents of informal urban areas have much higher HIV prevalence than those living in formal urban areas. Among people ages 15–49 years, HIV incidence is 1.7 times higher in females than in males. The incidence among young females, ages 15–24, is over four times higher than in males in this age group (2.5% versus 0.6%) (217).

Kenya serves as another example. According to the 2014 Kenya HIV estimates, 65% of HIV infections are found in nine of Kenya’s 47 counties (218). According to the 2012 AIDS Indicator Survey, by region, infection rates in Nyanza in western Kenya were more than twice as high as in any other region and differed by sex (Fig 6.1) (183). Key populations, which tend to be concentrated in certain areas, amount to less than 2% of the population but account for one-third of new infections (183).

Fig. 6.1. HIV prevalence among women and men ages 15–64 years by region, Kenya AIDS Indicator Survey, 2012

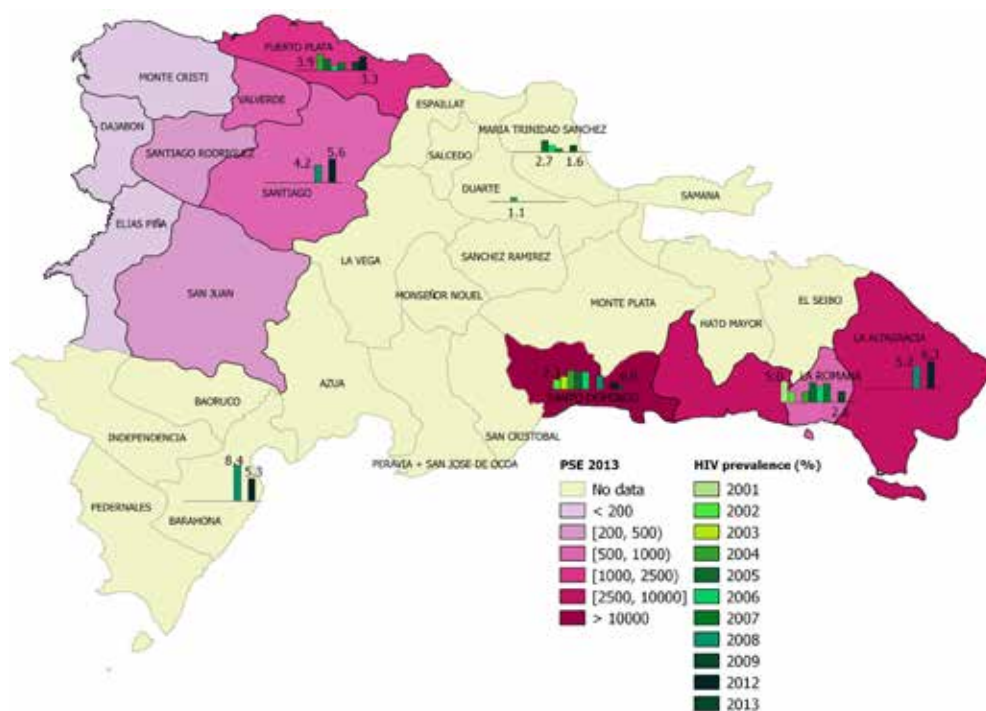


Source: NASCOP, 2014 (183).

The tools for identifying these variations and using data for programming are improving. Rather than relying on one estimate for HIV prevalence for a country as in the past, now programmes often have subnational data from surveillance, surveys and programmes,

with HIV prevalence data disaggregated by sex, age, risk behaviour and location. Geographic mapping can be used to plot estimated HIV prevalence, estimated HIV incidence, population density, estimated population size and location of key populations, as well as the coverage and the proportion of HIV-positive cases identified by existing testing services (see Fig. 6.2 for an example from the Dominican Republic). Population-based surveys now include questions about HIV testing access, thus providing information about populations and locations with high unmet need for testing (183). Cost estimates and budgets can now be informed by actual expenditure analysis, not only at the national level but even at the site or facility level. Countries should use all available data, as well as tools for analysis and mapping, to help inform strategic decision-making. This includes decisions about how to maintain wide coverage of essential testing services, such as for pregnant women and clients with TB and STIs, as well as how to increase focused coverage for populations at high risk and for groups previously underserved.

Fig. 6.2. Population size estimates (PSE) and HIV prevalence estimates among female sex workers, by province, in the Dominican Republic



Source: UNAIDS, WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria, unpublished report from Dominican Republic data, 2015.

National programmes can benefit from collaborations with research partners, universities, local and international implementing partners, national statistics offices, procurement specialists and civil society organizations to gather a full array of high-

quality data and apply a wide range of tools to understand and analyse these data to inform HTS strategies (see Chapter 10).

A crucial feature of any HTS approach is its **linkage to care and treatment services** for those identified as HIV-positive and to prevention services for those at ongoing risk of HIV acquisition. The effectiveness of linkage varies considerably among different HTS approaches. In general, linkage to care may be easier when HTS is facility-based; still, not all facilities have successful client follow-up and enrolment. Although linkage may often be lower in community-based settings than in facilities, high levels of linkage can be achieved with support and intensive interventions. Thus, proactive linkage approaches are a critical component of comprehensive HTS. See section 3.6, which outlines various approaches that may be useful for facilitating linkage to care and treatment following HIV testing.

The success of linkage should be measured by enrolment in care and not by intermediary process indicators such as the number of referral cards issued. Without strategies that ensure linkage and enrolment in care, the effect of HTS in reducing HIV transmission, morbidity and mortality cannot be fully realized (see section 3.6). Tracking systems should be established to monitor and evaluate the success of linkage to care approaches and identify areas for improvement. The costs associated with different linkage strategies for a given HTS approach also should be considered when assessing which are most successful and should be scaled up (see Annex 5).

Financial and human resources should be allocated to ensure that HTS is available to, and used by, the largest possible number of people with HIV who remain undiagnosed.

This chapter discusses key strategic decisions regarding the implementation of HTS along with tools to help inform decisions. As a first step to reaching the first 90 of the global fast track 90–90–90 targets (that is, 90% of people with HIV diagnosed) (20), an **in-depth analysis of country-specific HIV epidemiology, HTS**

coverage and cost is needed. This analysis can help to identify the optimal combination of approaches to HIV testing. Financial and human resources should be allocated to ensure that HTS is available to, and used by, the largest possible number of people with HIV who remain undiagnosed.

6.1.1 Routinely offered HTS versus focused HTS

When HTS is routinely offered, every child, adolescent and adult in a given geographical location or setting is offered HIV testing. This routine testing approach can be delivered in health facilities or in the community.

Routinely offered HTS in a facility setting is often referred to as PITC (126).

- PITC is highly acceptable to both clients and providers. It is feasible, assists in the diagnosis of people with HIV who do not report or perceive their own HIV risk (219) and increases HIV case finding among infants, children and adolescents as well as adults.
- Routine offer of HTS normalizes HIV testing and reduces barriers such as stigma and discrimination, which prevent some people from seeking services.
- In high prevalence settings PITC will result in a high proportion of HIV-positive cases identified and be cost-effective, as it enables the testing of many people at a low unit

cost (220). However, it tends to reach people at later stages of disease; people diagnosed through PITC have significantly lower CD4 counts than those diagnosed through community-based approaches (3, 221).

- HIV prevalence may vary among client populations in different clinical services or facilities. Therefore, the proportion of people diagnosed HIV-positive should be closely monitored to assess whether the HIV testing strategy needs to be more focused. For example, programmes could prioritize PITC in certain clinical services or in facilities with higher positivity rates.
- PITC alone will not be adequate to reach global coverage targets, as it is available only to those who attend health facilities. Many people with HIV, especially men, key populations and adolescents during the first few years of their infection, may be asymptomatic and, therefore, unlikely to seek facility-based services unless it is for other reasons. However, the percentage of people who test HIV-positive in facility-based HTS will likely decrease as HTS and ART coverage increase. For example, in ANC settings with low HIV incidence and where a high proportion of women with HIV have been previously diagnosed, few new cases will be identified.

Routinely offered community-based HTS. In some settings approaches such as home-based (door-to-door) HTS are used to try to reach all people in a geographical area.

- This approach can be acceptable and feasible (3).
- If well-designed, it can help to reach groups such as men and adolescents who may utilize health services infrequently. Additional strategies to reach couples (222) and men, such as weekend and evening home visits, may further increase access (204).
- The proportion of HIV-positive cases identified is usually lower, but the mean CD4 count at the time of diagnosis is generally higher, than with facility-based testing (3).
- This approach is unlikely to be cost-effective outside high prevalence settings.
- Linkage to HIV care and treatment services may be difficult unless efforts to support linkage are prioritized (223).

Given current levels of undiagnosed HIV infection in many settings, and the need to use limited funds most efficiently to reach the largest number of undiagnosed people, focused community approaches to HIV testing are needed, in addition to testing in health facilities to reach men, adolescents and key populations. Home-based testing will likely be needed to achieve 90% coverage levels in high prevalence settings. However, it will likely be unfeasible in most settings, and some form and level of targeting based on epidemiology and coverage should be prioritized to increase cost-effectiveness.

Focused HTS aims to reach specific groups of people who remain undiagnosed or to prioritize implementation in specific geographical areas or clinical settings according to epidemiology and current levels of HIV testing coverage. A strategy for focused HTS should take into account the cost and the cost-effectiveness of delivering different HTS approaches in relation to locale, HTS venue, populations reached and successful linkage to care. For example, even if unit costs of outreach testing for key populations are higher

than for testing in ANC, the cost per new HIV diagnosis may be significantly lower, as the proportion of HIV-positive cases identified is likely to be much higher.

HTS can be focused on a particular:

- **population**, such as a key population or partners and family members of people with HIV (index testing). Other groups may include men and adolescents in high prevalence settings and other underserved vulnerable groups (for example, migrant workers), according to context.
- **geography**, such as districts or counties with high HIV prevalence or, more specifically, transport hubs, border crossings or specific urban locales where key populations work or reside. Other examples include workplace, home-based or school-based programmes in specific settings with low current HIV testing coverage and high HIV prevalence or incidence.
- **health facility type**, such as facilities with a high proportion of HIV-positive cases identified.
- **service**, such as offering routine testing in clinical services where HIV prevalence is likely to be high, including TB, STI, and hepatitis services and harm-reduction clinics.
- **indicator conditions**, such as offering HTS to people with specific clinical conditions associated with HIV, such as cervical or anal cancer, herpes zoster or unexplained fever (129).

The challenges to focused approaches to HIV testing are that, by definition, they reach only certain subpopulations, and they may be more expensive due to the effort required to reach these groups. In a clinical setting they may be more complicated to deliver and may miss people who do not disclose risk behaviours to health-care providers. They may also increase stigma and discrimination if they are seen to target certain people. For services focused for key populations, countries need strong political commitment to providing acceptable services and avoiding harm to these clients, whose behaviour may be criminalized. Qualitative research and community consultation will be critical to designing and developing approaches to deliver HTS that can reach specific populations.

Focused HTS may miss the emergence or re-emergence of high infection rates in clinics or geographical areas where testing is not or no longer offered. In countries with limited resources, decisions to focus testing on specific sites, certain clinical services and people with indicator conditions will have to be made with careful ongoing monitoring to assess the effectiveness of the approaches. Variations and trends in incidence throughout the country will also need monitoring to ascertain whether focused approaches continue to be focused on the right places and populations.

Countries need political commitment not only for providing services to key populations but also to develop systems for collecting and analysing epidemiological and programmatic data concerning them while protecting client confidentiality.

6.2 Strategic decision-making for selecting approaches to HIV testing

As discussed in Chapter 4, HTS can be delivered in different ways and to different people. HTS can be offered in a variety of settings in both health facilities and the community. To facilitate the diagnosis of as many people with HIV as early as possible, countries need to select a strategic mix of approaches to deliver HTS based on epidemiologic data, available resources and the populations that most need HTS. Also, the selection of HTS approaches should support timely and complete linkage to prevention, treatment, care and support services for those testing HIV-positive.

To develop and implement the optimal combination of approaches to HIV testing, countries will need to review national and subnational epidemiology, current HIV testing coverage (for example, the number and proportion of those ever-tested and tested in the last 12 months by population, age and sex), the costs and cost-effectiveness of different approaches and the human and financial resources available. A mix of HTS approaches that maximize linkage will likely be most cost-effective and have the greatest impact if they are focused on geographic locations and populations with high HIV prevalence (224).

6.2.1 Steps for selecting strategic approaches to HIV testing services in a national programme

1. Set HTS coverage targets.

- **Review the most recent data**, including data on HIV prevalence and incidence (if available), the estimated number of people with HIV in the population and the proportion undiagnosed, to understand where disproportionate undiagnosed HIV burden exists geographically and by age, sex and population group.
- **Coordinate with treatment scale-up.** The primary reason for diagnosing people with HIV is so that they can benefit from ART. Therefore, it is important to directly link HIV testing and ART targets. Plans for major scale-up of ART services will not succeed without testing. Likewise, major scale-up of HTS, which will create demand for ART, will have limited benefit without concurrently expanding ART capacity. Identify sites, geographic areas and populations where targets for enrolment in HIV care or initiation on ART are not aligned with HIV testing coverage, the proportion of HIV-positive cases identified and linked to HIV care and treatment services, and adjust plans accordingly.

2. Review effectiveness and identify gaps.

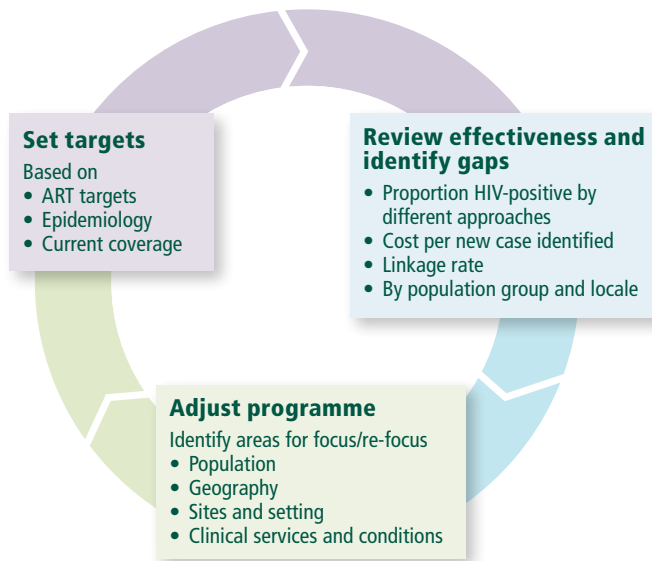
- **Analyse HTS data** to see what is being achieved by specific approaches in various sites and locations in terms of numbers and proportions of people tested, new cases diagnosed and enrolment in care.
- **Assess commodity and human resource needs, availability and policies** to identify barriers to and opportunities for expanding or shifting the focus of programmes (for example, availability of rapid test kits or trained lay providers and policies regarding task sharing).
- **Assess available HTS resources**, including investments by the government and all funding partners.

- **Revisit and revise national targets and approaches to HIV testing** so as to better reach those who are undiagnosed and to capitalize on comparative advantages and cost-effectiveness, taking into account linkage and enrolment in treatment.

3. Adjust programmes.

- **Develop and follow a national consensus plan** for expanding and refocusing HTS in line with the treatment plan.
- **Evaluate implemented programmes** through routine programme monitoring, programme-specific evaluations, surveillance and population-based surveys.

Fig. 6.3. Steps to assess and improve selection and implementation of HIV testing service approaches



6.2.2 Identifying populations and locations with high HIV prevalence and incidence

Identifying populations at high risk for HIV infection and where they live and spend time is important for developing successful HTS. Although it is impossible to know the exact number of people with HIV infection or the number of new infections in a given area, these numbers can be estimated through the analysis of data from multiple sources. Typically, these sources include surveillance data from HIV testing among pregnant women, national household surveys, smaller studies among groups of interest such as key populations and modelling exercises such as those conducted through UNAIDS' Spectrum AIDS Impact Model (AIM) (225). Although any one data source has limitations, when used together they can paint an informative picture of HIV epidemic trends.

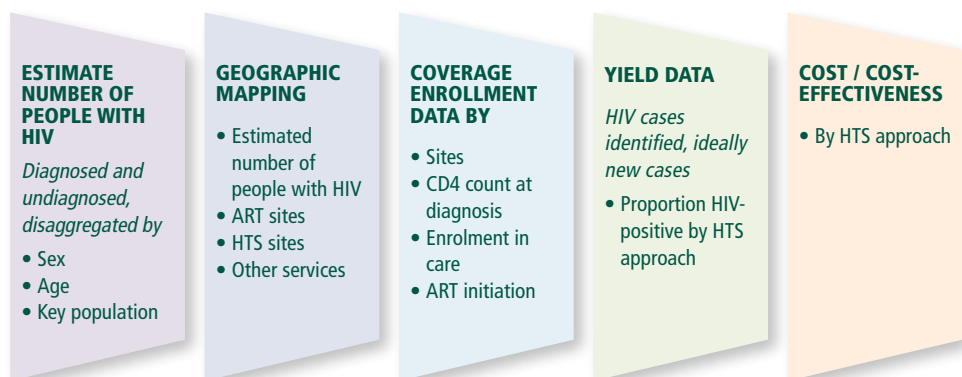
Data from national population-based surveys provide the most accurate information if response rates are high and there are no large biases or exclusions of specific population groups. National surveys often can determine prevalence only at the regional or provincial level. Thus, programmatic data at the district level or even the facility level should be explored for more detailed information on HIV testing coverage and the proportion of HIV-positive cases identified.

National household surveys or ANC surveillance will seldom identify key populations and marginalized vulnerable groups. Specific approaches are needed to identify key populations and people that standard surveys do not reach or identify. There may be significant differences in knowledge of HIV status between the general population and marginalized populations, such as undocumented migrants, where the great majority of those with HIV may not be aware of their status.

Data relevant to HIV testing include:

- **national and sub-national HIV prevalence** (and/or incidence) and population size estimates among:
 - men and women, stratified by age group to identify which ages are at highest risk
 - pregnant women attending antenatal clinics
 - key populations and other priority populations;
- **number and proportion of people who are aware of their HIV status.** Depending on the data available, this may be the proportion of individuals who have ever been tested for HIV or of people who were tested in the last 12 months and received their results. These data should be disaggregated by sex, age, geographic region, service delivery setting and population type;
- proportion of people tested HIV-positive who have been **enrolled in HIV care** and treatment services;
- **CD4 count at diagnosis**, stratified by gender and age to identify the proportion and distribution of late presenters in the population;

Fig. 6.4. Critical HIV testing services data to inform strategic planning



- **HTS uptake**, by HTS approach (from studies among key populations, for example);
- **proportion of those tested who are HIV-positive**, by population, HTS approach or facility;
- **cost and cost-effectiveness** of various HTS approaches (see section 6.2.4).

6.2.3 Understanding HIV testing service delivery and gaps

Following epidemiologic analysis, an assessment of current HTS coverage and mapping of HTS can determine how well services are covering populations in need. This exercise could include the following:

- **Mapping of current services**, including availability, uptake (by sex, age and population), coverage rate, funding source and location for all current HTS, including:
 - clinical settings providing PITC in ANC, TB, STI, harm reduction, outpatient and inpatient services
 - HTS for key populations
 - standalone testing sites (VCT)
 - specific services, such as VMMC in priority countries
 - community-based and mobile HTS
 - HIV testing at educational institutions
 - workplace HTS
 - private health-care providers (who offer HTS);
- **Identification of gaps in current HTS coverage in relation to HIV burden**, by geographic location and population, focusing on areas of highest prevalence or incidence that are not being reached by available services;
- **Assessment of barriers to HTS**, including social, cultural and geographical factors, psychosocial, behavioural factors, stigma and discrimination, gender and legal factors (including age of consent requirements) and structural and health system factors that may impede access;
- **Assessment of the linkage** between HTS and other programmes, in particular, enrolment in HIV treatment and care programmes following an HIV-positive diagnosis;
- **Review of policies on who can perform tests**, including whether lay providers can collect specimens, perform RDTs and issue test status reports; whether point-of-care testing is permitted; and what education, training and certification are required for those conducting tests;
- **Assessment of site performance**, including the quality of test performance.

Case example: Strategic planning for HIV testing services: data use workshops in the Republic of South Africa

In 2012 the National Department of Health (NDH) in the Republic of South Africa, with support from the US Centers for Disease Control and Prevention and the University of California at San Francisco, held a series of workshops to build capacity for the use of programme and surveillance data in strategic planning for HIV testing programmes. These workshops included sessions on compiling data from multiple sources to generate tables, charts and maps and on analyses of programme gaps and needs. This work led to action plans for improving programme alignment to populations and geographic areas with disproportionate HIV burden.

Decision-makers were interested in understanding where best to scale up community HTS and where facility HTS coverage needed strengthening. Participants concluded that, while the number of people tested in the community had increased from 2011 to 2012, community testing strategies still contributed a small proportion of the overall numbers. They also found that testing coverage in provinces and districts was not well-matched with HIV prevalence. These findings helped to guide efforts to increase HTS coverage in the higher burden districts, including expansion of community-based testing in those areas.

Sources: CDC and NDH, unpublished, 2015.

6.2.4 Assessing costs and cost-effectiveness

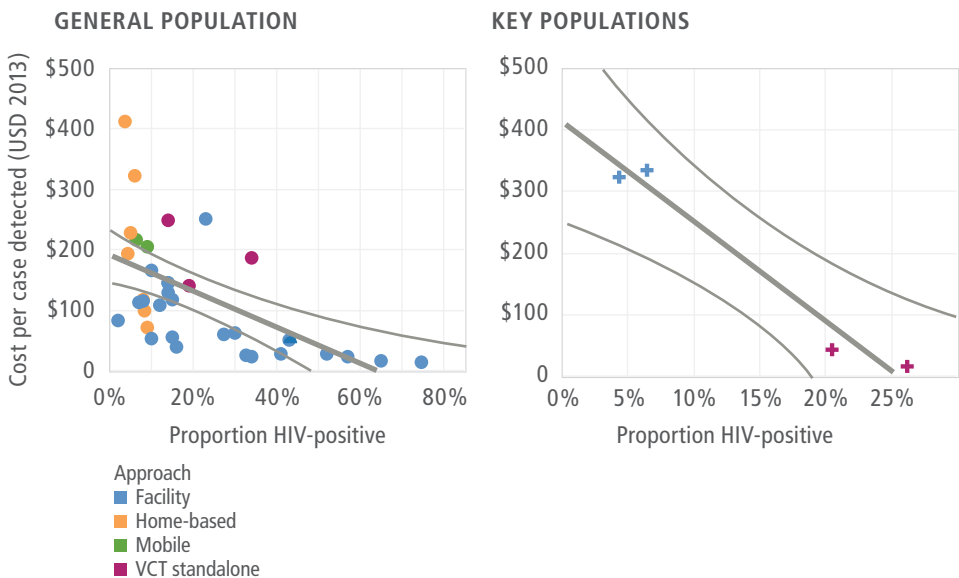
Cost-effectiveness analyses compare the costs and health impacts of different intervention options to identify interventions that provide good value for money. Such analyses are useful for optimizing the allocation of public health resources (226). Although important for decision-making, cost-effectiveness is only one consideration for countries designing a national HIV testing strategy. Acceptability, social and contextual factors and public health impact should be taken into consideration.

Comparing the costs associated with a given HTS approach can be challenging. Costs for similar services often differ significantly between countries and by HTS approach within a country. For example, a recent literature review from Botswana found that reported HTS costs for different approaches ranged from US\$ 5 to US\$ 75 per person tested (227). Differences in programme costs may be due to general cost differences between countries and to differences in what specific services are provided (for example, referral to a clinic for those testing HIV-positive versus enhanced linkage support), cadre of staff employed (for example, nurses versus community health workers), the ease of reaching different populations, the capacity of the health system and the level of HIV testing coverage. Also, the policies regarding who can perform HIV tests, as well as the specific testing strategy and algorithm employed, may affect costs. Direct cost comparisons of different HTS approaches are easier to interpret when they are from the same country and use the same costing inputs.

However, costs for similar HTS programmes can differ even within a country. For example, in Uganda the cost per case detected in home-based testing programmes ranged from US\$ 71 (228) to US\$ 322 (220). The cost per case detected in the latter programme was higher because it used a household index approach to testing, it tested a large number of children and adolescents, and it identified fewer HIV-positive cases. It is important not only to assess the cost per person tested but also the cost per HIV-positive case identified – and, ideally, per new case identified (Fig. 6.5). For example, the cost per person tested in a community-based programme may be higher than the cost per person tested among the general population in a facility-based setting. However, the cost per case identified may be lower in the community-based programme, or similar to those of other approaches, because of the high prevalence among key populations and their poor access to other testing venues.

Fig. 6.5 summarizes the literature on HTS studies examining cost. As the figure illustrates, facility-based approaches in low-income countries generally have the lowest cost per case identified, regardless of the proportion found to be HIV-positive. Home-based programmes, nearly all of which were in low-income countries, generally find a low proportion of HIV-positive cases and have a wide range of costs per case identified. (See Annex 5 for details.)

Fig. 6.5. Cost per case detected and proportion HIV-positive among the general population and key populations in low- to upper middle-income income countries



Source: Annex 5.

A common approach to estimating costs involves identifying and estimating costs incurred in the following broad categories:

- personnel (for example, staff salaries and allowances);
- recurrent costs (for example, HIV test kits and commodities, printed materials, office supplies);
- capital expenses, often amortized over their useful life and discounted annually at 3% (for example, office space, vehicles, equipment);
- Other economic costs, such as clients' time, donated goods and use of existing equipment may also be included, depending on the goals of the analysis.

These costs can be added to compute the total expected cost of an intervention per year. Considering the extent of costs averted also is important; for example, successful PMTCT prevents paediatric infection and thus avoids subsequent treatment costs that would have been required for the lifetime of an infected infant.

It is also important to recognize and estimate the costs averted and health impacts associated with earlier HIV diagnosis. Since 2002 average CD4 counts at ART initiation have remained at around 200 cells/ μ L (39). This indicates that people continue to be diagnosed late and to start treatment, on average, about eight years after being infected (229, 230). To maximize the therapeutic and preventive benefits of ART, early diagnosis and effective linkage to HIV care and treatment are critical. Therefore, approaches to HIV testing that achieve earlier diagnosis but cost more than other options may be more cost-effective than approaches that cost less but diagnose people later in the course of their infections. Many countries also combine HIV testing with testing and treatment for syphilis in ANC settings. Countries should assess the costs and the benefits of this, particularly countries that are prioritizing dual elimination of HIV and syphilis.

Health outcomes that can be used in cost-effectiveness analysis of HTS include:

- numbers of people tested
- numbers of HIV cases identified
- numbers of early diagnoses (CD4 >350 cells/ μ L)
- numbers of infections averted (when linked to prevention, PMTCT and ART)
- numbers of disability-adjusted life years or number of quality-adjusted life years gained (dependent not only on being diagnosed but also on CD4 count at diagnosis and whether linked to ART).

One challenge with cost-effectiveness analysis is that cost-effectiveness estimates will be overly optimistic if they omit important costs such as transportation or rent. Also, the health benefits associated with HTS are not derived from the HIV test itself, but rather from the treatment and prevention interventions that occur subsequently, which should ideally be taken into consideration in the analysis. Thus, the effectiveness of linkage from HTS to treatment is crucial to cost-effectiveness. Another challenge is that cost-effectiveness analyses may not be widely generalizable across settings. Furthermore, the cost of a programme, and hence its relative cost-effectiveness, depends greatly on the details of the programme itself. For example, a programme designed to reach sex workers by running late-night "moonlight" mobile camps at various locations can have

significantly different costs than a similar approach provided in the daytime or only in a fixed location, such as a brothel. Still, both HTS approaches may be necessary to reach this key population. Finally, different approaches may be cost-effective for different populations.

Therefore, assessing which HTS approaches make the most efficient use of resources requires a detailed understanding of the approaches themselves, including how and to whom they are delivered. The final selection of HTS approaches should be informed not only by cost-effectiveness but also by HIV prevalence, unmet need (the estimated number of people with HIV who remain undiagnosed), priority populations for the country and the anticipated proportion testing HIV-positive.

Case example: Cost-effectiveness analysis for assessing different HTS strategies for PMTCT

Four illustrative country scenarios were developed based on data from Namibia, Kenya, Haiti and Viet Nam, with national HIV prevalence among females ages 15–49 years of 17%, 7%, 3% and 0.1%, respectively. Subnational HIV prevalence estimates were used to divide each country into high, medium and low burden areas (see Annex 6 for specifics of country scenarios and methodological details). Different levels of coverage for pregnant women, including coverage of ANC, HTS and ARV services, were then assigned to each sub-area for the following four strategies:

- highly focused HTS (very high coverage¹ for high burden areas and low coverage² for medium and low burden areas)
- focused HTS (very high coverage¹ for high and medium burden areas, low coverage² for low burden areas)
- current coverage (current coverage levels from national surveys)
- universal HTS (very high coverage for all pregnant women).

Standardized unit costs were applied for all scenarios except health services costs, which varied by country and were obtained from the WHO CHOICE database (2010).³ Costs included HIV testing (HIV test kits and counselling services), PMTCT costs (HIV testing, maternal and infant ARVs and health services) and total costs (PMTCT costs and paediatric treatment costs for 20 years).

Health outcomes, costs and cost-effectiveness from this analysis can be examined in different ways. The narrowest approach is to assess the number of HIV-positive cases identified under the different scenarios, the cost of HIV testing, and thus the cost per HIV case detected. In this case study the average HIV testing cost per HIV-positive mother identified across approaches in Namibia were US\$ 17.00–18.40,

1 Very high coverage was defined as ANC coverage of 95%, HIV testing among ANC attendees of 95% and ARV coverage among mothers who tested HIV positive of 95%.

2 Low coverage was defined as the current country level of ANC coverage, 20% HIV testing among ANC attendees and 95% ARV coverage among mothers who tested HIV-positive.

3 http://www.who.int/choice/cost-effectiveness/inputs/health_service/en/

in Kenya US\$ 15.07–23.80, in Haiti US\$ 29.80–35.60, and in Viet Nam US\$ 400–570. Considering this narrow definition of health benefits and costs associated with these programmes, of the four scenarios highly focused HTS was the most efficient way to detect new cases within a given country. However, highly focused HTS also results in the fewest number of HIV-positive mothers being identified, as less focused approaches provide coverage to more women.

The main limitation to considering only HIV testing costs and HIV-positive cases detected is that this approach does not account for paediatric infections averted and downstream health effects of infections, nor for the costs for providing PMTCT or for treating infected infants whose mothers did not receive PMTCT. These are important health outcomes and costs that decision-makers should consider.

Based on a broader analysis that considers PMTCT costs (including HIV testing) and infections averted by the different programmes, the current-coverage HTS approach was the least efficient in each country scenario, indicating that resources are not currently being distributed as efficiently as they could be (Appendix table 6.2A). When considering infections averted and PMTCT costs, in all four country scenarios highly focused HTS was again the most efficient strategy, followed by focused HTS and then universal HTS, which averts the greatest number of infections. Although the differences in efficiency between approaches were modest, implementing a universal HTS approach averts twice the number of new infections that highly focused HTS averts, while also costing approximately twice as much. This budgetary reality may have bearing on decision-making for HTS implementation in the context of limited resources.

Finally, the above analyses are still somewhat incomplete in that they ignore the downstream costs required to provide ART to infected newborns. When the cost of 20 years' worth of future treatment for paediatric infections was considered in addition to HIV testing and PMTCT costs, universal HTS for all pregnant women saved the most in terms of total costs in the three generalized epidemic country scenarios (that is, Haiti, Kenya and Namibia). This means that universal HTS both saves money and improves health outcomes compared with focused approaches. In Viet Nam, which has a concentrated HIV epidemic, all approaches were cost-saving compared with no PMTCT programme. The focused approaches saved slightly more than the universal approach. However, the number of HIV-positive mothers identified and paediatric infections averted was twice as high in the universal approach as in highly focused approaches.

Therefore, if a decision-maker is concerned about all current and future costs and health outcomes associated with a PMTCT programme, the most efficient approach for the generalized epidemic scenarios would be universal HTS for all pregnant women. This approach identifies the most HIV-positive mothers, minimizes the number of infections among infants and actually saves money compared with other approaches. In the Viet Nam-based scenario of a concentrated epidemic, the highly focused, focused or universal approach could be considered cost-effective, and all three have lower costs than no intervention.

Another consideration in addition to cost-effectiveness is a country's current coverage of both ANC and PMTCT services. In a situation where there is poor

ANC and/or PMTCT coverage, and programmes are planning their scale-up, a phased approach in which high prevalence areas are targeted first, followed by areas of lower prevalence, would likely be the most rational use of resources. However, in reality, achieving the highly focused testing and retention goals defined in this case study is likely to be difficult, and costs for reaching the final 5–10% of pregnant women are likely to be higher than for reaching women who access programmes on their own.

Ultimately, programme managers need to make difficult decisions based on available resources for HTS. Conducting cost-effectiveness analyses such as in this case study will provide information on the most efficient approach to reach the maximum number of people who need testing, treatment and care with given resources. Other non-economic reasons, such as the programmatic logistics of either initiating or withdrawing HTS, should be thought through when evaluating whether incremental gains in efficiency are worthwhile.

6.3 Developing a strategic, efficient and cost-effective HIV testing services plan

Routine HIV testing in clinical settings and focused HIV testing approaches in and outside of facilities for particular populations remain a priority for high prevalence settings. Evidence suggests (see case example above and Annex 6) that routine HIV testing for pregnant women can be beneficial and cost-effective, even in low prevalence settings if the costs due to averted HIV infections among infants and improvement of mothers' lives are considered. However in many settings with low HIV prevalence and limited resources, implementing all of these approaches will be challenging and focused testing based on the positivity rate, and the resultant cost per HIV case detected can guide prioritization; if HTS coverage is low, countries could consider geographic prioritization.

Table 6.1 suggests the combinations of HIV testing approaches that countries could consider based on epidemiological context.

As HTS are scaled up, more people will become aware of their HIV status and be treated, and HIV prevalence and incidence will decrease. As a result, the proportion of people who test HIV-positive will begin to drop. Some clinical settings, such as TB, STI, harm reduction and key population clinics, likely will continue to find a higher proportion of HIV-positive people than general outpatient settings. In generalized epidemic settings, offering routine HIV testing to children in specialized facilities, such as malnutrition and under-5 clinics, may also yield higher rates of HIV-positive case detection. Routine monitoring data should guide ongoing adaptation of programme strategies to keep pace with shifts in context and disease burden over time.

In some settings programmes should implement location-specific prioritization cautiously and review this prioritization regularly, as HIV prevalence may not always be a good indicator of trends in HIV incidence. If HTS is not provided in some facility- or community-based settings and data are not collected regularly through surveillance or

surveys, changes in the underlying epidemiology of different groups may be missed in these underserved areas.

Ensuring that HIV testing programmes are reaching their intended populations and identifying previously undiagnosed HIV-positive people will require continued monitoring and evaluation. For long-term success, the impact of different HTS approaches on uptake, the proportion that test HIV-positive, cost and changes in the prevalence of HIV in different population groups must be evaluated and measured regularly, and programmes must be adjusted appropriately.

Table 6.1. Summary of routinely offered and focused HIV testing approaches that can be considered for generalized and concentrated epidemic settings

Approaches to HIV testing	Generalized epidemic settings		Concentrated epidemic settings	
	Routinely offered	Focused	Routinely offered	Focused
Health facility-based approaches				
1. Primary care settings for adults, adolescents and paediatric clients (including integrated VCT)	✓			✓
2. Antenatal clinics	✓		✓	✓
3. TB clinics	✓		✓	
4. STI clinics	✓		✓	
5. Drug dependence and harm reduction services	✓		✓	
6. Indicator condition-based testing	✓		✓	
7. Risk-based screening		✓		✓
Partner/index testing (in all HTS)				
1. Index testing of family members		✓		✓
2. Partner testing (for all partners)		✓		
3. Partner testing (for all partners of people with HIV)		✓		✓
Community-based approaches				
1. HIV and multi-disease campaigns	✓	✓		
2. Home-based/door-to-door testing	✓	✓		
3. Mobile/outreach for key populations		✓		✓
4. Mobile/outreach for the general population (for example, men, young people)		✓		
5. Workplace testing		✓		
6. School/educational institution testing		✓		
7. Services for orphans and vulnerable children	✓	✓		
8. HIV self-testing*	✓	✓		✓
Geographic prioritization				
1. Regional (for high prevalence areas) – facility- and/or community-based		✓		✓
2. Facility (by proportion of cases diagnosed HIV-positive)		✓		✓

* As yet, WHO does not formally recommend HIVST, but pilot projects and programmes should be considered. See Annex 12 for details on HTS approaches and considerations by epidemic setting.

DIAGNOSTICS FOR HIV DIAGNOSIS

7

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KEY POINTS

- Rapid diagnostic tests (RDTs) are a critical tool for scaling up HIV testing services. They can be performed by trained lay providers, health-care workers and laboratory professionals in various settings, irrespective of the infrastructure, as they do not require specialized equipment or specimen collection by venepuncture.
- **Immunoassays** such as enzyme immunoassays (EIAs), chemiluminescence immunoassays (CLIAs) and electrochemiluminescence immunoassays (ECLs) are best suited to settings with high throughput of clients and where infrastructure (electricity, cold storage, climate-controlled rooms) and skilled staff are consistently available. These assays are typically used only with serum/plasma specimens, which require specimen collection by venepuncture.
- **The length of the window period** is determined primarily by the type of serological assay used and by an individual's immune response.
- **The first-line assay (A1)** for any testing algorithm should be the most sensitive assay available, with more specific assays used as second-line (A2) and third-line (A3), irrespective of the assay format.
- **Retesting to verify HIV diagnosis** is recommended:
 - for all individuals with newly established HIV-inconclusive results and
 - for all individuals who have tested HIV-positive, before they enrol in care and start ART.
- **Retesting** is also recommended for certain individuals with ongoing risk who test HIV-negative.
- **Retesting** is not recommended for individuals on ART. For individuals who have taken PEP, for infants exposed to PMTCT regimens via their mothers and for individuals taking PrEP, negative status should be interpreted with caution.

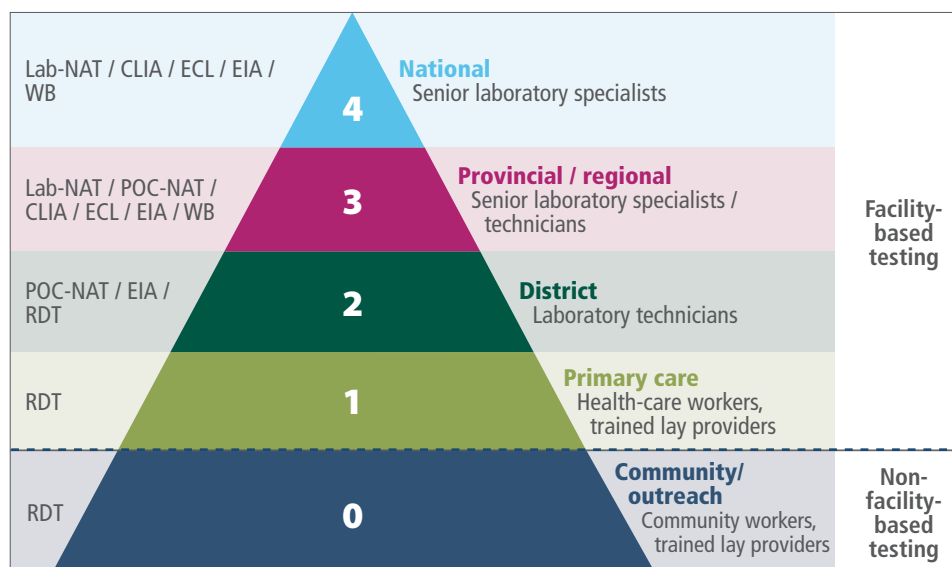
7 DIAGNOSTICS FOR HIV DIAGNOSIS

See glossary on page xii and Annexes 7 and 8 for a detailed description of HIV *in vitro* diagnostic (IVD) formats discussed in this chapter.

7.1 Overview of HIV diagnosis

HIV testing may take place at any level of the health-care system, and a diagnosis can be established for a majority of individuals on the same day. Many people will access HIV testing in their community (level 0) or in primary care facilities (level 1). Fig. 7.1 depicts how HIV testing services are typically organized and shows the different assay formats that could be available at each of the levels (for both facility-based and community-based testing). The degree of infrastructure required for the assay format, such as need for reliable electricity and climate-controlled testing rooms, as well as the staff skills and competencies required, will determine how complex an assay can be used in a given testing setting.

Fig. 7.1. A tiered testing service, with assay format menu and staff qualifications



Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; CLIA: chemiluminescence immunoassay; ECL: electrochemiluminescence immunoassay; EIA: enzyme immunoassay; WB: Western blot; RDT: rapid diagnostic test.

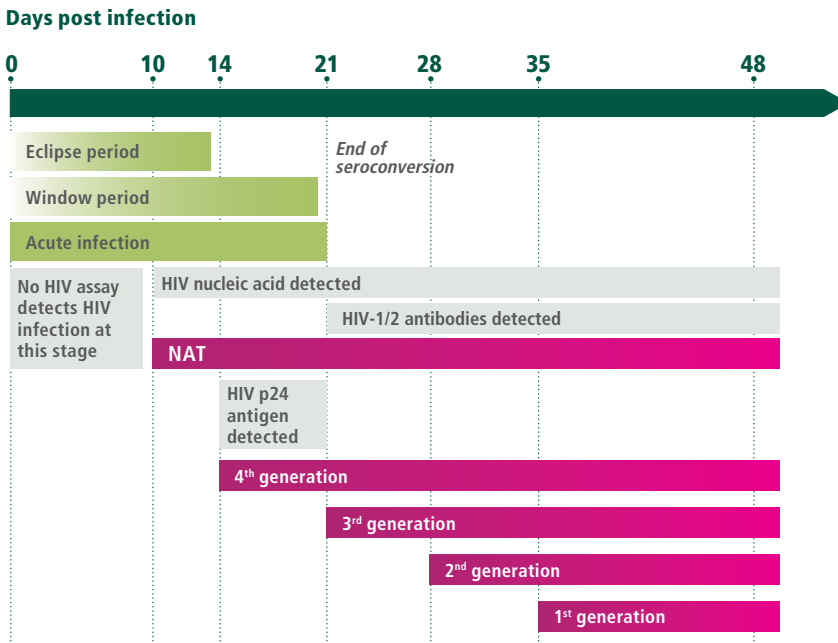
Source: WHO, 2012 (231).

7.1.1 Basic principles for performing HIV testing

All HIV testing should be performed in accordance with the assay manufacturer's instructions for use (the package insert). In addition, SOPs and job aids should be developed that help testing providers to minimize testing and reporting errors and, thus, to improve the quality of the testing results. See Chapter 8 for details on how to assure the quality of HIV testing.

For people over 24 months of age, HIV is typically diagnosed through the detection of HIV antibodies (a serological marker) and/or HIV p24 antigen rather than direct detection of the components of the virus itself (virological markers). Serological assays used for HIV diagnosis detect HIV-1/2 antibodies, with fourth generation assays incorporating detection of both HIV-1/2 antibodies and HIV p24 antigen. When initial HIV testing cannot discern a diagnosis, supplemental assays may be used, such as assays that detect HIV p24 antigen only or assays that can detect specific types of HIV-1/2 antibodies. These are discussed in detail in section 7.1.2. Fig. 7.2 illustrates the types of assays that can be used at different points in the natural history of HIV infection.

Fig. 7.2. Detecting HIV-infection with various formats and generations of in vitro diagnostics over the natural history of infection



Source: Rosenberg et al., 2015 (1).

Table 7.1. HIV serological assays

Generation	Antigen source and attributes of the assays
First generation	Crude viral lysate as antigen
	Relatively sensitive but lacked relative specificity. Detects immunoglobulin G antibodies (IgG) only.
Second generation	Recombinant proteins and synthetic peptides as antigen
	Improved specificity and sensitivity. Detects IgG only.
Third generation	Recombinant proteins as antigen, with same antigen conjugated to enzyme (antigen sandwich)
	Further refines sensitivity and specificity. Detects IgG and immunoglobulin M antibodies (IgM).
Fourth generation	Recombinant proteins as antigen and monoclonal antibodies
	Detects IgM and IgG antibodies and HIV p24 antigen; therefore, increased sensitivity in early infection, that is, during seroconversion.

For a period of about 10 days following HIV infection, known as the **eclipse period**, no currently available serological or virological assay can detect any marker of HIV infection. The end of the eclipse period is marked by the appearance of HIV RNA or DNA detectable by nucleic acid testing (NAT) and then HIV p24 antigen, detectable by immunoassay (IA). The period prior to detection of HIV-1/2 antibodies is often referred to as “acute infection” (1, 23). The number of HIV virus particles rises rapidly during acute infection and may be associated with higher infectivity and rate of transmission. As the level of HIV-1/2 antibodies increases, these antibodies form immune complexes with free HIV antigen circulating in the bloodstream. Thus, free HIV antigen is captured (complexed) and, therefore, unable to bind to monoclonal antibody presented on the test device. As a result, the level of detectable HIV antigen decreases. The detection of HIV-1/2 antibodies by serological assay signals the end of seroconversion and, therefore, the window period for diagnosis.

The duration of the window period depends on three main factors: (1) the genetics of the **virus**, (2) the genetics and immunocompetence of the **host** and (3) what exactly the **assay** detects (antigen, antibodies). In particular, the format of the assay determines its ability to detect early HIV antibodies (including IgM, IgA, IgG); this may also depend on the specimen type, such as oral fluid, venous or capillary whole blood and serum/plasma. The shortest window period is generally observed with fourth generation serological assays, followed by third and then second generation assays, with first generation assays having the longest window period. Among RDTs, those using oral fluid specimens exhibit the very longest window period, irrespective of their generation, likely because the concentration of HIV-1/2 antibodies is lower in oral fluid than in other specimen types. However, they have been successfully used in many settings, particularly where high HIV incidence is not expected (180, 232, 233).

7.1.2 Types of HIV assays

Serological assays are the most commonly used assays for the diagnosis of HIV. The type and format of the assay selected will depend on a variety of factors, most importantly ease of use and the characteristics of the testing site such as storage facilities, infrastructure and level of staff skills.

The test results of any visually read assay (such as RDTs or simple assays) should ideally be reread by an independent second reader within the time frame recommended in the instructions for use. Timely rereading is critical; the second reader must not read the test result after the maximum incubation time specified by the manufacturer. The second reader need be trained only in reading the test results and does not necessarily need to be trained to perform the assay itself. Table 7.2 describes different formats of HIV assays and their characteristics.

Diagnostic sensitivity is defined as the percentage of HIV-infected individuals who are identified as HIV-positive by the assay. **Analytical sensitivity** describes the smallest amount of analyte (HIV-1/2 antibodies and/or HIV-1 p24 antigen) that an assay can accurately measure. **Seroconversion sensitivity** refers to the ability of any assay to detect HIV infection during or soon after seroconversion. It is important to note that the adaptive immune response may decline after HIV acquisition, which results in lower levels of specific gp41 HIV antibodies. Thus, false-negative test results may be more common with RDTs that contain gp41 as their antigen source, and particularly for oral fluid specimens, as the level of HIV-1/2 antibodies in oral fluid is orders of magnitude less than in other specimen types (180, 234, 235). Other variables to consider when choosing an assay include the HIV variants in a particular geographical region, for example, HIV-1 group O or HIV-2. HIV-1 group O is prevalent in western Africa, but the strain has been reported worldwide. Some, but not all, current assays claim detection of group O HIV infections (9, 97, 236).

Diagnostic specificity is defined as the percentage of HIV-uninfected individuals who are identified by the assay as HIV-negative. **Analytical specificity** is the ability of an assay to identify a particular analyte (HIV-1/2 antibodies and/or HIV p24 antigen), rather than others, in a specimen and thus rule out false reactivity. False reactivity refers to a reaction on a given assay that is not confirmed by additional testing and, therefore, is ruled as false (not true). An understanding of false reactivity, including cross-reactivity within the specific testing population, is critical to constructing accurate testing algorithms (237, 238). Heightened false cross-reactivity is likely to be related to alteration of the immune response, that is, polyclonal B-lymphocyte activation caused by exposure to an infection other than HIV (237). These heightened rates of cross-reactivity are observed particularly for assays containing one antigen; they may vary in different populations and over time. Additional exogenous factors and endogenous substances have some effect on the performance of certain generations of assays (239–241). Therefore, it is important to understand the limitations of the assays; these are typically described in the manufacturer's instructions for use. Table 7.3 lists causes of false-negative and false-positive test results.

Table 7.2. Formats of HIV assays and their operational characteristics

Type	Format	Number of steps	Time to result	Specimen throughput	Specimen type	Storage conditions	Testing locations ^c
Rapid diagnostic tests	Immunofiltration (vertical flow)	3–4	<3 minutes	5 per 5 minutes ^b	Serum, plasma, venous/ capillary whole blood	~2–30 °C or 2–8 °C	Community and all facilities
	Immuno chromatographic (lateral flow)	1–2	15–30 minutes	10 per 15 minutes ^b	Serum, plasma, venous/capillary whole blood, oral fluid	~2–30 °C	Community and all facilities
Simple assays	Indirect solid-phase enzyme immunoassays (e.g. comb or bead assays)	3–4 ^a	<30 minutes	8 per 30 minutes ^b	Serum, plasma	2–8 °C	Levels 1, 2
	Agglutination	2 ^a	2 hours	15 per 2 hours ^b	Serum, plasma	2–8 °C	Levels 1, 2
Immunoassays	Enzyme immunoassay (microtitre plate)	Manually loaded ^a	2–3 hours	90 per hour ^b	Serum, plasma	2–8 °C	Levels 2, 3, 4
	Enzyme immunoassay (simple immunoanalysers)	Moderately automated ^a	<2 hours	50 per hour	Serum, plasma	2–8 °C	Levels 3, 4
	Random access chemiluminescence and electrochemiluminescence immunoanalysers	Highly automated	<2 hours	100 per hour, no need to batch	Serum, plasma	2–8 °C	Levels 3, 4
	Qualitative nucleic acid testing (laboratory-based)	Highly automated ^a	<5 hours	Depends on format	Whole blood, dried blood spot	Cold chain	Levels 3, 4
Assays for supplemental use only	Western blot, line immunoassays	Manually loaded ^a	<8 hours	15 per 8 hours ^b	Serum, plasma	2–8 °C	Levels 3, 4
	RDTs for supplemental use only	Depends on format	Depends on format	Depends on format	Depends on format	~2–30 °C or 2–8 °C	Levels 1, 2
	Qualitative nucleic acid testing (point-of-care)	Depends on format	<1 hour	Depends on format	Whole blood	~2–30 °C	Levels 2, 3
	Qualitative nucleic acid testing (laboratory-based)	Highly automated	<5 hours	Depends on format	Whole blood, dried blood spot	Cold chain	Levels 3, 4

^a Precision pipette required.^b If batched in one run.^c See Fig. 7.1.

Table 7.3. Common causes of false results in HIV serological assays

Potential causes of false non-reactive (negative) test results, irrespective of assay format
Biological error
Ongoing seroconversion
Divergent HIV strain
Inhibitory factors in specimen
Human error
No specimen or insufficient specimen added
Too much buffer added
Test kits stored outside of recommended storage conditions (either too hot or too cold) during transport or storage, leading to denaturation of reagents or test devices
Use of expired reagents or test devices
Manufacturing error
Manufacturing defects due to lapse in quality management system
Potential causes of false-reactive (positive) test results, irrespective of assay format
Biological error
Non-specific IgG binding
Cross-reactive antigens
Contaminating proteins in specimen
Human error
Test kits stored outside of recommended storage conditions (either too hot or too cold) during transport or storage, leading to denaturation of reagents or test devices
Over-interpretation of weakly reactive test lines on visually read assays
Manufacturing error
Manufacturing defects due to lapse in quality management system

It is recommended that any reactive HIV test result be confirmed with a second assay (in settings where prevalence is $\geq 5\%$) or with both a second and third assay (in settings where prevalence is $< 5\%$). HIV serological assays typically have exceptionally high sensitivity and specificity compared with those of assays for other infectious diseases. That being the case, there is generally a trade-off that favours sensitivity over specificity for the first-line HIV assay so as not to miss true positive specimens. Additional testing is required to resolve cases of false reactivity (that is, to rule out false positives) and to verify reactivity (that is, to rule in true positives).

Annex 7 describes each test format in detail.

7.1.3 Use of fourth generation serological assays

Fourth generation serological assays (RDTs, EIAs, CLIAs, ECLs) that detect both HIV p24 antigen and HIV-1/2 antibodies have the potential to identify infected individuals earlier in the course of disease. In other words, these assays greatly shorten the diagnostic window period (Fig. 7.2). Thus, fourth generation serological assays are a suitable choice for a first-line assay when seroconversion sensitivity is preferred, such as in blood screening.

Certain fourth generation serological assays can produce a result that indicates whether the assay is reactive to HIV p24 antigen or to HIV-1/2 antibodies, rather than combined detection of these markers. Thus, it is theoretically possible to identify individuals with acute infection (HIV p24 antigen present but non-reactive for HIV-1/2 antibodies). However, recently published data show that the HIV p24 antigen detection component of some fourth generation RDTs lacks analytical and diagnostic sensitivity (242–245). A further caveat is that the presence of HIV p24 antigen should not always be interpreted as acute infection. This is because levels of free and circulating HIV p24 antigen can be detected again late in the course of HIV infection, when the immune (antibody) response wanes and a lack of HIV-1/2 antibodies (and, therefore, rising titres of HIV p24 antigen) are observed.

Due to the high sensitivity of both third and fourth generation serological assays, a certain low level of false reactivity is to be expected. Therefore, any testing algorithm using a third or fourth generation serological assay as the first-line assay should include more specific second-line and third-line assays to verify the HIV diagnosis and rule out false reactivity.

7.1.4 HIV RDTs for use in infants and children

Many settings use HIV-1/2 RDTs to assess HIV exposure in infants and children younger than 18 months and to diagnose HIV infection in children older than 18 months. The performance of these assays is acceptable for infants younger than four months. Concerns have been raised, however, concerning the reliability of certain serological assays between four and 18 months, most notably for second generation RDTs that do not include detection of IgM (220, 246, 247). For this reason HIV testing of the mother is preferable, whenever possible, to rule out HIV exposure of the infant and to diagnose the mother. Where possible, use of virological testing to rule in HIV infection should be considered if HIV infection is suspected. Serological testing of the child, according to the validated national testing algorithm, should be repeated after 18 months of age to assess final status, with the caveat that exposure to ART may lead to false-negative results with certain serological assays.

7.1.5 Specimen types used for HIV testing

Specimen integrity is critical to the accuracy of HIV testing. Each manufacturer specifies in the instructions for use the recommended specimen collection procedures, the storage

requirements and specimen stability after collection. These instructions always take precedence, but for a broad summary, see Table 7.4. When the instructions for use issued with the assay do not include a certain specimen type within the intended use, it means that the assay manufacturer has not validated that specimen type for use with that assay.

Table 7.4. Specimen types and processing requirements

Specimen type	Time to processing/storage/time to testing
Venous whole blood Whole blood freshly collected by venepuncture	Use the specimen immediately.
Serum Freshly collected whole blood is allowed to coagulate, and the serum fraction is collected away from the clotted red blood cells.	Collect whole blood, mix by hand 4–5 times immediately, and let stand for the clot to form. Process within 30 minutes of collection. Store at 2–8 °C, and test within 5 days or as specified by the instructions for the assay to be used.
Plasma Freshly collected whole blood is added to the recommended anticoagulant, such as EDTA, heparin or citrate. After centrifugation, the plasma is separated. Use only anticoagulants validated by the assay manufacturer.	Collect whole blood, mix by hand 8–10 times immediately, and centrifuge for up to 10 minutes. Process within 6 hours of collection. Store at 2–8 °C, test within 5 days or as specified by the instructions for the assay to be used.
Capillary whole blood Capillary (finger-stick) whole blood is collected using a lancet and a specimen transfer device.	Use the specimen immediately, with the specimen transfer device recommended by the instructions for use. Note that the specimen transfer device may or may not include an anticoagulant. An anticoagulant contributes to accuracy. <i>The hanging drop method, whereby blood is dropped directly from the fingertip onto the test device, is not recommended, as it does not ensure that the specimen volume is accurately added.</i>
Oral fluid Oral mucosal transudate (not saliva) is collected from the gums using a collection device.	Use the specimen immediately, with the specimen transfer device recommended by the instructions for use.
Dried blood spot (DBS) Venous or capillary whole blood is applied to a filter paper by hanging drop or microcapillary. Whole blood is later eluted from the filter paper and used for the test procedure.	Store at 4 °C for up to 3 months, at –20 °C for longer. The use of specific assays with DBS should be validated by the manufacturer. When the manufacturer has not validated their assay for DBS, the use of DBS is considered “off-label”, or unauthorized for returning medical results.

7.1.6 HIV-2 diagnosis

Some assays can discriminate between HIV-1 and HIV-2 antibodies, but differentiation between dual infection and mono-infection remains challenging for HIV testing programmes. Dual infection with HIV-1 and HIV-2 in one individual is quite rare, but misclassification of HIV type can affect the efficacy of ART and so affect the health of the individual (248, 249). Dual reactivity observed in any given discriminatory HIV-1/HIV-2 assay is more likely to be caused by cross-reactivity than true dual infection. Recent data suggest that the amount of cross-reactivity between HIV-1 and HIV-2 may be significant. Evaluations conducted by the WHO Prequalification of In Vitro Diagnostics Programme observed rates of cross-reactivity between 3% and 57%, which would potentially incorrectly over-diagnose HIV-2 by a large degree (250).

In settings where HIV-2 is present, to determine the virus type or diagnose coinfection, appropriate supplemental testing should be performed, including serological assays specific to HIV-1 and to HIV-2 and virological technologies.

7.1.7 Multiplex, multi-analyte, multi-module testing

Multiplex testing refers to testing using one specimen in the same test device for detection of HIV and other infections, for example, *Treponema pallidum* (syphilis), hepatitis C and hepatitis B. Offering combined or discriminatory detection of two or more analytes in one device has several advantages over separate tests. These include:

- less overall specimen volume needed and thus fewer finger-sticks
- cost-savings through lower cost per analyte tested
- improved client flow, with both results available at the same time
- overall service delivery efficiencies, with less time required per analyte per visit.

Multiplex RDTs are in development for anti-HIV/HBsAg (hepatitis B), anti-HIV/anti-HCV, anti-HIV/anti-HCV/HBsAg and HIV/anti-*Treponema pallidum* (syphilis). Further data on their diagnostic accuracy and impact on outcomes important to clients are required.

Multi-analyte testing refers to a similar principle, whereby the same platform with different sets of serological reagents can be used to test one or more specimens for a wide variety of analytes – for example, anti-HIV/anti-HCV/HBsAg. Current multi-analyte platforms, in the form of simple immunoanalysers, and random access chemiluminescence and electrochemiluminescence immunoanalysers are best suited to facilities with medium to high throughput, that is, greater than 100 specimens per day. Typically, they are most suitable for district, provincial and national laboratories (levels 2, 3, 4), as the current platforms may require certain precision steps, utilize serum/plasma specimens and require constant electricity supply and regular maintenance.

Multi-module testing refers to testing a specimen with one testing system comprised of multiple modules (platforms) for each category of analyte. For example, serological testing can be performed with the same system (different platform) used for clinical chemistry and haematology. As with multi-analyte testing, current multi-module systems are usually best suited to medium to high throughput facilities located in district,

provincial and national laboratories (levels 2, 3, 4). The requirements of multi-module testing are similar to the requirements of multi-analyte platforms.

7.1.8 HIV self-testing

To date, three commercial HIV RDTs specifically labelled and packaged for self-testing are available; several others are in development. In general, these RDTs use oral fluid or capillary whole blood specimens. Development of assays for HIVST that meet regulatory standards is critical to both reducing the cost of and improving the quality of assays available for HIV self-testing. For more information see <http://www.hivst.org>. See section 7.3 for additional comments.

7.2 HIV testing strategies for diagnosis (after 18 months of age)

WHO recommends standardized testing strategies to maximize the accuracy of HIV diagnosis while minimizing cost and increasing simplicity (251). A testing strategy for diagnosis describes a testing sequence for the specific testing objective of diagnosis (as opposed to screening only) taking into consideration the presumed HIV prevalence in the population (19). In both high and low prevalence settings, three different assays may be required to establish the diagnosis of HIV infection.

The testing strategies for diagnosis described in this section have been developed assuming that all HIV serological assays used will have sensitivity of at least 99% (lower bound of the 95% confidence interval) and specificity of at least 98% (lower bound of the 95% confidence interval) and will aim to result in an overall positive predictive value for the testing strategy of 99% or higher (44, 251).

These testing strategies apply equally to facility-based testing (for example, in laboratories, standalone HIV testing sites, clinical facilities and other testing services) and non-facility-based testing (for example, community-based testing conducted outside of conventional health facilities). Also, these testing strategies are applicable to all serological assay formats and combinations of assay formats. All personnel who perform testing, including specimen collection, the testing procedure and reporting of HIV status, should adhere to these testing strategies. This includes both laboratory personnel and other health workers who are trained for these tasks, including through task sharing. Annex 7 presents the mathematical model used as a rationale for development of these strategies.

7.2.1 Serological testing strategy for HIV diagnosis in high prevalence settings

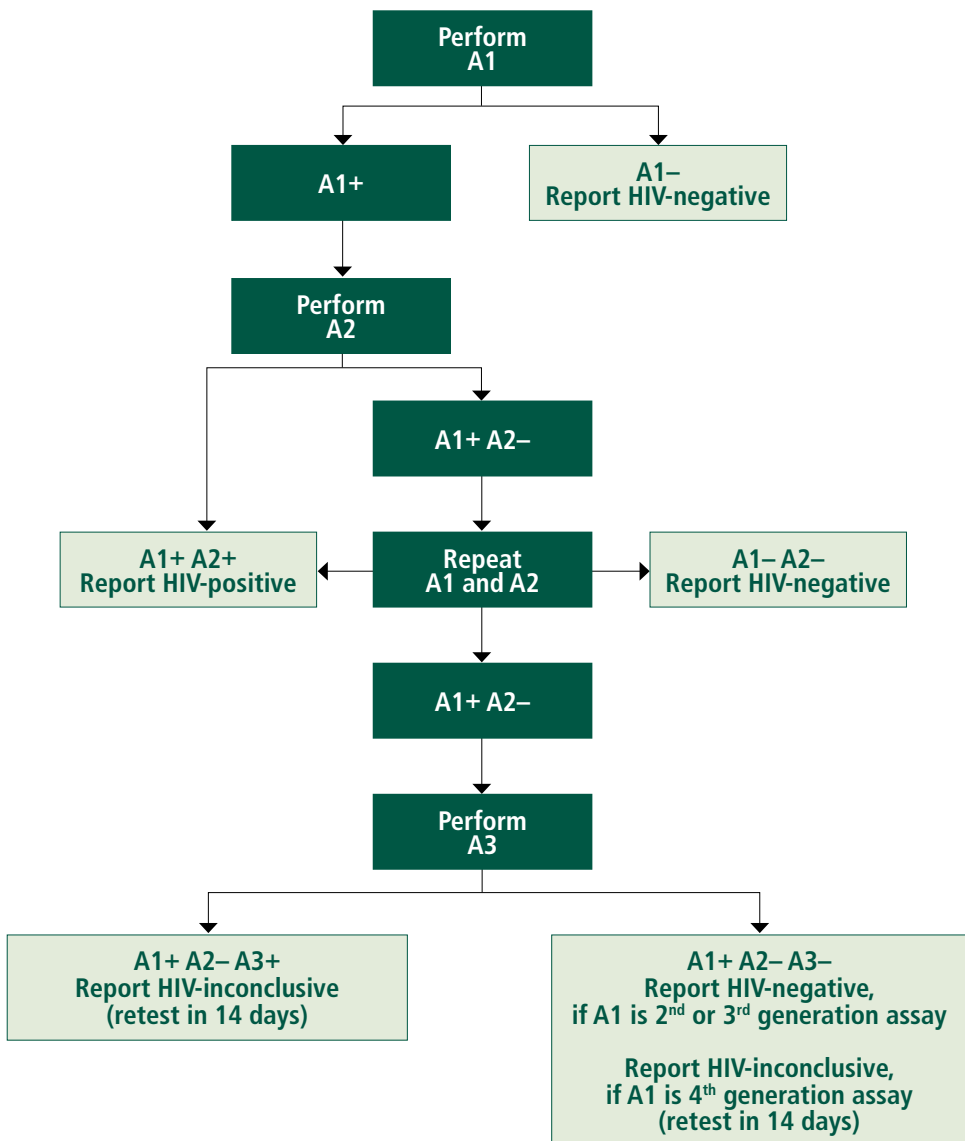
The testing strategy depicted in Fig. 7.3 applies in high prevalence settings, that is, a national or subnational prevalence of $\geq 5\%$ in the population to be tested. These settings may include generalized HIV epidemics and epidemics concentrated in key populations. The figure describes the sequence of assays and the number of tests to be performed. Assay 1 (A1), Assay 2 (A2) and Assay 3 (A3) should be three different serological assays that do not share the same false reactivity. This testing strategy is intended for use with

serological assays. It would require adaptation if NAT technologies were used as A2 or A3.

All specimens are first tested with one assay (A1), and specimens that are non-reactive (A1-) are considered HIV-negative and reported as such. A1 should be the most sensitive assay available, taking into account diagnostic sensitivity, seroconversion sensitivity and analytical sensitivity.

Any specimens that are reactive on the first assay (A1+) should be reflexed (tested again) using a separate and distinct second assay (A2) comprising a different antigen preparation to avoid false cross-reactivity with A1. For specimens that are reactive both

Fig. 7.3. Testing strategy for HIV diagnosis in high prevalence settings



on the first-line assay and the second-line assay (A1+; A2+), HIV status should be reported as HIV-positive. All individuals that are diagnosed HIV-positive should be retested prior to starting ART to verify their HIV-positive status (see section 3.4).

Specimens that are reactive on the first-line assay but non-reactive on the second-line assay (A1+; A2-) should be repeated using the same specimen with the same two assays. When the test uses finger-stick whole blood, a new specimen will have to be taken and the same two assays repeated.

Following repeated testing, if the results remain discrepant (A1+; A2-), the specimen should be reflexed (further tested) using a separate and distinct third-line assay (A3).

- If the third assay is reactive (A1+; A2-; A3+), an HIV-inconclusive status is reported, and the client should be asked to return in 14 days for retesting.
- If the third-line assay is non-reactive (A1+; A2-; A3-), the HIV status is reported as HIV-negative. **If the first-line assay (A1) is a fourth generation assay, however, the test result A1+; A2-; A3- should be reported as HIV-inconclusive, and the client should be asked to return for retesting in 14 days.**

For individuals with A1+, then A2-, then A3+, **using the reactive test result from the third assay as a tiebreaker to rule in HIV infection and issue an HIV-positive diagnosis is not recommended**; it over-selects for false-positive results and, therefore, leads to greater potential for misdiagnosis of HIV infection (252–258).

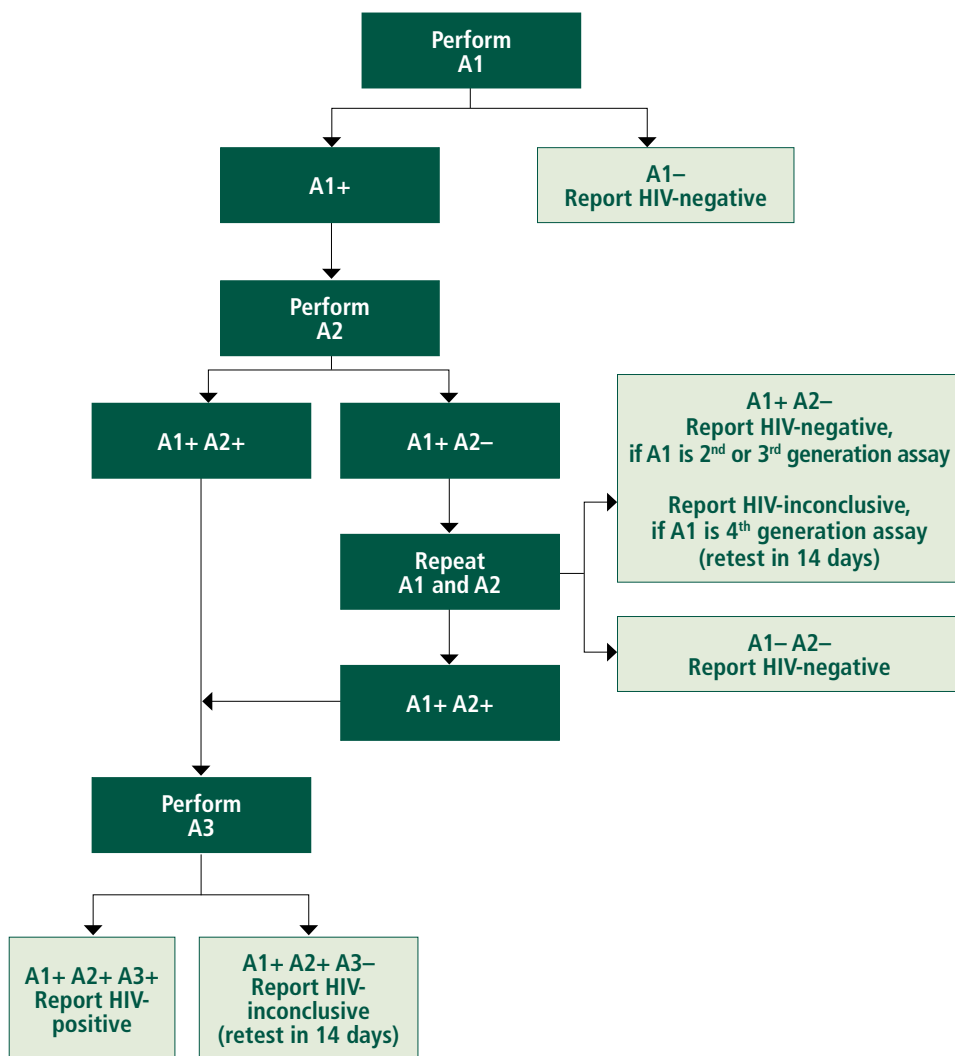
In some settings where HIV testing is offered, it may not be feasible to conduct all three assays on the same day in the same facility, for a variety of reasons. Where the third-line assay is unavailable, any individual with an initially reactive result on A1 (A1+) or discrepant results on A1 and A2 (A1+; A2-) should be referred to a higher-level facility, with a record of their test results, for additional testing. Annex 7 presents the rationale for this testing strategy.

7.2.2 Serological testing strategy for HIV diagnosis in low prevalence settings

The testing strategy shown in Fig. 7.4 should be used for HIV testing in low prevalence settings, that is, with an HIV prevalence of <5% in the population to be tested. This includes settings with low-level HIV epidemics and testing of the general population in areas with concentrated HIV epidemics.

The figure describes the sequence of assays and number of tests to be performed. Assay 1 (A1), Assay 2 (A2) and Assay 3 (A3) should be three different serological assays that do not share the same false reactivity. This testing strategy is intended for use with serological assays and would require adaptation if NAT technologies were used as A2 or A3.

Fig. 7.4. Testing strategy for HIV diagnosis in low prevalence settings



All specimens are first tested with one assay (A1), and specimens that are non-reactive (A1-) are considered HIV-negative and reported as such. A1 should be the most sensitive assay available, taking into account diagnostic sensitivity, seroconversion sensitivity and analytical sensitivity.

Any specimens that are reactive on the first-line assay (A1+) should be retested using a separate and distinct second assay (A2) comprising a different antigen preparation to avoid false cross-reactivity with A1.

Specimens that are reactive on the first-line assay but nonreactive on the second-line assay (A1+; A2-) should be repeated using the same specimen with the same two

assays. When the assay uses finger-stick whole blood, a new specimen will have to be taken to be tested with the same two assays.

A specimen that remains reactive following repeat testing with the first assay but is non-reactive on the second assay (A1+; A2-) is considered HIV-negative and reported as an HIV-negative status. The negative predictive value of the test result of A2- is very high. **If the first-line assay (A1) is a fourth generation assay, however, the test result A1+; A2- should be reported as an HIV-inconclusive status, and the client should be asked to return for retesting in 14 days.**

In a low prevalence population, the positive predictive value based on two test results is too low to provide an HIV diagnosis. Therefore, for specimens that are reactive on the first and the second assays (A1+; A2+), a third separate and distinct assay (A3) should be used to confirm the results and issue an HIV-positive diagnosis.

- If the third test result is also reactive (A1+; A2+; A3+), the status is reported as HIV-positive. Retesting to verify the HIV diagnosis should be performed prior to enrolment in care or ART (see section 3.4).
- If the result of the third assay is non-reactive (A1+; A2+; A3-), then the test result is discrepant and inconclusive HIV status should be reported. The client should be asked to return in 14 days for additional HIV testing.

In low prevalence populations, for individuals with A1+, then A2- test results, an HIV-negative status should be reported. There is no need for specimens to be reflexed (tested again) on a third assay; the negative predictive value of A2 is high ($\geq 99\%$), meaning the probability that the negative result observed on A2 is truly negative is $\geq 99\%$.

In some settings where HIV testing is offered, it may not be feasible to conduct all three assays on the same day in the same facility. Any individual with an initially reactive result on A1 (A1+) or dual reactive results on A1 and A2 (A1+; A2+) should be referred to a higher-level facility, with a record of their test results, for additional testing. Annex 7 presents the rationale for this testing strategy.

7.3 HIV testing algorithms

An HIV testing algorithm describes the specific assays used in a given HIV testing strategy (19). Combinations of RDTs or combinations of RDTs and EIAs can provide results as reliable as, or even more reliable than, testing using the conventional EIA/Western blot combination and at much lower cost when they are correctly chosen (251, 259).

7.3.1 Selecting assays for validation of testing algorithms

Order of assays to be used within a testing algorithm

A given testing strategy is populated with the assays available and is then called a testing algorithm. First-line assays should have the ability to identify any potential HIV-positive specimen and, thus, should have superior diagnostic sensitivity. These assays (sometimes referred to as screening assays) are likely to detect all true positive specimens as well as some specimens that are false-positive. Second-line and third-line assays are used to confirm the initial reactivity observed in the first-line assay, and so they should have superior diagnostic specificity, to rule out false reactivity.

It is essential to minimize the potential for shared false reactivity through careful selection of the combination of HIV assays used by validating testing algorithms. The choice of first-line (A1), second-line (A2) and third-line (A3) assays all must be validated. Where possible, assays based on different antigen preparations should be used in combination. Assays from different manufacturers are more likely to be made of different antigen preparations. Increasingly, however, WHO has noted that manufacturers sell finished or semi-finished products to other manufacturers under re-branding or re-labelling arrangements, making it difficult for the user to determine the antigen preparation used. In the absence of information about the antigen source, a validation study to determine the optimal testing algorithm should be conducted. If the validation panel is chosen carefully, this study provides data on the degree of cross-reactivity.

Performance characteristics

The following performance characteristics should be considered when selecting assays to validate as testing algorithms (see also Table 7.5):

- highest sensitivity (clinical, analytical, seroconversion) for first-line assay, irrespective of format
- highest specificity for second- and third-line assays, irrespective of format
- lowest invalid rate, irrespective of format
- lowest inter-reader variability, if a visually read assay, for example, an RDT or simple assay.

In resource-limited settings HIV testing services may use combinations of RDTs or combinations of RDTs/EIAs/supplemental assays rather than EIA/Western blot combinations¹ (251, 259, 260).

Annex 7 presents an example of validation of an HIV testing algorithm.

¹ In some countries immunofluorescence assays (IFAs) and Western blot are still used as supplemental assays. However, these assays are generally less sensitive, as they are first generation assays, and they can be expensive. They are being replaced by more specific supplemental rapid diagnostic tests that use recombinant proteins and/or peptides.

Operational characteristics

In addition to performance characteristics, various operational characteristics should be considered in the selection of assays. Performance evaluations, including the evaluation that is part of the assessment conducted by the WHO Prequalification of In Vitro Diagnostics Programme, take into account these characteristics in order to assess the suitability of assays for use in both facility-based and non-facility-based testing.

Due to differences in regional or country requirements for specific operational characteristics, testing algorithms should always be validated in the context in which they will be used before large-scale implementation. Table 7.5 lists these considerations.

Table 7.5. Specific considerations for selection of HIV diagnostics

Performance characteristics	Minimum requirements or options	
Clinical sensitivity		
First-line assays	≥99% for RDTs, 100% for EIAs	
Second-line/third-line assays	≥99% for RDTs, 100% for EIAs	
Clinical specificity		
First-line assays	≥98% for RDTs and EIAs	
Second-line/third-line assays	≥99% for RDTs and EIAs	
Seroconversion sensitivity (window period)		
First-line assays	Best possible, that is, shortest window period	
Inter-reader variability (if a visually read assay)		
Rate of variability when the same test result is read by more than one reader	≤5%, usually a result of faint test results (test lines for RDTs/test spots for simple assays)	
Invalid rate		
Rate of invalid test devices, if RDT or simple assay; rate of invalid test runs, if EIA	≤5% (Higher invalid rates lead to more wastage.)	
Operational characteristics		
Specimen type		
Are any specimen types excluded from use on the assay? (Strictly observe the instructions for use of each assay.)	Venous whole blood	Capillary whole blood
	Serum	Oral fluid
	Plasma (including specific anticoagulants)	
Detection type		
For second and third generation assays, does the assay detect each analyte separately?	Combined detection of HIV-1/2 antibodies	
	Discriminatory (separate) detection of HIV-1 and HIV-2 antibodies. <i>Additional HIV-2 supplemental testing should be available.</i>	
For fourth generation assays, does the assay detect each analyte separately?	Combined detection of HIV p24 antigen and HIV-1/2 antibodies	
	Discriminatory (separate) detection of HIV p24 antigen and HIV-1/2 antibodies. <i>Utility depends on availability of additional p24 antigen supplemental testing. If not available, retest in 14 days.</i>	

Operational characteristics

Subtype detection

Relevant subtypes for testing population?	Groups M, N, O
Does the assay exclude any subtypes?	

Time to result for 1 specimen (minimum reading time)

Is shorter or longer incubation time desirable?	Immunofiltration RDT	Less than 5 minutes for batch of 5 specimens
	Immunochromatographic RDT	Minimum of 15 minutes, maximum of 30 minutes for batch of 10 specimens
	Agglutination	2 hours for batch of 15 specimens
	EIA	2 hours for batch of 90 specimens

Endpoint stability – maximum reading time

How long is the test result stable? Is a longer or shorter reading time desirable?	May range from “read immediately” to “stable for up to x minutes”
--	---

Ease of use

Consider combination of the following aspects	Specimen collection requirements, for example, finger-stick whole blood or venous whole blood by venepuncture	
	Number of steps in the test procedure	Number of steps that require precision
	Ease of reading the test band, line, spot, that is, few faint bands	Ease of interpretation of testing results, that is, more bands = more complicated

Extent of infrastructure required at testing sites

Are there any infrastructure requirements that would prohibit use of certain assays?	Refrigeration for storage of test kits	Refrigeration of reconstituted reagents and controls
	Electricity/generator	Temperature-controlled work space

Storage/stability

Transport requirements for test kits (temperature, humidity)	Any excursion ranges accepted during transit? Any specialized shipping requirements?
In-use stability for specific reagents (temperature, humidity)	Any specific requirements once reagents are opened or once the specimen is added to test device/cartridge?

Equipment/consumables required but not provided in the test kit

Reasonable exclusions from the test kit. Can these be obtained from the manufacturer/distributor or obtained separately?	Lancets, alcohol swabs, cotton wool for finger-stick whole blood	Blood collection equipment for venous whole blood
	Other general laboratory consumables: gloves, precision pipettes, etc.	

Operational characteristics	
Specimen throughput and individual testing service delivery models	
Throughput per operator/provider	RDTs if ≤ 10 specimens per hour per operator with limited laboratory infrastructure EIAs if ≥ 40 specimens per day per operator with standard laboratory infrastructure
Technical skill of staff conducting testing	
Number of precision steps required	For example, counting of multiple drops, timing of steps required, use of precision pipette, interpretation of results
Is phlebotomy required?	
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) Colour control upon addition of specimen and/or certain reagents with some EIAs
Availability of internal test kit controls and external quality control specimens	Compatibility with quality control materials; some are available but separately from test kit.

7.3.2 Rationale for validation of testing algorithms

The combination of assays used in a testing algorithm(s) should be validated at the national or regional level. It is suggested to select one testing algorithm, with a back-up assay for the first-line assay and a back-up assay that can serve as the second-line or third-line assay. The number of algorithms used in a country should be limited, with back-up assay options in the case of lot failures or stock-outs and to respond quickly to recalls or corrective actions recommended by the manufacturer.

National or regional validation is important to ensure that the chosen testing algorithms:

- are relevant in the testing population, for example, subtype distribution and interfering factors that might lead to cross-reactivity (see Table 7.3);
- do not involve assays that share high levels of the same false reactivity in the testing population, for example, especially avoid A1 and A2/A3 assays that falsely identify the same specimen as positive;
- are feasible to implement.

Regular review of the testing algorithm, every three to five years, will ensure that assays continue to perform adequately, that improved assays are introduced and that there is competition among manufacturers. It is critical that testing algorithm validation studies are well-conducted. The programmatic suitability of testing algorithms should be considered in any review of existing testing algorithms. Also worth consideration are rates of HIV-inconclusive status, rates of discrepant test results (A1+; A2-) and invalid rates, as well as needs for retraining and for revision of SOPs and job aids.

7.3.3 Suggested methodology for validation of testing algorithms

At the national or regional level, programmes should establish a working group consisting of diagnostic and programmatic experts to develop the validation study protocol, devise a list of candidate assays, conduct the study and analyse the results. For harmonization and standardization, programmes should inform implementing partners about the validation exercise and ask them to follow the resulting testing algorithms. Thus, the process consists of three phases:

- Phase 1: Identify candidate assays
- Phase 2: Conduct validation study according to the prescribed methodology
- Phase 3: Monitor implementation of the testing algorithm(s).

The aim of this study is not to reconfirm the diagnostic accuracy of the assays, for example, diagnostic sensitivity and diagnostic specificity, but rather to ensure that the most appropriate testing algorithm(s) is being used in the country or region. Annex 7 presents an example of validation of a testing algorithm.

7.4 Retesting to verify HIV status

Retesting refers to using the same testing algorithm on a second specimen from the same individual. *Supplemental testing* refers to further testing of the same specimens with additional assay(s) to obtain more information.

For information on messages for retesting, see Chapter 3.

7.4.1 Retesting of individuals who test HIV-negative

The vast majority of individuals do not require retesting to verify an HIV-negative status, particularly in the absence of any ongoing risk. However, it is important to accurately identify individuals who test HIV-negative and may require retesting in certain circumstances.

HIV-negative individuals with ongoing risk

Certain individuals who test HIV-negative warrant retesting:

- people from key populations
- people with a known HIV-positive partner
- people with known recent HIV exposure
- pregnant and breastfeeding women in high incidence/prevalence settings
- individuals seen for a diagnosis or treatment of STIs
- TB patients with a possible recent HIV exposure or who are at higher risk for HIV exposure
- outpatients with clinical conditions indicative of HIV infection
- individuals taking PEP or PrEP.

Annex 7 describes the intervals for retesting, in addition to other key information.

HIV-negative people taking PrEP

Optimal intervals for retesting individuals on PrEP have yet to be determined. HIV testing is required to identify individuals who are uninfected before starting PrEP, to minimize development of resistance. In addition, periodic retesting is needed for those on PrEP to identify new infections. Specific WHO guidance on the frequency of testing for those on PrEP is in preparation.

7.4.2 Retesting clients with HIV-inconclusive status

WHO recommends that clients with HIV-inconclusive status be retested in 14 days in order to:

- rule in seroconversion, if HIV reactivity evolves to concordant between A1 and A2, that is A1+; A2+;
- rule out seroconversion, if HIV reactivity remains unchanged, with likely non-specific false-positive reaction for A1 and A3 (the negative predictive value for A2 will be very high);
- rule out specimen mix-up, particularly if a unique client identifier and consecutive specimen identifiers are not assigned; or
- rule out random error, either user/operator error or test device error.

Specimens from individuals with clinical signs meeting the WHO criteria for stage III or IV may have discrepant test results and an HIV-inconclusive test result due to a decrease of HIV antibodies with advanced disease progression and/or impaired or reduced immune response.

If the HIV status is the same upon retesting, then the individual should be considered HIV-negative. If HIV status is not the same upon retesting, the individual or the specimen may be referred for additional testing at a higher-level facility.

7.4.3 Retesting to verify HIV-positive diagnoses before initiating care or ART

Since 2013 WHO has recommended initiation of ART for all people with CD4 counts of <500 cells/mL (13). Further, WHO recommends ART initiation based solely on HIV serological diagnosis, without additional immunological (CD4 count) or virological (NAT) testing, for certain populations, including all pregnant women, serodiscordant couples, people with TB or viral hepatitis (HBV or HCV) coinfection and children less than 5 years of age (but over 24 months of age) (9). Thus, it is critical that policy-makers, programme managers and providers be aware of and reduce the risk of misdiagnosis of HIV status.

To ensure that individuals are not needlessly placed on life-long ART (with potential side-effects, waste of resources, psychological impact of misdiagnosis), **WHO recommends that all individuals be retested to verify their HIV status prior to enrolling in care and/or starting ART.**

Misdiagnosis, irrespective of its scale, **is of critical importance**. Any incorrect diagnosis, whether a false-positive or a false-negative, has deleterious personal and public health consequences, often with severe repercussions.

As noted, *retesting* refers to the testing of a new specimen for each newly diagnosed individual, conducted by a different provider using the same testing algorithm, prior to initiation of ART. Retesting should be conducted at a different site, ideally the site where the decision about ART initiation will be made. Retesting according to this procedure aims to rule out possible technical or clerical errors, including specimen mix-up through mislabelling and transcription errors, as well as random error either by the provider or of the test device. Retesting will not exclude misdiagnosis related to poor choice of a testing algorithm. However, with adequate validation of the testing algorithm, this risk should be minimal.

Certain testing services, such as PMTCT services operating with Option B+, are programmatically organized to conduct HIV testing, provide a diagnosis and offer immediate initiation of ART irrespective of CD4 count. In these programmes it may not always be feasible to retest at a different site, although it should usually be feasible for a different provider to conduct retesting on a new specimen.

If the HIV status is the same upon retesting, the individual's HIV-positive status should be considered verified. If the status is not the same upon retesting, the individual or their specimen should be referred for additional testing at a higher-level facility.

WHO recommendation

Retest all clients diagnosed HIV-positive with a second specimen and a second operator using the same testing strategy and algorithm before enrolling the client in care and/or initiating ART, irrespective of whether or not ART initiation depends on CD4 count.

Source: WHO, 2014 (57).

7.4.4 Retesting people on ART

The effect of ART in suppressing viral replication may extend to suppression of the immune response and, thus, of antibody production. Therefore, non-reactive test results, particularly on assays using oral fluid, must be interpreted cautiously. Individuals undergoing HIV testing must be made aware of the risk of incorrect diagnosis if they do not disclose that they are on ART. All individuals receiving HIV testing should be asked if they have been tested previously and told they are HIV-infected and/or if they are now on ART or have ever received ART.

WHO recommendations

Retesting is warranted for the following populations:

Individuals testing HIV-negative who:

- have ongoing risk for HIV infection;
- can identify a specific incident of HIV exposure in the preceding four weeks; OR
- are pregnant, in high HIV prevalence settings; for those who test HIV-negative in the first trimester, retesting should be offered in the third trimester, during labour or shortly after delivery.

Individuals whose HIV status is inconclusive, irrespective of risk.

Individuals diagnosed HIV-positive should be retested to verify their HIV diagnosis prior to initiation of care and/or treatment.

Retesting is **not** recommended for individuals on ART.

Source: WHO, 2010 (12, 57); WHO, 2014 (12, 57).

QUALITY ASSURANCE OF HIV TESTING

8

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KEY POINTS

- **Quality assurance** implemented through quality management systems is essential **for any testing service**, ranging from HIV testing conducted in laboratories and health facilities to community-based settings, including rapid diagnostic tests (RDTs) performed by lay providers.
- It is the ethical responsibility of all people conducting HIV testing (including lay providers) and all programmes or facilities offering HTS to **conduct testing according to quality management system principles** to ensure the highest level of quality and accuracy.
- All programmes should use the document entitled *Improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results (121)* for guidance on **how to plan, implement and improve** the quality of HIV testing.
- **In vitro diagnostics (IVDs) should meet regulatory standards** according to national guidelines. In addition, WHO conducts an independent prequalification assessment of IVDs, with particular emphasis on HIV RDTs and IVDs intended for use at or near to the point of care in resource-limited settings.
- In certain situations providers may refer individuals to another site for additional testing to verify their HIV status. **Consistent, clear, confidential and accurate record-keeping and communication are critical** at both the initial testing site and the referral centre.

8 QUALITY ASSURANCE OF HIV TESTING

Definitions

Quality management system: a system to **direct and control an organization** with regard to quality.

Quality assurance (QA): a part of quality management focused on **providing confidence** that quality requirements will be fulfilled.

External quality assessment (including proficiency testing) (EQA): inter-laboratory comparison to determine if the HIV testing service can provide the correct test status.

Quality control/process control (QC): a material or mechanism which, when used with or as part of a test system (assay), monitors the **analytical performance** of that test system (assay). It may monitor the entire test system (assay) or only one aspect of it.

Quality improvement (QI): a part of quality management focused on **increasing the ability** to fulfil quality requirements.

Source: WHO, 2010 (11).¹

8.1 Assuring the quality of HIV testing results

Ensuring correct HIV test results is a priority and a crucial component of WHO's 5 Cs for HTS (44). Recent reports suggest that the quality of HIV testing may be suboptimal in many settings. Misdiagnosis of HIV status – both false-positive and false-negative results – has been reported (40, 42, 43, 238, 258, 261). It is a priority for ministries of health and national AIDS control programmes to implement robust quality management systems that deliver high-quality and accurate reporting of HIV status (262).

Any programme considering the expansion of HTS, including facility-based testing (laboratories, clinical facilities), community-based testing and testing conducted at point of care should have the following elements in place:

1. a national **HIV testing policy** that is regularly updated and linked to the national laboratory policy and strategic plan;

¹ See also, ISO 9000:2005. Quality management systems – Fundamentals and vocabulary. Geneva: International Organization for Standardization; 2005 (<https://www.iso.org/obp/ui/#iso:std:iso:9000:ed-3:v1:en>, accessed 30 June 2015).

2. access to **quality-assured in vitro diagnostics** with adequate **pre-market and post-market regulatory controls**;
3. validated **national testing algorithm(s)** with back-up options in accordance with the appropriate WHO-recommended **testing strategy** (44);
4. **quality management systems** for all HIV testing, irrespective of where testing takes place;
5. adequate **training and supportive supervision** of HIV testing providers, with requirement for certification;
6. **accreditation** (or registration/certification) of testing sites, where applicable;
7. accurate **forecasting** and, therefore, quantification, with **procurement systems** in place to avoid stock-outs of test kits and critical consumables (44, 97).

Countries implementing HIV testing should ensure that a comprehensive training package has been developed and training conducted that focuses on ensuring the competency of HIV testing providers. All providers should have adequate hands-on training on the requisite SOPs in order to perform individual assays and follow national testing algorithms. In addition to training on specific test procedures and testing algorithms, training should also include (1) how to keep testing records as standardized logbooks or testing registers, (2) an understanding of the importance of QC, (3) an understanding of the importance of EQA schemes (proficiency testing programmes) and of the role of providers who perform HIV testing in these schemes and (4) how to respond to site supervisory visits and any recommended corrective actions.

At the country level the national reference laboratory, with mandate from the ministry of health, should plan and implement a variety of quality assurance activities to monitor and improve the quality of testing. These activities may be decentralized at the provincial or district level depending on the scope of the activities. These activities include promoting the use of standardized logbooks or registers, implementing EQA schemes, extraction and analysis of EQA data and implementation of corrective actions. These key activities should be systematically planned and implemented to maximize their impact on the accuracy of HIV testing (Fig. 8.1).

A quality management system requires a continuous cycle of quality assurance regardless of where HIV testing is carried out or the type of assays used. It is critical that quality assurance is not seen as a one-off activity or an activity that is undertaken by one person only. Instead, quality assurance should be seen as an integral part of the continuing roles and responsibilities of each and every staff member. Through this framework countries can **plan, implement, evaluate, improve and sustain** quality assurance activities. Such frameworks and provisions apply not only to test accuracy but also to ensuring the quality of pre-test information and post-test counselling.

Planning focuses on planning for QA through engaging leadership, establishing a national QA coordination team, defining roles and responsibilities, reviewing and developing policies that include QA and financing and staffing for QA.

Implementing focuses on implementing QA through training of HIV testing providers and their certification, site accreditation (may also be called site registration or

Fig. 8.1. Quality assurance cycle: a continuous quality assurance and improvement process



Source: WHO, 2015 (97).

certification), supportive supervision, adequate quality/process control, documentation and record-keeping and ensuring a robust supply chain.

Monitoring focuses on evaluating quality through post-market surveillance and EQA, using data for decision-making, making improvements, undertaking advocacy and communication, and increasing country ownership.

For information on how to implement a quality system, particularly for HIV testing at the point of care, see WHO/CDC guidance on this topic, *Improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results (97)* and *Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach (263)* (http://www.who.int/diagnostics_laboratory/publications/HIVRapidsGuide.pdf).

The responsibility for ensuring the quality of testing should be seen as a continuum throughout each tier of the health system. Users of HTS should also demand quality in the testing services provided to them, in both community-based and facility-based HTS. Table 8.1 details roles and responsibilities of HTS staff.

Table 8.1. Roles and responsibilities for all staff to ensure the quality of HIV testing services

Level	Where	Counselling	Testing	Records	Supplies
0 Community	Outside of facilities (home-based, mobile, outreach)	Monitor own performance Conduct client exit interviews	Adhere to SOPs Conduct QC Participate in EQA schemes	Keep accurate testing records	Ensure sufficient test kits and supplies
1 Primary	Facility-based (stand-alone, clinical, laboratories)				
2 District	Clinical facilities, district laboratories	Monitor own performance Conduct client exit interviews Provide supportive supervision of counselling in levels 0, 1, 2 Suggest corrective actions	Adhere to SOPs Conduct QC Participate in EQA schemes Provide supportive supervision of testing processes in levels 0, 1, 2 Suggest corrective actions	Aggregate data (EQA schemes, NCs) on a monthly basis	Order test kits/supplies from national level Distribute QC specimens & EQA scheme panels
3 Provincial	Clinical facilities, provincial laboratories				
Level	Where	General roles/responsibilities			
4 National	National reference laboratory	Validate national testing algorithms Perform lot verification testing for post-market surveillance Produce QC specimens and EQA scheme panels Evaluate data (EQA schemes, NCs) from all districts/provinces on a monthly basis, suggest corrective actions Develop site SOPs and job aids Conduct training using standardized hands-on curriculum			
	Ministry of health	Ensure testing sites' readiness for accreditation (laboratories, clinical facilities) or site registration (stand-alone sites, community programmes) Establish national HIV testing policy that includes QA Establish national QA coordination team Allocate resources for QA Procure, store and distribute test kits/supplies			
	Regulatory bodies	Set national regulatory standards for IVDs Set standards for accreditation/certification of testing sites Respond to field safety notices arising from post-market surveillance			

SOP: standard operating procedure; EQA scheme: external quality assessment scheme; NC: non-conformance; IVDs: in vitro diagnostics.

Sources: Taegtmeyer et al., 2003 (264); WHO, 2010 (11); WHO, 2015 (97).

8.2 Regulations for in vitro diagnostics

Before an HIV assay is marketed and after it is on the market, its quality must be assured. In vitro diagnostics (5) (hereafter referred to as diagnostics) are classified by regulatory authorities according to the risk they may pose to public health and individual health, taking into account the potential outcomes and impact if the result is incorrect. Diagnostics for HIV usually attract the highest level of scrutiny in their pre-market assessment review, given the high impact of an incorrect result on individual and public health in terms of HIV transmission.

The WHO Prequalification of In Vitro Diagnostics Programme promotes and facilitates access to safe, appropriate and affordable diagnostics of good quality (265). The current state of regulation for diagnostics in many countries is less than optimal, both for pre-market assessment and post-market surveillance. Therefore, WHO independently reviews the quality, safety and performance of diagnostics that are available in markets in resource-limited settings.

8.2.1 Pre-market assessment of diagnostics

WHO conducts the prequalification assessment of diagnostics using a standardized procedure to determine if the product meets WHO prequalification requirements. The assessment consists of three key components:

- review of safety, quality and performance of the assay as presented in a **product dossier** prepared by the manufacturer
- desk review of the quality management systems applied during production, followed by a **site inspection**
- independent **laboratory evaluation** of performance and operational characteristics.

The publication *Overview of the prequalification of in vitro diagnostics assessment* (265) provides further information. Annex 8 provides additional details about how the WHO prequalification assessment is conducted.

8.2.2 Post-market surveillance of diagnostics

Once a product is placed on the market, its quality, safety and performance must be monitored to ensure that diagnostics continue to meet standards. WHO has established a system for post-market surveillance of diagnostics that supplements the obligations of manufacturers, who must also conduct their own post-market evaluation activities.

In this context post-market surveillance consists of:

- **proactive post-market surveillance** (to identify any problem before use) through in-country lot verification testing, both before and after distribution of test kits to testing sites; and
- **reactive post-market surveillance** (when a problem has been identified during use of the diagnostic) through reporting and evaluation of complaints, including reports of adverse events, and any required actions to correct the problem and prevent recurrence.

WHO's *Guidance for post-market surveillance of in vitro diagnostics* provides further information (http://www.who.int/diagnostics_laboratory/postmarket/150210_pms_ivds_guidance.pdf?ua=1).

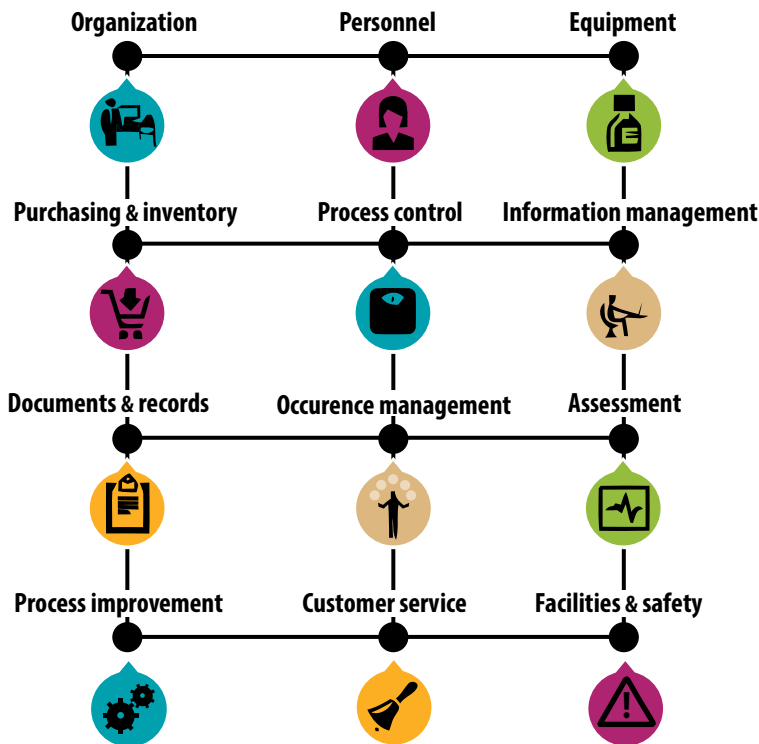
Annex 8 provides a detailed description of activities that contribute to post-market surveillance.

8.3 Quality management systems, irrespective of the testing setting

A quality management system can be implemented to varying degrees, but the basic principles still apply to any service providing HIV testing results. Any site conducting HIV testing should implement a quality management system that incorporates the elements summarized in Fig. 8.2 and detailed in the following pages.

The WHO *Laboratory quality management system: handbook (266)* (<http://www.who.int/ihr/publications/lqms/en/>) provides further guidance on quality management systems.

Fig. 8.2. The 12 components of a quality management system





Organization

Irrespective of their location, both facility-based testing services (laboratories and clinical facilities) and community-based testing services should have a commitment to assure quality. All testing services should have a quality policy that specifies the following aspects of the quality of HTS:

- ensuring that competent staff (including lay providers) are employed (see "Personnel" below)
- ensuring purchase of quality-assured test kits, equipment and consumables (see "Equipment" and "Purchasing and inventory")
- ensuring QC of testing processes (see "Quality control")
- creating and managing documents (see "Information management")
- keeping records confidential (see "Information management")
- recording and following up on complaints (see "Occurrence management")
- evaluating and following up on results of EQA schemes/proficiency testing and on-site supervision (see "Assessment").

A generic quality policy may be developed nationally for all types of testing sites that are similar on the basis of, for example, assay formats used, infrastructure available and type of testing providers. These policies may require adaptation, based on input from management and other staff and volunteers, to ensure that they are appropriate to the specific site.

How to implement

- Ensure that **policies, processes and procedures** are relevant for the specific type of testing service.
- Ensure that there is **professional commitment** to the quality of the HTS, with regular management review of the quality policy.
- Assign one staff member in each HTS site as the quality representative, who **champions the quality** of all aspects of the HTS.



Personnel

All testing services must employ the number of trained, certified and supported personnel to conduct each of the elements of HIV testing that is adequate for the expected number of tests conducted and the number of people being served. To assess and manage human resource planning, tools such as the WHO Workload Indicator for Staffing Need (WISN) (http://www.who.int/hrh/resources/wisn_user_manual/en/) can be useful to calculate the number of health workers and lay providers needed to provide adequate HTS.

All personnel, including those taking specimens, conducting testing, providing reports of HIV status and data clerks and other auxiliary staff, must be trained adequately. All staff

members should have appropriate qualifications, such as certifications according to national guidelines, and demonstrated proficiency in performing the tasks within their scope of work.

Both pre-service and in-service training, including periodic refresher trainings, should be part of the training requirements for all testing services. This is particularly important for sites with very low specimen throughput or where HIV testing is performed occasionally. In addition, regular **supportive supervision** and ongoing **mentoring** of all staff are essential. Ensuring the psychological and physical well-being of HIV testing providers is critical. In particular, good vision is required for visually read assays.

How to implement

- Develop a site **organogram** that describes the roles and responsibilities of all staff members in the testing service, including those who may collect specimens, who may perform testing, who may report HIV status and who may double-check test results and HIV status reports.
- Maintain **training checklists** for all staff members.
- Encourage a yearly **bidirectional performance appraisal** to discuss any issues that may affect a provider's ability to perform his or her assigned tasks.

Furthermore, at a national level, it is critical to have:

- national human resources planning and management systems, including human resource information systems;
- strong pre-service education institutions;
- standardized and coordinated in-service training (with hands-on practicum and competency-based assessment);
- an inclusive national policy that supports task sharing, with scope for lay providers to conduct testing and issue test reports;
- recruitment and retention strategies, especially for rural and underserved areas;
- advancement of health worker regulation and policy, including capacity-building of regulatory bodies and professional associations.



Equipment

Regardless of where testing takes place and whether it is performed using HIV RDTs or laboratory-based diagnostics, it is critical to have appropriate equipment available and fully functional.

For testing services using primarily RDTs, it is important to have **timers** and access to **refrigerators** if ambient temperatures will exceed the manufacturer's recommended storage temperatures.

For HTS that rely on laboratory-based techniques, **calibration and maintenance of equipment** is paramount for providing accurate testing results.

How to implement

- Maintain an **inventory** of all equipment.
- Ensure that all equipment in the inventory is subject to **preventive and corrective maintenance** on an appropriate cycle, depending on throughput.
- Ensure that equipment that is not working is prominently labelled as such and, therefore, not used in any process to provide testing results.
- Ensure that **SOPs** exist for all equipment, with instructions, for example, on how to turn on and off, how to clean and any calibration that the user must make.



Purchasing and inventory

Purchasing refers to activities that must be undertaken at the programmatic level to ensure that adequate supplies of test kits and other items required for the testing process are available on-site.

Stock-outs of HIV test kits or any essential consumables, such as lancets, alcohol swabs or specimen transfer devices, are one of the biggest sources of poor quality and client dissatisfaction with HTS. Lack of the first-line assay (A1) may lead to use of a less sensitive assay instead (A2 or A3 instead of A1). The lack of single-use specimen transfer devices will lead to an incorrect specimen volume added, which will increase the risk of an inaccurate test result.

It is necessary to ensure that an adequate system is in place at the testing service site to **track procurement of test kits, reagents and consumables** (venous or capillary blood collection supplies) when they are ordered and when received. Each HIV testing service should then track consumption of all test kits and consumables so that they can inform the central medical stores (or other purchasing body) when they need to replenish stock. As stocks are received, it is critical to take special note of expiry dates and to order ahead, allowing adequate time for the next delivery.

Further information is available in *WHO manual for procurement of diagnostics and related laboratory items and equipment* (http://www.who.int/diagnostics_laboratory/procurement/en/). A second edition is planned for 2015.

How to implement

- Maintain a **list of inventory requirements**, for example, assays, consumables or additional supplies such as gloves, lancets, alcohol swabs and disposal containers.
- Ensure adequate physical **space to store test kits** (including refrigeration if room temperature is above manufacturer's recommended storage conditions) and record storage temperatures.
- Do not split larger test kits into smaller quantities.

It is critical at the national level to have regulatory processes and procedures that support the procurement of quality-assured diagnostics, equipment and other items required for providing HTS.

For additional information see Annex 8.



Quality control

Quality control, also known as process control, refers to processes and activities to ensure that **testing procedures** are performed correctly, that **environmental conditions** are suitable and that the **assay** works as expected. QC intends to detect, evaluate and correct errors due to assay failure, environmental conditions or operator performance before test results are reported as the HIV status. Hence, QC is a multi-step 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 record the temperatures.
 - Check 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 and/or external QC specimens) and that the results are within QC acceptance criteria.
 - Ensure that a second reader will reread (double-check) all visually read assays.
- After testing (post-analytical):
 - Double-check the report of the test status to the client.

Ideally, a **second reader** should make a blinded rereading of any visually read assay. This is standard practice for visually read assays, both for HIV and for other conditions. 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, then an HIV status is reported as is. If the two readers do not agree, HIV testing should be repeated using a new specimen and a new test device. Interreader disagreement for RDTs ranges from 0 to 1.6% (9, 250).

Internal QC refers to processes within the assay that check whether the test procedure is working; the appearance of a control line for HIV RDTs is an example of internal QC.

Only a few RDTs contain a control line that indicates that the specimen has been added. Instead, most RDTs contain a control line that indicates only the flow of liquid, rather than that the specimen has been added or that the correct volume of specimen has been added.

Test kit controls (known as positive and negative controls) may be supplied by the manufacturer. They are standard for most assay formats, with the exception of RDTs. Few HIV RDTs have accompanying test kit controls, making QC problematic.

As an addition to or even a substitute for the test kit controls, **external quality control specimens** may be produced. These are prepared and validated by the QC specimen provider (usually the national reference laboratory or a commercial entity) for the assay separately from the manufacturer. The dried tube specimen methodology is useful in this regard. See Annex 8 for information about the preparation of QC specimens for RDTs.

Any test kit controls should be run according to the manufacturer's instructions, and external QC specimens should be run:

- once weekly, preferably at the beginning of the week
- for any new operator (including trained staff members who have not conducted testing for some time)
- for each new lot of test kits
- for each new shipment of test kits
- when any environmental conditions (for example, temperature and humidity) fall outside the range recommended by the manufacturer.

How to implement

- Establish criteria for **specimen acceptance or rejection** and specimen storage, retention, disposal and referral of the specimen to another site for testing.
- Establish criteria for **QC of qualitative and quantitative assays** with established limits of acceptability.



Information management

Information management consists of the **paper-based and electronic systems** for storing records and documents, including emails or text messages that provide testing results or reminders to clients. It is closely linked to documentation and record-keeping.

To assure the quality and integrity of the test status given to a client, HTS must minimize the risk of transcription errors. Assigning client identification numbers and specimen identification numbers to each subsequent specimen received from the same individual will reduce the possibility of transcription errors. It will also protect the confidentiality of people undergoing HIV testing. Linking a series of HIV test results also is critical when retesting is used to verify a client's HIV-positive diagnosis or to resolve a client's HIV-inconclusive status.

It is critical that all information be kept **confidential**, with access restricted to qualified staff.

Automated electronic RDT readers that can accommodate one or many brands of RDTs are increasingly becoming available. Many of these RDT readers can connect to 3G or 4G wireless networks. Such connectivity also can be useful for quality assurance, for procurement and for data management.

How to implement

- Each client who enters the service should be assigned a **unique client identifier** so that the results of each subsequent specimen tested from the same person can be tracked. An identifier number comprised of three letters and three numbers could be used for the client identifying number, for example, AAA 000, AAA 001, etc.
- Each specimen should be assigned a unique **specimen identifying number**. An 8-digit consecutively assigned number is sufficient for the specimen identifying number, for example, 0000 0001, 0000 0002, etc.



Documents and records

Documentation is critical to ensure that a correct HIV status goes back to the correct individual undergoing testing. **Documents** are policy, process and procedural documentation for all aspects of the testing service and its quality management system. It is critical that documents are approved prior to use, revised when necessary and removed from circulation when they become obsolete.

Job aids are useful tools for HTS. These are short, concise documents that describe each test procedure, how to interpret test results according to the validated testing algorithm and how to refer for retesting. Annex 8 presents an example of a generic job aid for an HIV RDT.

Records are generated as a result of performing testing activities. It is critical that these are filed correctly and stored for up to five years. Records are particularly important for retesting referrals to rule in or rule out HIV infection and community-based testing services where the results may be confirmed at another testing facility.

The types of records required for a quality system are:

- specimen request forms
- testing/laboratory logbook
 - The logbook should record details to identify the person undergoing testing (client identifier, name [optional], date of birth [optional]), the assays used (with lot numbers and expiry dates), the test results (preferably, band intensity when using RDTs), both readers' results (when using RDTs), date of test run, name of operator and QC results.
- overall status as given to the individual
- referral slips for retesting or other post-test services
- staff training records and other personnel records
- internal and external audit reports
- non-conformance and complaint records, with action taken
- equipment maintenance records and inventory charts.

How to implement

- Ensure that SOPs exist for all procedures, including specimen collection and processing requirements, testing algorithms and all test procedures, with QC and final reporting (in accordance with a validated testing algorithm).
- Keep equipment maintenance records and temperature records for refrigerators, freezers and the testing room.
- Keep laboratory notebooks, testing registers and forms used to record testing results.

For an example of a standardized testing register, or logbook, see *Improving the quality of HIV-related point-of-care testing: ensuring reliability and accuracy of test results (97)* or *Guidelines for assuring the accuracy and reliability of HIV rapid testing: applying a quality system approach (263)* (http://www.who.int/diagnostics_laboratory/publications/HIVRapidsGuide.pdf).



Occurrence management

Occurrence management refers to processes for detecting and documenting non-conformances and then implementing any necessary corrections. A **non-conformance is something that went wrong**; a problem has occurred and needs to be addressed. A non-conformance might be a lack of documented processes or procedures or when documented processes or procedures are not followed. For occurrence management to have a meaningful effect, it must be investigated and the problem corrected.

The following sources of data may be used to check if there are problems or potential mistakes made:

- internal audit reports
- supervisory visit reports
- QC data, including higher than expected rates of invalid results (for example, when using RDTs, if no control line appears or a high background on the test strip obscures the reading window)
- results of EQA schemes (proficiency testing)
- a higher than expected rate of discrepant test results.

How to implement

- Establish a system to immediately **capture quality issues or problems**, and then identify the root cause and implement corrective action.
- To identify non-conformance, **routinely monitor indicators**, such as turnaround times for each assay, turnaround time for an overall testing report, rate of discrepant results, rate of invalid results, rate of specimen rejection, rate of test kit stock-outs, rate of supplies stock-outs and frequency of expiration of test kits.



Assessment

Testing services should undertake both internal and external assessment to assure the quality of testing. 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 has enough familiarity with the process to conduct an audit.

External quality assessment assures that assays are performed accurately, results are reproducible, and errors are detected and corrected to avoid misclassification or incorrect diagnosis. EQA usually takes the form of participation in EQAs (also called proficiency testing), which include following up any unacceptable EQA results with corrective actions.

The objectives of participating in EQA schemes are to:

- evaluate testing competence
- assess performance of specific testing providers
- evaluate the reliability of HIV testing procedures
- establish the accuracy of reports of HIV status
- provide information for self-evaluation.

Annex 8 presents additional details on how to implement EQA schemes.

Rechecking specimens using dried blood spots (DBS) as an EQA mechanism is no longer recommended, given the recommendation to retest all HIV-positive individuals prior to starting ART.

Another form of external assessment is **accreditation** of testing sites (may be referred to as registration or certification) by an external certification body.

How to implement

- All testing sites (facility- and community-based) should participate in **EQA schemes**.
- All testing sites (facility- and community-based) should receive support through **on-site supervision**.
- All testing sites (facility- and community-based) should be **registered, certified or accredited**, according to national guidelines.



Process improvement

Testing services need to identify areas requiring improvement, plan and undertake improvements and evaluate their effect. This is sometimes referred to as **quality improvement (QI)**. 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 to the flow of clients through the testing site. Programmes may use data from internal audits, participation in EQA schemes and on-site supportive supervision to improve testing processes.

A **corrective action** is an action taken to address a problem, removing its root cause or reducing or eliminating its recurrence. A **preventive action** is an action taken to avoid a possible problem or reduce the likelihood that it will happen. Data from EQA activities and process control can guide corrective and preventive actions in the framework of continued process improvement.

Process management links closely with activities associated with occurrence management.

How to implement

- Site supervisors should **proactively identify opportunities** for improvement of services and then relay these to a higher level of management for implementation of better working practices.



Client service

Programmes need to ensure client (customer) satisfaction with the testing service. This includes both so-called internal clients, such as doctors, nurses, counsellors and other health-care workers, and external clients, such as individuals undergoing testing, professional associations and regulatory agencies. Ensuring client satisfaction means meeting their expectations of quality, for example, delivering **accurate results in a timely manner**.

How to implement

- Seek feedback from clients through, for example, **periodic exit interviews**. Feedback may focus on such aspects as convenience of opening hours, friendliness of the testing environment and satisfaction with post-test counselling.
- Establish a **client suggestion box** for anonymous reporting, including complaints.



Facilities and safety

It is critical that testing facilities are well-designed and maintained. The testing site, including where counselling takes place, where specimens are taken and where the test is performed, should be clean and comfortable, with adequate lighting (for reading visually read assays) and free of any potential hazards.

It is imperative to follow the assay manufacturer's recommendation for the ambient temperature of areas where testing is performed. Where possible, testing should take place in climate-controlled areas. There must be proper **waste disposal** for biological (infectious and non-infectious), chemical and paper waste and sharps.

Facilities should be organized to protect the **confidentiality of clients**, including a separate waiting room for those requiring additional testing, as how long a person stays in the same waiting room or how often a person leaves and returns may imply the result of their first assay (A1).

It is critical to guard against harm to any client, HIV testing provider or other person at the testing site. This means that a **safe working environment** must be maintained by and for all staff, with necessary procedures in place. These procedures include universal precautions (assuming that all specimens are potentially infectious), prevention of and/or response to needle-stick injuries or other occupational exposures, chemical and biological safety, spill containment, waste disposal and use of personal protective equipment.

For HIV testing that takes place outside of a facility, programmes must ensure that the providers can conduct the testing without hazard to themselves or to the 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 on **biological and chemical safety** measures.
- One staff member at each testing site should act as a **safety champion**.

8.4 Quality improvement for HIV testing

Quality assurance is not a once-and-done occurrence. Testing providers and managers must continually monitor and evaluate their programme and improve the quality of services. To maintain a coherent, functioning quality management system that addresses national, subnational, facility and community concerns, all stakeholders must be involved at every level to monitor quality and make improvements. Middle- and low-income countries have applied a range of 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 that need to be addressed.

HIV TESTING IN THE CONTEXT OF SURVEILLANCE

9

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KEY POINTS

- In light of the individual and public health benefits of widely available ART, WHO and UNAIDS recommend that countries work toward enabling **all participants in biological surveillance to receive their HIV status**.
- **Key populations and vulnerable groups should be prioritized** in HIV surveillance activities. In generalized epidemics additional periodic national population-based surveys are recommended.
- HIV surveillance activities that issue results back to participants should use the **same testing strategies** (tailored to HIV prevalence) **and testing algorithms as used for HIV diagnosis** (see Chapter 7).
- HIV surveillance systems **should use programmatic data whenever possible**, particularly data from PMTCT programmes and HIV diagnosis.
- HIV surveillance activities are encouraged to **collaborate with biological surveillance activities for other, overlapping epidemics** such as TB, STIs and viral hepatitis. This collaboration expands monitoring and enhances the efficiency of the HIV response.
- Providers of HTS are encouraged to **participate in HIV case reporting**, which should be part of a country's national HIV surveillance system. Case reporting data are used to assess the number of people in need of treatment and care and to inform the planning and allocation of resources.

9 HIV TESTING IN THE CONTEXT OF SURVEILLANCE

9.1 Overview

The surveillance of HIV is essential for monitoring epidemic trends and evaluating the effectiveness of a country's response. HIV sentinel surveillance and population-based and community surveys that include HIV testing are important components of HIV surveillance. They are used to estimate the prevalence and geographical distribution of infection, identify and characterize key populations at risk for HIV infection and track trends over time. Countries need these data to inform effective policies, strategic plans and programmes and to set evidence-based programme targets.

HIV testing is a component of HIV surveillance. The type of testing strategy and algorithm applied affects biological surveillance results. This chapter updates previously published WHO/UNAIDS guidelines for HIV testing in the context of surveillance, last revised in 2009 (http://www.who.int/hiv/pub/surveillance/hiv_testing_technologies_surveillance.pdf) (267). Advances in HIV testing, treatment and care have prompted this update. In particular, the wide availability of treatment, increasing evidence of the patient-level and public health benefits of treatment and an unmet demand for HIV testing have propelled a move away from surveillance using unlinked anonymous testing (UAT), in which remnant specimens that cannot be linked back to the study participant are tested for HIV. In the current context the use of UAT raises ethical concerns (268–270). In addition, opportunities to use leftover specimens from testing for other analytes (infections) for HIV biological surveillance are diminishing, as RDTs are more commonly being used, which leave no remnant specimen.

As HIV programmes evolve, countries increasingly want to use programme data to complement or to replace data generated from sentinel sites. ANC clinics with PMTCT services, in particular, may seek to use programme data in place of conducting annual sentinel surveys. As biological surveillance is not the primary purpose of testing in programmes, any use of these data requires a thorough assessment of the potential impact that a transition from HIV sentinel surveillance to the use of programmatic data may have on national estimates, given the potential bias introduced by a different sampling frame.

The aim of this chapter is to help countries with different epidemic contexts (generalized or concentrated) and populations to adopt an appropriate approach to HIV testing in the context of biological surveillance (99, 271–274). The chapter provides technical information for providing HTS and for HIV surveillance systems in the following areas: (1) populations selected for biological surveillance; (2) approaches for HIV testing in the context of surveillance; (3) the use of programme data for biological surveillance; and (4) HIV case reporting.

With an extensive consultative and review process by international experts and WHO regional offices, the UNAIDS/WHO Working Group on Global HIV/AIDS/STI Surveillance developed, reviewed and revised the guidance included in this chapter.

9.2 Populations selected for biological surveillance

The populations selected for HIV biological surveillance depend on the state of the epidemic. For low-level and concentrated epidemics, HIV infection is mainly confined to key populations, as well as context-specific subgroups. Key populations include men who have sex with men, people in prisons or other closed settings, people who inject drugs, sex workers and transgender people. Other groups at high risk for HIV, depending on country context, may include: long-distance truck drivers, military personnel, and in sub-Saharan Africa young women. Children and adolescents from key populations and vulnerable groups are at increased risk for HIV, and their inclusion in surveillance is important. Countries must take into account, however, domestic laws governing child protection in addition to ethical considerations for conducting research among children. UNICEF provides further guidance on these issues (275). Surveillance activities among key groups must not place new burdens on these populations and must undergo appropriate ethical review (273, 276). Specific guidance has been developed to ensure that surveillance adequately covers these populations, as these populations are often underserved and their access to HTS is often insufficient (277).

In generalized epidemics, where HIV transmission is established among the general population, national population-based biological surveys are used to obtain estimates of HIV prevalence (272). Additionally, sentinel surveillance may be conducted among attendees (pregnant women) in ANC services (271). It is recommended that programmes shift from using ANC surveillance data to PMTCT data. For further information, see section 9.5 and *Guidelines for assessing the utility of data from prevention of mother-to-child transmission* (<http://who.int/hiv/pub/surveillance/2013package/module3/en/>).

In some regions HIV presents a significant challenge to the control of TB and, likewise, TB is a major burden among people with HIV. HIV testing for biological surveillance should include people with diagnosed or presumed TB and, where feasible and appropriate, HIV biological surveillance should incorporate TB screening as routine practice among those found to be HIV-positive (278).

HIV testing for surveillance should also include people at risk of other STIs, including HCV and HBV infections. The management of infections diagnosed as part of HIV surveillance should follow WHO guidelines (279–282).

Given the overlap of the HIV and TB epidemics, and the shared risk factors for HIV, STIs, HCV and HBV infections, countries should seize any opportunity to integrate biological surveillance activities. This integration can both expand epidemic monitoring and response and enhance efficiency. For all these closely linked diseases, WHO recommends that HIV biological surveillance activities adopt a collaborative approach to maximize the return on investment and meet programme objectives (279, 283).

WHO recommendations

- HIV surveillance should prioritize key populations as well as other vulnerable groups.
- Biological surveillance should be conducted among people with presumed or diagnosed TB or at high risk for other STIs, including HBV and HCV infections.
- WHO recommends a collaborative approach to surveillance of HIV and closely linked infections to expand epidemic monitoring and response and enhance efficiency. Any of these infections that are diagnosed as part of HIV surveillance activities should be managed according to WHO guidelines.
- It is recommended that programmes move from using ANC surveillance data to PMTCT programmatic data. However, WHO still recommends regular, national population-based surveys and sentinel surveillance among ANC clinics in countries with generalized epidemics.
- WHO recommends that surveillance systems use the same testing strategy (tailored to HIV prevalence; see Chapter 7) and the validated national testing algorithm recommended for HIV diagnosis. This is particularly critical when test results and an HIV status are reported back to an individual.

Sources: UNAIDS/WHO, 2003 (271); UNAIDS/WHO, 2005 (272); UNAIDS/WHO, 2011 (273); WHO, 2013 (274); UNICEF, 2013 (275); WHO, 2013 (275); UNAIDS/WHO, 2015 (277); WHO, 2012 (278); UNAIDS/WHO, 1999 (279); WHO, 2003 (280); WHO, 2003 (281); WHO, 2015 (282); UNAIDS/WHO, 2004 (283); WHO, 2014 (284).

Case examples: Test result discrepancies between surveillance and programmatic data in antenatal care services

Across nine countries with generalized HIV epidemics, substantial discrepancies in HIV test result were reported between on-site PMTCT diagnostic testing and central-level testing done for ANC sentinel surveillance. The reasons for these discrepancies are unknown. Discrepant results may be caused by suboptimal stock management, operation or interpretation of field-based HIV rapid tests or suboptimal operation or interpretation of laboratory-based EIA tests. Suboptimal testing strategies and algorithms for surveillance and diagnosis may be one factor contributing to the difference in test results. To prevent such discrepancies, it is important not only to monitor and improve the quality of diagnostic and surveillance testing, but also to encourage programmes and countries to use a testing strategy and a validated national testing algorithm that are suitable for both HIV diagnosis and biological surveillance.

Source: CDC, unpublished, 2014.

9.3 Returning HIV test results to participants in biological surveillance

In the past HIV surveys that collected biomarkers typically did not return test results to study participants. The 2009 WHO guidance on ethical principles in HIV surveillance stated that participants in surveillance must be given the opportunity to learn their status (276). At a September 2014 WHO/UNAIDS global meeting to update the *Guidelines for using HIV testing technologies in surveillance*, the group further discussed ethical considerations concerning returning HIV status to participants in surveys.

The group reached consensus on the importance of surveillance systems' assuring that all participants receive their HIV status and that this should be prioritized in any biological surveillance activity. At the same time, all efforts must be made to prevent any adverse consequences of informing participants of their status, especially in surveys that collect biomarkers among marginalized or criminalized populations. Any consideration of potential additional costs should factor in returns in life-years saved due to earlier diagnosis and treatment.

Details on the meeting discussion and conclusions can be found in *Routine feedback of test results to participants in HIV clinic-based surveillance and surveillance surveys: WHO and UNAIDS meeting on HIV testing in surveillance* (268).

WHO recommendation

HIV surveillance systems should work toward assuring that all participants in biological surveillance receive their HIV status to further facilitate appropriate linkage to care. However, all efforts must be made to prevent any adverse consequences of informing participants of their HIV status, especially in surveys among marginalized and criminalized populations.

Sources: WHO/UNAIDS (276); Baggeley et al., 2015 (268).

9.4 Approaches for HIV testing in the context of surveillance

Linked testing is the HIV testing approach used in surveillance that enables participants to receive their HIV status. Linked testing can be **confidential** (using personally identifiable information) or **anonymous** (using only a code or number as a unique identifier). This approach contrasts with **unlinked anonymous surveillance**, which is no longer recommended. With linked HIV testing, the participants should receive pre-test information and post-test counselling as well as their test results and their HIV status (see Chapter 3). Chapter 7 provides details on HIV testing strategies and algorithms for linked testing.

In **linked confidential testing**, the participants agree to be tested for HIV with the assurance that their HIV status will remain confidential and will be available only to the participant and, on a need-to-know basis, to health-care staff. As with all HIV testing, the staff member must obtain the participant's consent before collecting the specimen

and conducting HIV testing (see box). The consent process must inform the person how the data are to be used, including security details of any registry where the data are maintained. The staff member collects the demographic details of the participant (for example, age, sex, marital status, geographical area of residence, parity, education and medical history) at the time the specimen is obtained and records this information on a surveillance form (either paper or electronic). The surveillance form should be indexed with an identifying code or other details (for example, the participant's name or the clinic's client/patient identification number) that can be used to match the form to the specimen. On completion of HIV testing, the demographic details collected on the surveillance form are linked to the result.

Consenting to HIV testing for biological surveillance

Informed consent is an essential part of HIV testing, including testing for surveillance. Consent should always be obtained individually and in private. To give informed consent, the participant must have an adequate understanding of the HIV testing process. Health workers should ensure that no one is coerced into testing, and participants must understand that they have the right to opt out at any point. Under no circumstance should HIV testing be mandatory. See Chapter 3 for details on obtaining consent for HIV testing.

In **linked anonymous** testing only the participant with knowledge of his or her unique study code can link himself or herself to the test result when provided with a list of results and study codes. The same methods are used for collecting and processing the specimen as for linked confidential testing, except that the specimen is labelled with an anonymous, unique study code. No personally identifiable information should be recorded. With this approach it is important not to collect too much information, which could identify the client through a combination of their characteristics. It is not possible to add participants in anonymous linked testing to a registry.

The variables to be collected for biological surveillance should be listed clearly on standardized surveillance forms. These variables may include results of other tests related to the HIV diagnosis (for example, CD4 cell count and viral load), results of tests for recent HIV infection, any STI diagnoses or diagnoses of co-morbidities including TB and information on previous use or exposure to ARVs. Which variables to include will depend on the setting, collaboration with other programmes and the intended outputs of biological surveillance.

The choice of confidential or anonymous linked testing will depend on the setting and the population to be surveyed. Linked anonymous testing may be preferred by surveillance system staff for hard-to-reach or marginalized populations, as participants may not want personally identifiable information to be linked to information on their risk behaviours, which may be stigmatized (for example, same-sex sexual partners). Confidential testing has the advantage of enabling health workers to refer positive participants to care promptly. However, confidential testing could introduce participation bias if the request for personally identifiable information deters people from participating.

WHO recommendations

Linked HIV testing approach for biological surveillance

- A linked HIV testing approach for biological surveillance, either confidential (using personally identifiable information) or anonymous (using unique study codes) **should be used**. This allows test results to be readily accessible to the survey participant, either during the study period or at a later date.

Source: UNAIDS/WHO, 2014 (285).

- Increasingly, countries are attempting to measure HIV incidence – the rate of new infections – through surveys that collect biomarkers, using assays that can distinguish recently acquired infections from established ones. Currently, these HIV incidence assays are intended only for population-level incidence estimates and not for individual disease staging, as they are not sufficiently accurate. Consequently, returning these test results to participants is **not recommended**.

Sources: UNAIDS/WHO, 2011 (286); UNAIDS/WHO, 2015 (287); UNAIDS/WHO, 2015 (288).

9.5 Using PMTCT programme data to replace ANC sentinel surveillance data

With the expansion of HIV testing, PMTCT services, and HIV prevention, treatment and care services, there are increasing opportunities to use data from HIV programmes along with or in place of HIV sentinel biological surveillance. In particular, as PMTCT programmes expand and evolve, the data that they routinely collect are increasingly robust and may be able to provide the same information as that collected through ANC surveys. PMTCT sites that endeavour to use routine programme data for surveillance should be high-performing, meeting the following criteria:

- high coverage of services, that is, >80% of the pregnant women in the population to be surveyed use these services;
- high data quality; for example, sites use routine data collection tools, collect all the variables needed for surveillance outputs and have high data completion rates (>90%);
- high uptake of HIV testing (>90%);
- high quality of HIV testing, supported by a quality management system (see Chapter 8).

HIV surveillance systems must assess the suitability of programme data for biological surveillance before using them. In PMTCT settings, for example, this assessment involves evaluating the likely impact of switching from ANC sentinel data to programme data on surveillance outputs; this can be assessed by comparing HIV prevalence estimates based on both PMTCT programme and ANC sentinel data. Any differences should be investigated to determine likely sources of error, which could be in record-keeping or in conducting assays, including interpretation of test results or using a different testing strategy and/or algorithm. Any differences in the populations included in the survey and programme data should also be examined.

Further guidance on methods for conducting this assessment in PMTCT sites can be found in WHO guidelines for assessing the utility of data from PMTCT programmes for surveillance among pregnant women (192). Detailed guidance on conducting ANC surveillance using PMTCT data can be found in *Conducting HIV surveillance among pregnant women attending antenatal clinics based on routine prevention of mother-to-child transmission of HIV (PMTCT) programme data* (289).

Advantages of using PMTCT programme data for biological surveillance include:

- Ideally, HIV-testing is undertaken as part of routine clinical practice.
- Participants have the choice and opportunity to opt out of testing.
- Participants receive their HIV status.
- HIV testing is conducted in a setting where the infrastructure and resources for pre-test information and post-test counselling already exist.
- Ideally, HIV-positive participants can be linked to HIV treatment and care services.
- HIV-negative participants with ongoing high risk of infection can be linked to HIV prevention services.
- HIV testing and the collection of demographic data are already being performed at these sites.
- Geographical coverage is broader, sample sizes are larger, and the surveillance period is longer.
- Data are collected annually.

Limitations of using PMTCT programme data for biological surveillance include:

- There is potential participation bias:
 - People obtaining HTS may not be representative of the larger population. For example, key groups may be underrepresented or overrepresented depending on the setting, or certain groups may not use health-care services.
 - People may opt out of HIV testing in a non-random pattern.
- Data quality is lower or varies among sites.
- The quality of HIV testing may differ among sites.
- Historical trend data are lacking.

The records of people testing as part of HIV programmes contain personally identifiable information (for example, client/patient identifier, name, date of birth, place or area of residence, clinic number) and sensitive medical data (for example, the results of medical testing, including HIV testing). Thus, to ensure confidentiality, the information needed for surveillance should be recorded onto specific surveillance forms without any identifiers. Unique study codes can be used to index surveillance participants' details (see section 9.3). In some instances, however, personally identifiable information may be needed for surveillance data processing, for example, to identify duplicates or to match records to other data (such as an HIV laboratory logbook or testing register) in order to

complete the surveillance dataset. In these circumstances the personally identifiable information should be permanently removed once the final dataset has been created.

Data from HIV testing records may be transferred to surveillance forms either manually or electronically. When it is done manually, a person on site copies data from routine data tools (for example, registers) onto paper or electronic forms (for example, using computers, tablets or other digital devices). When it is done electronically, the site may elect to send a digital image of the data (such as a scan or photo) to a central location for data management. If routine data are captured as a digital image, personally identifying information can be excluded by physically covering this information before making the digital image. Data security and confidentiality must be ensured throughout this process.

WHO provides further guidance on data confidentiality in *Guiding principles on ethical issues in HIV surveillance* (276). UNAIDS provides guidance on maintaining health identifiers and confidentiality in *Considerations and guidance for countries adopting national health identifiers* (290).

9.6 HIV case reporting

WHO recommends that HIV case reporting form part of a comprehensive national HIV surveillance system (274). HIV case-based surveillance entails reporting all new HIV diagnoses (including those diagnosed at death) to a designated central monitoring body.

Information collected for case reporting should include the clinical stage of the infection, demographic characteristics of the client (for example, sex, age, risk group), date of diagnosis, place of diagnosis and the date and source of the report. Other information collected may include results of routine baseline testing, such as measures of CD4 cell count and viral load, or the results of a biomarker test for recent HIV infection. Programmes must use the validated national testing algorithm for all HIV case reports (see Chapter 7).

Countries that undertake case reporting should provide HTS with protocols detailing how and where to report a diagnosis. Requirements for the confidentiality and security of case reporting data are the same as described in section 9.3. Where case reporting systems retain identifiers to aid in deduplication, enhanced data security may be needed. **Deduplication is essential to any case reporting system.** Systems that do not collect names must use a client/patient identification system, which will allow deduplication. Using a Soundex code, which is created by an indexing system for names,

WHO recommendation

HIV case reporting should form part of a comprehensive national HIV surveillance system. This entails the reporting of all new HIV diagnoses to a designated central monitoring body by HTS providers. Deduplication of case reports is essential to any case reporting system.

Sources: WHO, 2006 (292); UNAIDS/WHO, 2011 (293); UNAIDS/WHO, 2013 (274).

may be an alternative to using a name (291). A Soundex code can be used alongside other demographic information to generate unique identifiers of records.

Further guidance on the definition of a case and on clinical staging for surveillance purposes can be found in *WHO case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV-related disease in adults and children* (292).



MONITORING AND EVALUATION

10

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KEY POINTS

- Monitoring and evaluation of HTS has expanded from measuring numbers such as the number of people tested to **measure HTS effectiveness and outcomes**. The focus is on the proportion of people with HIV who know their status, particularly among those at highest risk, including people from key populations.
- In most settings **key population-specific data** cannot be collected from routine programme monitoring; therefore, WHO recommends investing in special surveys in addition to strengthening routine surveillance.
- Analysing the proportion of people diagnosed HIV-positive **by type of site** is critical for determining where national programmes should allocate resources. HTS programmes should ensure a good balance between facility and community outreach testing strategies.
- In addition to attaining high coverage rates and identifying a high proportion of HIV-positive cases, the quality of HTS depends on **accurate diagnosis** and **effective linkage** to HIV prevention, treatment and care services. It is important to document SOPs, QC results and results of EQA (such as proficiency testing) and to monitor and measure linkage to prevention, treatment and care. Linkage of clients to HIV prevention, treatment and care services is a key measure of HTS.

10 MONITORING AND EVALUATION

10.1 Background and key issues

Depending on epidemiological and social context, as well as available resources, countries can utilize multiple HTS approaches. Using strategic information, programmes can tailor service delivery approaches to maximize HTS coverage and uptake and so

Disaggregating service statistics can help countries set targets for HTS and better link and align HTS with enrolment in prevention, treatment, care and support services.

diagnose more people with HIV. Disaggregating service statistics by HIV diagnosis, by service delivery point and/or by population subgroups can help countries set targets for HTS and better link and align HTS with enrolment in prevention, treatment, care and support services (44).

Adjusting for retesting in HTS coverage estimates. There are three different type of retesting that WHO recommends within HIV programmes: (1) retesting people at on-going risk for HIV infection (for example, retesting pregnant women in settings of high HIV incidence/prevalence in their third trimester and in the breastfeeding/postnatal period, and retesting among populations at high ongoing risk for HIV infection, for example, key populations, at least annually); (2) retesting people with HIV-inconclusive test results; and (3) retesting to verify HIV-positive diagnosis before initiating care and/or ART (10, 12). Several HTS indicators are more meaningful as measures of access and coverage if they count the number of individuals who have been tested rather than the number of tests performed. When using *routinely collected programme data* to determine coverage, counting unique individuals over the period of a year as well as across many potential HTS sites can be challenging. Using unique client identifiers for individuals is one way to keep track of retesting and avoid double reporting, if electronic systems are available to easily link data through these unique client identifiers. Another approach is to record information about prior testing in the HIV testing register. Then, repeat testing and retesting can be counted and subtracted from the total number of tests performed for the same individual. *Population-based surveys* asking if a person has ever tested for HIV are another method that minimizes risk of double-counting people who retest. Surveys are particularly helpful to determine testing coverage among hard-to-reach populations. For most settings WHO recommends investing in surveys to estimate service use that are representative and appropriately powered (277).

Handling disaggregation by several variables. Disaggregation of HTS data at the national level is important to ensure that critical populations are accessing HTS (see box). The optimal examination of HTS strategic information requires simultaneously disaggregating service statistics by multiple dimensions, such as numbers of individuals tested by age, sex, test result, diagnosis (HIV-positive or HIV-negative), service delivery point and key population status. Computers can make such multiple disaggregations fairly easy, but tabulating these figures from paper-based registers is time-consuming.

Special efforts are needed to design paper-based tools that support disaggregation of these data without placing an undue burden on those responsible for collecting and analysing the information.

Categories to consider for disaggregation of variables

Below is a list of variables to be considered for disaggregating HTS data depending on strategic information analysis and intended use of the information:


- **Age:** <1, 1–9, 10–14, 15–19, 20–24, 25–49, 50+
- **Sex:** male, female, transgender
- **Test result:** HIV-positive, HIV-negative, inconclusive, unknown (not confirmed)
- **Population:** pregnant or breastfeeding women, partners, key populations (men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers, transgender people), serodiscordant couples, infants and children, adolescents, TB clients/patients, hepatitis patients
- **Geographic area:** district, region, province, facility, other
- **Service delivery point:**
 - facility-based, for example, ANC clinics, outpatient care, inpatient care, TB clinics, STI clinics, HTS clinics, integrated HTS
 - community-based, for example, home-based, door-to-door, mobile outreach
 - other, for example, HIV self-testing
- **Retesting status:** new testers, type of retesters (HIV-negative at on-going risk; retester after discrepant result (HIV-inconclusive); retester (HIV-positive) to verify diagnosis before starting ART)
- **CD4 count at diagnosis,** where CD4 testing is routinely available: <200; 200–349; 350–500; >500 cells/mm³.

10.2 Selection and use of indicators

Monitoring and evaluation of HTS has expanded and evolved from measuring coverage in terms of the number of tests performed to measuring knowledge of HIV status among different populations and estimating the proportion of people with HIV who know their status. There is increasing focus on determining what populations are underserved by HTS as well as how programmes can engage people from populations at highest risk who do not know their HIV status.

Thus, the increased effectiveness of HTS is measured not only in terms of the number of people tested for HIV but also more people knowing their status, particularly those with HIV and those at highest risk. The most critical outcome indicator is the number and proportion of people with HIV who are aware of their status (indicator HTS.1; see Table 10.1). This indicator reports on the first 90 of the 90–90–90 programme target – that is,

Table 10.1. Newly recommended global indicator for HIV testing services

Indicator	Numerator (N)/ Denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
<p>HTS.1 People with HIV diagnosed % of people living with HIV who have been tested HIV-positive</p> 	<p>N: Number of people with HIV who have been diagnosed and received their results</p> <p>D: Number of people with HIV</p>	<p>Sex, age (<1, 1–4, 5–9, 10–19, 15–19, 20–24, 25–49, 50+ years), key population, other target populations</p>	<p>Best estimate based on available data sources, e.g.:</p> <ol style="list-style-type: none"> Based on facility data: <p>N: Cumulative number of reported new HIV diagnoses minus deaths;</p> <p>D: national estimate of people with HIV based on internationally consistent modelled estimates, e.g. Spectrum AIM.</p> <ol style="list-style-type: none"> Based on population-based surveys collecting HIV status and with a question to assess whether respondents know their positive status. The indicator will be calculated as people with HIV who report knowing their status. Based on population-based surveys collecting HIV status without a question to assess whether respondents know their positive status. Construct a plausible range and midpoint based on: the higher value of (the percentage of survey respondents with HIV who have been tested in the past 12 months and received the results) and (the percentage of all people with HIV on care) as the lower end of the range, and the percentage of people with HIV ever tested as the upper end of the range. <p>Other surveys, related programme data and modelled estimates can be used as additional data sources for developing and triangulating estimates.</p>	<p>Critical to determine the proportion of people living with HIV who know their HIV status, as this knowledge is the entry point to the continuum of care.</p> <p>Disaggregated estimates can reveal gaps in diagnosing people with HIV. The proportion of people with HIV who know their HIV-positive status should also be globally reported for target populations where these are collected as national indicators, including:</p> <ol style="list-style-type: none"> % of key populations % of pregnant women who have been tested in the past 12 months and know their status.

Source: WHO, 2015 (95).

that 90% of people with HIV are diagnosed. This information might be obtained from representative sample surveys. Other indicators, based on programme data or special surveys, also can help assess and guide a country's testing strategy by measuring the proportion who know their status among specific priority groups – pregnant women and key populations, for example. More efforts to measure these populations are needed, especially where new HIV infections are common in these groups.

As for priority populations, people with HIV who are already receiving services for other reasons (for example, pregnancy or TB) are more accessible for HIV testing, and their data are relatively easily captured. In contrast, data are scarce on the proportions of key populations and adolescents with HIV who are aware of their status. More efforts to measure these populations are needed, especially where new HIV infections are common in these groups. It may also be useful to track knowledge of HIV status in populations that are eligible for ART regardless of CD4 count, as recommended in WHO's consolidated ART guidelines (13).

HIV testing is the gateway to the HIV services cascade. Thus, the strength of linkages to prevention and care services should be measured.

In addition to attaining high coverage rates, the quality of HTS depends on accurate diagnosis and effective linkage to HIV prevention, treatment and care services. The monitoring of HTS quality starts with the review of national testing policies and standards, the quality of test kits and testing strategies/testing algorithms being used, the

accuracy of diagnoses and the quality of counselling and referrals provided. Also, the laboratory-based aspects of HTS need to demonstrate quality, as measured through documentation, SOPs, QC results, and the results of external quality assessments (such as proficiency testing). As HIV testing is the gateway to the HIV services cascade, the strength of linkages to prevention and care services should be measured (95). Finally, monitoring should assess the alignment of HTS policies, programmes and practices with human rights norms and standards, especially in HTS services for key populations.

Analysing HTS coverage and quality data further, by type of site, is critical for determining where national programmes should allocate resources. As described in Chapter 6, site-specific coverage data can be compared with epidemiologic information about the site's catchment area or intended clientele to gauge how resources might need to be reallocated to match coverage with need.

A full listing and descriptions of WHO-recommended indicators for HTS appear in *Consolidated strategic information guidelines for HIV in the health sector* (www.who.int/hiv/topics/me/en/). Reference sheets for these indicators appear in Annex 13.

Case example: Testing changes to strengthen linkage to care, Ministry of Health Uganda

Quality improvement requires the identification of relevant and specific interventions followed by a tracking period to determine which are most successful at resolving the issues identified. Uganda adopted this approach to improve linkage and enrolment from HTS into care and treatment.

In Uganda people diagnosed HIV-positive are linked to care and treatment within the facility or at other facilities based on clients' preferences. Staff members who conduct PITC at three health facilities in Uganda proposed several interventions that could be implemented in facilities to improve linkage to care. These included: (1) changing the HIV testing point from the laboratory to a designated room, (2) visual reminders for staff to update HTS registers, (3) slips to refer newly diagnosed clients to the ART clinic, (4) providing HIV-positive peer escorts to the ART clinic, (5) enrolling HIV-positive clients into care on the same day.

When assessed, two of the five interventions – peer escorts and same-day enrolment – proved to significantly improve linkage. When these improvements were introduced, the percentage of HIV-positive clients linked to care rose from 58% in August 2013 to 89% in April 2014.

Source: Annex 3.

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