ICAP Approach to Strategic HIV Testing

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ABOUT ICAP

ICAP was founded in 2003 at Columbia University's Mailman School of Public Health. A global leader in HIV and health systems strengthening, ICAP provides technical assistance and implementation support to governments and non-governmental organizations in more than 21 countries. ICAP has supported work at more than 5,200 health facilities around the world. More than 2.2 million people have received HIV care through ICAP-supported programs and over 1.3 million have begun antiretroviral therapy.

Preface

This guide was developed as part of a four-part series that aims to support ICAP teams in the implementation of effective strategies that support reaching the global 90:90:90 targets.[1] The four documents describe ICAPs approach to:

1) **Targeted HIV Testing.** This document describes innovations that support an increase in yield in HIV testing, especially among key subpopulations that have historically been hard to reach.
2) **Antiretroviral Therapy Initiation in the Era of Treat All.** This document describes approaches to ensuring high uptake and coverage of antiretroviral therapy (ART) in the context of the "treat all" approach.
3) **Differentiated Service Delivery.** This document describes key considerations for the implementation of differentiated service delivery models.
4) **Viral Load Scale-Up.** This document describes key considerations for preparing for national implementation and scale-up of routine viral load monitoring.

These guides can be used to assist countries in thinking through successful strategies to increase targeted HIV testing, improve ART coverage and retention in care, and maximize services to ensure viral load suppression. All four documents highlight areas that need to be prioritized, while maintaining a focus on critical issues not adequately covered in other resources. They are intended to complement the "ICAP Package of Care for People Living with HIV" (see Annex 1).

The target audience of this guide includes health managers at the national and sub-national level who oversee HTS, as well as program and clinical staff supporting the implementation of HTS and their community-based partners.

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[1] Targets are that 90 percent of all people living with HIV know their HIV status; 90 percent of all people with diagnosed HIV infection receive sustained ART; and 90 percent of all people receiving ART have viral suppression.

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Acronyms

HIS	Health information system
HIVST	HIV self-testing
HTS	HIV testing services
KP	Key populations
MSM	Men who have sex with men
PEP	Post-exposure prophylaxis
PITC	Provider-initiated testing and counseling
PLHIV	People living with HIV
PCR	Polymerase chain reaction
RDT	Rapid diagnostic test
STI	Sexually transmitted infection
SW	Sex workers
TG	Transgender people
TB	Tuberculosis
VCT	Voluntary counseling and testing
WHO	World Health Organization

Executive Summary

This document focuses on the first of the three global 90:90:90 targets: by 2020, 90 percent of all people living with HIV will know their HIV status. This ambitious goal implies a departure from established strategies for testing that, to date, have resulted in the diagnosis of an estimated 40 percent of all people living with HIV (PLHIV).

Strategic approaches to HIV testing that maximize both the **coverage** of testing services in geographic areas and populations where the burden of HIV is generally high, and the **yield** of testing programs (i.e., the proportion of all tests performed that identify a new case of HIV) will strengthen the efficiency of HIV testing services and support reaching the first 90 target. Several innovative approaches have been developed to bring HIV testing into community settings and increase both the coverage and yield of HIV testing. This document describes these approaches and offers key considerations for building them into an HIV testing strategy. Key considerations include:

- The use of national and sub-national data to inform testing strategies
- Assessment of existing gaps in testing coverage
- Inclusion of the needs and preferences of populations that are currently underserved by testing and are at high risk for HIV
- An understanding of human resources and infrastructural capacity to expand and strengthen HIV testing services

The document also describes approaches to linking individuals to HIV treatment following a positive HIV test result.

Introduction

People's knowledge of their HIV status is essential to the success of the global HIV response. The overarching goals of HIV testing services (HTS) are to:

- Make testing for HIV available to those who need it
- Deliver accurate, timely results
- Link clients to appropriate services based on their serostatus

For HIV-positive individuals, timely linkage to treatment will ensure optimal health outcomes and prevent onward transmission of HIV. For individuals who are HIV-negative, HTS should facilitate access to appropriate prevention services and resources, including voluntary medical male circumcision, male and female condoms and lubricant, contraception, needle and syringe exchange programs, pre-exposure prophylaxis (PrEP), and post-exposure prophylaxis (PEP).

Globally an estimated 40 percent of all PLHIV are unaware of their status.[1] This proportion is far from the first of the global 90:90:90 targets—that, by 2020, 90 percent of PLHIV will know their status.[2] Reaching this target will require strengthening HTS **efficiency** (i.e., coverage and quality of services delivered to the geographic areas and populations where the burden of HIV is high); and **yield** (i.e., proportion of all tests performed that identify a new case of HIV).[3] Several innovative approaches have been developed to improve the efficiency and yield of testing by bringing HTS into community-based settings. These approaches have the potential to reach individuals who experience barriers to accessing facility-based testing or are unaware of the availability and benefits of HTS. These approaches include:

- Mobile testing in the community
- A "one-stop model" that integrates HTS with other needed services
- Workplace testing
- Partner and family testing
- Social network testing
- Home-based testing
- HIV Self-testing

The World Health Organization (WHO) recently released guidance on the use of HIV self-testing (HIVST), in which individuals perform a rapid diagnostic test (RDT) for HIV on themselves, either with the assistance of a provider or independently, in the setting of their choice.[4] The guidance also describes strengthened partner notification systems to identify sexual and drug injecting partners of PLHIV and provide them with HTS.[4] In addition to these innovative methods, provider-initiated testing and counseling (PITC) and voluntary counseling and testing (VCT) procedures can be optimized to increase efficiency and yield. The adoption of a tailored mix of testing approaches will enable programs to target testing efforts to geographic locations and specific populations where they are needed most.

The purpose of this document is to describe key considerations for a targeted testing strategy that combines an array of testing approaches to improve testing coverage (especially among those who have never previously tested) and to increase testing yield. The document also describes approaches to strengthening linkage to HIV treatment following a positive test result.

I. Considerations for a Targeted Testing Strategy

The development of an effective strategy for implementing HTS takes into consideration characteristics of national and local epidemics and gaps in current HTS, where data indicate higher prevalence of HIV, the needs and preferences of populations that are the focus of targeted testing, the scope and capacity of existing HTS provision, and available resources for HTS (see Box 1).

Box 1

Targeted testing strategies are informed by considerations of:

(number of persons reached through HTS) **AND**

% (yield of HIV-positive cases identified through HTS) **AND**

$ (resources needed to implement HTS)

National and subnational data relevant to HIV testing. The first step in developing targeted testing strategies is to conduct an analysis of national and subnational epidemics (including consideration of geographic and socio-economic context) and populations at highest risk and in need of services. Even within generalized epidemics, regional differences in prevalence and affected populations will call for distinct approaches. Based on a comprehensive understanding of the nature and dynamics of the epidemic and gaps in current services, HTS approaches can be adapted and deployed to optimize uptake of testing and testing yield (i.e., the proportion of clients undergoing HIV testing who test positive). In addition to yield, the overall number of new cases of HIV identified and the cost of testing strategies in relation to testing outcomes are important implementation considerations.

Current HTS achievements and gaps. Scrutiny of routinely-collected program data for high-yielding testing efforts can guide effective strategies for HTS. Comparison of program data with epidemiologic data can reveal where testing coverage and yield are low relative to need. Assessment of HTS coverage in PITC settings with patient populations with relatively high HIV prevalence (e.g., tuberculosis [TB] and sexually transmitted infection [STI] clinics) can help to identify missed opportunities for reaching PLHIV. Additionally, subpopulations and areas in which PLHIV are more likely to be diagnosed at later stages of disease may represent a gap in HTS to be addressed with focused efforts. Program data however, will not capture information on people who are fully disenfranchised and hidden from the health care system. Additional sources, including published surveillance data and Demographic and Health Surveys can provide insight into populations at risk for HIV and not engaged in HTS.

Needs and preferences of target populations. Uptake of HTS is greater in settings that are familiar and easily accessed by target groups. Planning for targeted testing should consider the specific needs and barriers that key and vulnerable populations face, including stigma, discrimination, poverty, and limited information about HIV infection and treatment. Equally important is an assessment of available resources to remove or mitigate barriers to testing, such as population-friendly and competent healthcare providers and local, community-based organizations. Members of the target population and established providers of health and social services for the population can provide input on testing needs and preferences.

Available human resources and infrastructure. Staffing and infrastructure requirements for community-based testing differ from facility-based testing. Trained lay workers may be incorporated into HTS staffing as outreach workers and counselors, and, in accordance with country guidelines, may provide testing in a variety of community and facility settings. In addition, community-based service providers who are established and trusted allies of populations and communities at risk for HIV are a valuable resource for engaging groups considered hard to reach. Wherever testing takes place, it is essential that conditions are adequate to ensure confidentiality and necessary infection control measures.

A. Priority Populations for Targeted Testing

Specific population groups are appropriate for targeted testing because they are: 1) At high risk for HIV infection; 2) At high risk of onward transmission if they are HIV-positive; and/or 3) Unlikely to access routinely-offered HTS. Priority populations for targeted testing include:

1. **Key populations (KP),** in which behavioral risk of HIV is elevated and discrimination and stigma impede access to health care services. This includes:
    - Sex workers (SW)
    - Men who have sex with men (MSM)
    - Transgender people (TG)
    - People who inject drugs (PWID)
    - People in prisons or other closed settings

2. **Vulnerable populations,** for whom a range of factors make them less able to protect themselves against HIV. This includes:
    - **Adolescent girls and young women (AGYW)** are a vulnerable population in which limited access to HIV education and limited opportunities to acquire skills for behavioral risk reduction coincide with limited economic resources and social, cultural, and gender norms and practices to create barriers to accessing HIV services.
    - **Adolescent boys** also face limitations to accessing HIV-related education and services. For boys as well as girls, adolescence is a period of high risk of HIV infection. In addition, in high prevalence settings, the number of undiagnosed, perinatally-infected adolescents may be high.
    - **Men, especially young men,** access HIV testing in smaller numbers than women, in part because there is no broadly-accessed entry point to HTS for men (as testing in antenatal clinics and sexual and reproductive health services provides for women). In high prevalence settings, this means that HIV-positive men are diagnosed later than women, which has negative consequences for their health and for the prevention of onward transmission.
    - **Migrant and itinerant workers** may experience multiple challenges to accessing services, including language barriers, limited access to transportation to health care services, and limited economic resources. HIV vulnerability also arises in the context of occupations that require prolonged periods away from home communities and established sources of health care, leading to the formation of concurrent sexual relationships and inability to access HTS. Fishers, miners, textile workers, and long-distance truckers are examples of groups who may experience vulnerability in the context of their work.

3. **Sexual and drug-injecting partners of PLHIV** are at risk of acquiring HIV because of shared behavioral risk. HTS allow partners to access appropriate services for HIV care—if they are found to be HIV-positive—or HIV prevention if they are HIV-negative.

4. **HIV-exposed infants** are at high risk of rapid disease progression, severe illness, and death; and early linkage to care and initiation of treatment are essential to reduce morbidity and mortality in HIV-positive infants.

B. Targeted Testing Approaches

Distinct approaches for targeted testing are appropriate for distinct populations. In addition, implementation of each approach must account for considerations such as the setting, health facility, and community-based collaborators. Table 1 provides an overview of approaches to targeted testing.

Table 1: Approaches to Targeted Testing

Approach	Target Populations	Key Considerations
Mobile testing and venue-based testing	Men in general populations; MSM, TG, SW, PWID, and other groups that have well-defined areas of socialization	Close collaboration with members of the target population and its allies can ensure that venues and testing locations are responsive to the population's needs and preferences. Referral systems to link individuals with reactive test results to HIV care and treatment settings convenient to the testing site and available at the time of testing are essential.
Workplace testing	Migrant or itinerant workers who may not consider themselves at risk for HIV, especially men	Workplace testing is a variant of venue-based testing that brings testing to populations that may not access care in routine settings. Concerns about confidentiality during testing and linkage can undermine the acceptability of workplace testing. Integrating HIV testing with other health services already offered at workplaces, such as TB testing, may improve acceptability and uptake of HTS.
Integrated service delivery ("one-stop model" or co-located services)	PWID, SW, adolescents, and other groups with multiple barriers to accessing health care	Comprehensive harm reduction approaches that combine HTS with sterile needle and syringe programs and medication-assisted treatment for opiate dependence can promote uptake of testing among PWID and other drug users. A one-stop approach may be more cost-effective than stand-alone HTS, but require greater resource investment and ongoing collaboration with KP service providers.
Home testing	Children and partners of known HIV-positive people, in settings with high HIV prevalence	Home testing can be effectively combined with other testing approaches (e.g., VCT, index client testing, multi-disease screening campaigns) to test individuals who do not access HTS in facilities and public venues.
Social network testing	AGYW, PWID, SW, and other KP with strong social networks	Peer educators and "champions" for HIV prevention and sexual and reproductive health can mobilize their social networks to engage in HIV education events and HTS.
Index-client testing and partner notification services	Family, sexual partners, and those who share injection equipment with PLHIV	Preferences for type of referral to voluntary HTS (from the index client, a provider, or both) vary across populations and areas. Consult with community stakeholders (include PLHIV) to ensure that the notification and referral systems are appropriately tailored to target populations. Partner notification systems for HIV are not widely available in many settings and would need to be developed and implemented.
HIV self-testing	MSM and other KP, partners of individuals accessing HTS, and couples; health care workers and others with concerns about confidentiality of HTS	Similar to home testing, HIVST can be effectively combined with index client testing to engage people at risk who do not access HTS. Procedures for confirmatory testing and linkage to care for confirmed HIV diagnoses are essential.
Health fairs and multi-disease screening campaigns/events	Men, especially young men and first-time testers	Media campaigns, large-scale service announcements, and the use of community volunteers, in conjunction with testing campaigns, can boost participation.
Targeted PITC	Facility wards based on yield (including TB, pediatric, and malnutrition); antenatal clinics and labor and delivery services; STI clients; and other outpatient clinics in high HIV prevalence settings	Where program data identify facilities or wards with high numbers and/or yield of HIV-positive cases, HTS can be intensified or streamlined to optimize PITC.
HIV birth testing	All HIV-exposed infants or high-risk infants*	Ideal for programs where 4–6 weeks HIV DNA polymerase chain reaction (PCR) testing coverage is >80% and treatment is available for newborns. Universal testing of all H-exposed infants is easier to implement since identification of high-risk infants is challenging.
*High-risk infants are defined as infants born to women with HIV who received <4 weeks of ART before delivery, or have a viral load >1000 copies/mL in the 4 weeks before delivery, or were born to women with incident HIV infection during pregnancy.		

i. Mobile Testing and Venue-based Testing

Mobile testing allows for flexibility in bringing HTS to different settings. Collaboration with social service providers who are known and accepted by KP and other populations can facilitate testing in non-traditional community-based settings, such as "moonlight" testing, in which trained outreach workers facilitate testing in community venues where MSM congregate in evening hours (see Box 2 for example). Experienced partner organizations can help establish adequate safety measures and procedures to maximize acceptability of testing in community settings. Procedures for appropriate follow-up for reactive RDT results, such as facilitated referral to a nearby facility with convenient hours, are essential.

Box 2: Mobile Testing

ICAP's MOSAIC Men's Health Initiative in South Africa tailored HTS to MSM using tents at identified hotspot areas/drop-in centers at convenient times, including evenings ("moonlight testing") and weekends, with a four-fold increase in HIV testing. In addition, through communities of practice consisting of a network of MSM-friendly service providers, MSM were linked to relevant services based on their HIV status.

ii. Health Fairs and Multi-Disease Screening Venues

HTS that are integrated into health fairs targeting multiple health issues (such as blood pressure measurement, eye and oral exams, etc.) can reduce stigma associated with HIV testing and achieve high testing coverage among groups that undergo testing infrequently, including men.[5]

iii. One-stop Models Tailored to KP Needs

Integration of HTS into established services tailored to KP needs, such as harm reduction services for PWID, is recommended as a client-centered approach to providing HTS and follow-up care for KP. In order to bring services to PWID and SW, programs must take into account the relevant policy and legal environment so as not to inadvertently expose KP to discrimination or prosecution.

iv. Workplace Testing

Providing HTS at the workplace may help remove barriers to testing and reach individuals who would not otherwise have tested at a health facility. This may include men, who in general are difficult to engage in HTS, or those employed in specific industries that offer an opportunity to reach a specific population. For example, in partnership with the Employment Bureau of Africa (TEBA), ICAP supported the establishment of TB screening, diagnostic, and treatment services, as well as HTS at three regional TEBA offices in Lesotho where migrant miners congregate to collect deferred pay. With availability of HTS on-site, the proportion of presumptive TB cases with documented HIV status increased from 13 percent to 83 percent in only six months, with 32 percent of presumptive TB cases testing HIV-positive.[6]

v. Home-based Testing

RDT performed in home settings by professional or trained lay providers reaches individuals who do not access HTS in facility or community-based settings. In order to reach the largest number of individuals, home-based testing must be adapted to the specific community and home visits should be scheduled at flexible times to allow for reaching individuals during the hours they are most likely to be home. Voluntary home-based testing can be an acceptable approach to index testing (i.e., offering HTS to the sexual partners, family members, and drug-injecting partners of PLHIV).

vi. Social Network Testing

Social network-based referral to HTS harnesses the power of group norms to increase the acceptability of HTS and the motivation to undergo testing. In this approach, individuals from KP groups who have undergone testing reach out to friends and sexual partners within the same KP, encouraging them to test and providing information or navigation to access HTS. Known, trusted members of one's social network who share similar risk factors for HIV and/or norms regarding testing can be compelling spokespeople for HTS. KP advocates and community members can provide essential input and feedback to develop procedures for social network testing that are responsive to the target population's needs and preferences, including concerns about the confidentiality of referral processes.

vii. Index Client Testing

Primary sexual partners and children of PLHIV have elevated rates of HIV compared to general populations. However, partners and family members may be unaware that they are at risk for HIV. Index client testing involves systematically identifying current and former partners and household members of individuals newly or previously diagnosed with HIV, and engaging them in HTS (See Box 3 for example). Testing can be done in the health facility via invitations for household members or through home-based testing. An ICAP study in Lesotho showed feasibility, acceptability, and high yield from targeted testing of household members of index clients.[7] This approach has also demonstrated efficacy in identifying HIV-positive children.[8]

viii. Partner Notification Services

Partner notification services help consenting PLHIV identify sexual and drug-injecting partners in order to offer them voluntary HTS. Procedures for assisted partner notification services are tailored according to the preference of the index client and the response of partners.[4] Types of referral include:

- **Passive referral**: HIV test counselors encourage and guide PLHIV to voluntarily disclose their HIV diagnosis to partners and family members and encourage them to get tested.
- C**ontract referral:** PLHIV initiate the passive referral process. If identified partners and family members do not access HTS within a set period of time, a health worker confidentially contacts them to offer voluntary HTS.
- **Dual referral**: PLHIV and providers jointly notify partners and family members and offer voluntary HTS.
- **Provider referral:** PLHIV give express permission to providers to confidentially notify partners and family members and offer them voluntary HTS. Provider referral may be performed without identifying the PLHIV initiating the referral.

Partners and family members reached through partner notification services can be referred to facilities for testing, can receive home-based testing, or can be provided with training and resources to conduct HIVST.

Box 3: Testing Family Members of New and Existing HIV Patients

In 2016, ICAP-supported HIV facilities across five counties in Kenya implemented procedures to test household members of existing and new HIV-positive patients ("index clients") for HIV. Tools were developed to track the outcomes of index testing.

- Newly-identified HIV-positive clients were counseled to bring partners and family members to the facility for testing, and transportation incentives were provided for parents bringing children for testing.
- For existing clients, clinic staff reviewed charts one week in advance of scheduled appointments and called those clients with family members with unknown HIV status. Clients were asked to bring family members to the appointment for testing.
- Clinic staff monitored testing of family members and partners and offered home testing for those who did not appear for testing as requested.

Data from the April - June period of 2016 showed that, among adult household members (20 years of age and older) tested for HIV, HIV prevalence was nearly 8 percent, while prevalence among younger members was about 1 percent.

ix. HIV Self-Testing

HIVST involves use of a single RDT that is performed and interpreted by the individual in a setting of his or her own choosing.[4] Reactive results require additional confirmatory testing according to the validated national algorithm for HIV testing. Because it can be used by individuals who may be unwilling or unable to access testing in facilities or community-based settings, HIVST can complement other testing approaches and fill in gaps in testing coverage. HIVST is not recommended for PLHIV on ART, as this can result in a false nonreactive result. An ICAP study in Lesotho showed high uptake and acceptability of HIVST.[7] A study in Malawi achieved high coverage for two successive years (77%), particularly among adolescents, and HIVST was shown to be safe, accurate, and acceptable.[9]

Essential components of HIVST kits include an oral fluid rapid test device; a description of the specificity and sensitivity of the test; detailed instructions for performing the test and interpreting the result; and steps to take and resources to access in case of a reactive result.

Education and training to ensure that users are able to perform self-testing correctly and interpret test results accurately are essential components of HIVST, and educational materials should be tailored to the linguistic preference, literacy level, and learning style of users.[10] Access to confirmatory testing following reactive results, and linkage services for confirmed HIV-positive diagnoses, are critical.

Although reported misuse of and social harm related to HIVST are rare, procedures should be in place to prevent, monitor, and mitigate related risks.

x. Optimizing Provider-initiated Testing and Counseling and Voluntary Counseling and Testing

PITC is the foundation of many HTS programs and should continue to be a core approach to testing. The proportion of HIV-positive cases identified by PITC may vary markedly between regions and facilities as well as within facilities, and therefore routine program data should be used to ensure the highest-yield sites have fully implemented PITC. PITC should be prioritized for ANC patients; patients receiving services for GBV; TB patients and presumptive TB patients; STI patients; orphans and vulnerable children; children presenting to care with severe and repeated illness, malnutrition, and faltering growth; and for all clients in higher-prevalence settings. In order to improve yield and efficiency, PITC may not be implemented in all settings but rather focused on entry points within the facility, specific facilities, or certain regions where this approach has been the most successful. Further, establishing procedures to integrate PITC into clinical settings can help optimize this approach (see Box 3).

Box 3: Targeted PITC in a High Prevalence Setting

ICAP-supported sites in Western Kenya undertook an initiative to streamline procedures for testing and improve testing yield in outpatient settings in high-volume facilities. HIV test counselors were stationed in the triage room with nursing staff and the following HTS eligibility screening questions were incorporated into triage:

- *Is HIV status known?*
  - STOP if known positive
- If status reported unknown (never tested in past) or declined to answer:
  - Offer testing
- If HIV status is reported negative, ask if tested in the last year.
  - If NO, offer testing
  - If YES, retest based on risk of recent exposure (sex worker, condom burst, needle prick, etc.)

Eligible patients were immediately linked to HTS; those identified as HIV-positive were immediately linked to HIV care in the facility. HTS tools were revised to include weekly and monthly summary forms to capture data disaggregated by age and point of testing service within the facility.

xi. HIV Birth Testing

HIV testing at birth (within the first two days of life) provides an opportunity for earlier identification of infants with HIV infection. The WHO recommends implementation of birth testing when coverage of infant virologic testing at 4–6 weeks is well-established.[11] Additionally, PEPFAR recommends implementation when over 80 percent of infants born to women receiving prevention of mother-to-child transmission of HIV (PMTCT) services receive virologic testing by two months of age, and immediate treatment regimens for newborns are available. Birth testing identifies infants infected during pregnancy and should not replace routine testing at 4–6 weeks, which identifies infections that occur during delivery and the early postpartum period.

Birth testing may be conducted using nucleic acid testing (HIV DNA PCR) or point-of-care tests. Several factors should be taken into consideration before implementing birth testing, including:

- Additional human resources for health required for birth testing
- The need for expanded systems to ensure return of results and linkage to services
- The potential for:
  - A decrease in the number of infants returning for follow-up testing at 4–6 weeks
  - An increase in false positives in settings where PMTCT coverage is high
- Costs associated with follow-up testing

See Annex 1 for additional information.

C. Ensuring Quality Service Provision in Targeted Testing

Targeted testing in community-based settings presents special challenges in terms of safeguarding the "5 C's" at the heart of quality HTS:

- **Consent:** Opt-out approaches to testing, in which HIV testing is performed after notifying clients that the test is normally performed (e.g., as part of antenatal care) should include explicit language regarding the right to decline or defer opt-out testing. People receiving HTS must be informed of the process for routine HIV testing and of their right to decline testing without losing access to other services, and they have a right to refuse testing. Verbal informed consent or assent must be obtained before a client is tested and counseled. Clients who feel coerced into HIV testing may be reluctant to engage in appropriate follow-up to HTS, including linking to care in the case of reactive test results. When engaging KP that are highly stigmatized and discriminated against, criminalized, or both, collaborating with organizations who have experience and expertise working with the population can be critical to building trust and increasing willingness of KP to engage with HTS. Special policies and practices to protect vulnerable populations from mandatory or compulsory testing may be needed.
- **Confidentiality:** HIV testing and counseling must always be conducted with attention to confidentiality. Privacy in community settings may be ensured by creating screened or separate spaces (or identifying another location that offers confidentiality) for providing test results and counseling clients. Providers who perform testing should guide clients through considering with whom to share test results and how. Shared confidentiality of HIV status with health care providers, a partner, family members, and trusted others can improve overall management of HIV, including linkage and adherence to treatment over time.
- **Counseling:** Providing training, supportive supervision, and mentorship in high-quality counseling to lay workers is essential as they join HIV testing teams providing HTS. Mobile testing efforts must include space for clients considering testing to ask any questions in a private setting (if they prefer). Procedures for conducting testing in community-based settings or in homes must include steps to provide high-quality post-test counseling for reactive and non-reactive test results.
- **Correct:** High-quality testing services are key to client acceptability and satisfaction. Quality assurance mechanisms should ensure that people receive a correct diagnosis. Quality assurance may include both internal and external measures and should receive support from the national reference laboratory. Training of individuals who conduct the testing is critical, as is ensuring that test kits are kept at an appropriate temperature. All people who receive a positive HIV diagnosis should be retested to verify their diagnosis prior to/at time of ART initiation (see "Retesting for Verification Prior to ART Initiation" section).
- **Connection:** Providing HTS where there is no access or poor linkage to treatment has limited benefit for those with HIV. Linkage may include referrals to other medical services, needed social services, and prevention services, all of which can strengthen clients' connection to HIV treatment services. Similarly, it is critical to link those found to be HIV-negative and at risk for HIV to HIV prevention services.

While innovative testing methods and community-based approaches to HTS hold great potential to reach populations most in need of services, they also present challenges regarding maintenance of quality standards outside of clinic settings, effective linkage to appropriate follow-up services, and matching testing strategies to the epidemic and target populations. As country programs expand HTS, sharing lessons learned and best practices will advance the collective portfolio of skills and strategies to control the HIV epidemic.

D. Quality Assurance in HIV Testing

i. Selecting a Testing Strategy and Algorithm

HIV testing strategy. A testing strategy describes a specific testing sequence that is to be used for HIV diagnosis. In order to ensure accurate results, HIV testing must follow a consistent testing strategy. The appropriate HIV testing strategy must be selected for the country based on HIV prevalence. The WHO recommends two testing strategies for HIV diagnosis, one for high prevalence settings (≥5%) and another for low prevalence settings (<5%). Because the positive predictive value of diagnosis declines with decreasing HIV prevalence, it is critical that testing strategies be selected on the basis of prevalence (to avoid misdiagnosis). An HIV diagnosis should not be made without **two** sequential reactive test results in **high prevalence settings** or **three** sequential reactive test results in **low prevalence settings**.

In high prevalence settings:

- In settings with greater than 5 percent HIV prevalence in the population tested, a diagnosis of HIV-positive should be made when **two sequential** test kits are reactive.
- Individuals testing A1+; A2–; A3+: should be considered HIV-inconclusive. The client should be asked to return in 14 days for retesting.
- Individuals testing A1+; A2–; A3–: should be considered HIV-negative.

Box 4: HIV Testing Strategy

A recent survey of 48 countries found that only 20 percent have adopted the WHO recommended HIV testing strategy for high and low prevalence settings.[12] Additionally, most countries surveyed diagnosed an individual testing A1+; A2–; A3+ as HIV-positive, not HIV-inconclusive as recommended by WHO. The interpretation of A3 as a tiebreaker may, theoretically, yield excess false-positive results.

In low prevalence settings:

- In settings with less than 5 percent HIV prevalence in the population tested, a diagnosis of HIV-positive should be issued to people with **three sequential** reactive tests.
- Individuals testing A1+; A2–: should be considered HIV-negative (unless A1 is a fourth-generation assay [Ab/Ag] and A2 is an Ab-only assay, in which case the result should be considered HIV-inconclusive and the client should be counseled and instructed to return in 14 days for retesting)
- Individuals testing A1+; A2+; A3–: should be considered HIV-inconclusive and asked to return in 14 days for retesting.

HIV testing algorithm. A testing algorithm is the combination and sequence of specific assays used in a given HIV testing strategy (see Box 5). The national testing algorithm should be universally and consistently applied for all HTS approaches (PITC, VCT, community-based HIV testing, test for triage, and HIVST).

Box 5: HIV Testing Algorithm

An HIV testing algorithm describes the specific assays used in a given HIV testing strategy. The combination of assays used in a testing algorithm should be validated at the national or sub-national level.

- **First-line assays** should identify any potential HIV-positive specimen and, thus, have superior diagnostic sensitivity.
- **Second-line and third-line assays** are used to confirm the initial reactivity observed in the first-line assay, 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 must all be validated. Where possible, assays based on different antigen preparations should be used in combination.

ii. Retesting for Verification Prior to ART Initiation

To ensure that individuals are not needlessly placed on life-long treatment or burdened with the social and psychological impact of misdiagnosis, the WHO recommends that all individuals be retested to verify their HIV status prior to/at time of enrollment in care and/or ART initiation, irrespective of whether or not ART initiation depends on CD4 count. Misdiagnosis has detrimental personal and public health consequences and must be avoided. Clear communication with clients about the need for retesting for verification can increase confidence in the diagnosis and reinforce the value of early ART initiation. Retesting of each newly diagnosed individual should be performed on a new specimen—ideally conducted by a different provider using the same testing algorithm—prior to/at time of ART initiation.[12]

Retesting for verification prior to/at time of ART initiation should be conducted:

- By a different tester with a newly collected specimen, ideally at the site where the decision about ART initiation is made
- Irrespective of the type of provider conducting HTS (health care provider, facility laboratory staff, counselor, lay counselor)
- Irrespective of the type of sample being collected for HIV testing (finger prick blood, venous blood, oral fluid sample)
- In all HTS approaches that are adopted in the country, including PITC, VCT, community-based HIV testing, and HIVST
- Irrespective of the type of national HIV testing algorithm that is adopted in the country (serial testing or parallel testing)

National programs should ensure that all people newly and previously diagnosed with HIV are retested for verification either before/at the time of enrollment in care and/or ART initiation. Documentation of testing and results should be incorporated into national tools used at the point where verification testing occurs (e.g., in HIV/ART medical records if done in the HIV clinic at HIV care enrollment, or in an HTS register if done in the context of facility-based VCT or in a lab). Implementing retesting prior to/at time of ART initiation does not eliminate misclassification if the national HIV testing strategy is not consistent with what WHO recommends for the respective setting. Retesting prior to/at time of ART initiation is complementary to—not a substitute for—routine quality control and external quality assurance activities (e.g., proficiency testing, onsite supervision).[13]

iii. Retesting Following HIV-Negative Test Results

HIV-negative people with a known recent exposure should undergo re-testing **four weeks** after a negative result to identify or exclude seroconversion. Retesting should also be performed for individuals with recent risk, such as a new or recent STI; those with clinical conditions indicative of HIV, including TB; and as part of the provision of PEP or PrEP. WHO recommends at least annual retesting for individuals with ongoing risk for HIV, including HIV-negative partners in sero-discordant relationships and KP. Regular retesting (e.g., every three months in high prevalence settings) should also be performed for pregnant women in areas of high HIV prevalence or incidence.

iv. Linkage to Services Following Testing

Linkage to treatment is the essential bridge from the "first 90" (HIV diagnosis) to the "second 90" (ART initiation). The health benefits of HTS ultimately derive from the treatment and prevention services that testing facilitates. Enrollment in care and prompt initiation of treatment for PLHIV ensures optimal health outcomes and helps prevent onward transmission of HIV. Globally, however, a substantial proportion of people diagnosed with HIV are not linked to timely HIV treatment. While linkage is generally stronger in settings where HTS and HIV treatment are co-located in the same facility, several interventions of varying intensity have been shown to improve linkage following a reactive RDT in community-based settings and can be incorporated into HTS.[14] Linkage procedures should be carefully monitored to ensure that they are fully implemented as planned, and to evaluate their effectiveness.

- **Two-way referral systems.** A designated facility staff member is responsible for receiving and tracking referrals from HTS and works closely with testing staff to proactively follow up on expected new clients. The designated staff member receives names and contact information for expected new patients, calls to schedule appointments if necessary, and makes reminder calls if clients do not present within an agreed upon period of time.
- **SMS reminders** can be sent by HTS staff known to the client in advance of linkage to care appointments, or for clients who miss linkage appointments.
- **Escorted linkage** to appointments, including to same-day appointments when possible, can improve linkage in groups that otherwise might be at risk of not engaging in HIV care (including stigmatized KP who frequently experience poor treatment when seeking services). HTS staff who have established rapport with clients during testing and delivery of test results can allay client concerns about discrimination and stigmatization at health facilities by offering to escort the client to the linkage visit. Escorted linkage can also be used as a follow-up measure for clients who do not link to care after SMS and/or telephone reminders.
- **Referral to co-located care.** Provision of HIV care and treatment where clients are already receiving other services (such as TB and ANC clinics and harm reduction services for PWID) improves linkage and timely initiation of treatment.
- **Linkages to HIV prevention services following negative test results.** A non-reactive RDT provides an opportunity for referral and linkage to prevention services to ensure that future infection does not occur. The range of HIV prevention tools includes PrEP for individuals at substantial on-going risk for HIV, voluntary medical male circumcision (VMMC) for heterosexual men, and population-specific services for KP (including harm reduction services for PWID, community-based support services for MSM, sexual and reproductive health services for SW, and health and social services for youth).

II. Monitoring and Evaluation of HTS

In order to implement targeted testing approaches, M&E systems for HTS must be adapted to effectively monitor and track clients, identify HTS successes and challenges, and inform changes designed to achieve desired program outcomes. Key M&E considerations for HTS—in particular relating to the elements of HTS described elsewhere in this document—include the following:

1. Ensuring that data systems meet HTS M&E needs. This includes systems for routine collection of program data, such as national health information systems (HIS).
2. Ensuring data-driven program planning and routine monitoring and use of data, including program evaluations
3. Establishing effective systems to document and facilitate linkage to treatment and prevention services, including linkage from testing conducted in non-facility-based settings
4. Ensuring data confidentiality and security in diverse settings
5. Addressing specific M&E concerns for various targeted testing approaches

A. Data Systems

HTS data systems within national and/or program contexts must be designed to meet the changing programmatic needs and priorities of MOH, implementers, and funders. These data systems may include a combination of paper-based and electronic tools for data collection, management, reporting, and data use for program assessment and improvement. Overall, data systems should be designed to capture and manage key information across the scope of services provided, thereby strengthening a program's capacity to document, report, and analyze HTS data for improved data-based decision-making. Roles and responsibilities of individuals collecting and documenting HTS information should be clearly defined.

i. Data Collection and Management

Paper-based tools - HTS register. In most contexts, a national HTS register will be used to document testing in health care facilities and mobile HTS settings. This register often serves as the exclusive source of data for HTS and must collect all data elements required for program monitoring, reporting, and evaluation.

Given the increasing interest in reaching KP at risk for HIV, HTS registers should be adapted to include a standardized way to record client KP group classification. The classification process may follow the guidance on KP classification provided by PEPFAR (see Annex 2) and be recorded in the HTS register. The HTS register should allow users to record all relevant KP groups into which an individual may be classified (i.e., in some cases more than one KP group). The HTS register currently used in Myanmar is an example of a tool that incorporates a type of KP group classification (see excerpt in Figure 1). While collecting KP information is important, programs must also consider the potential stigma and confidentiality issues that may arise from the disclosure of such information.

Further, HTS registers may require modification to incorporate fields documenting referrals and confirmed linkage to relevant services. Of highest priority is documenting referrals and linkage to care and treatment for individuals testing HIV-positive. An example of this type of field—from the Lesotho national HTS register—is shown in Figure 2. Note that the addition of a field intended to document confirmed linkages will need to be accompanied by clear procedures describing how this information will be collected and documented under a variety of scenarios (e.g., linkages within a health facility and linkages to other facilities). Other types of referrals and linkages that may be documented in an HTS register include referrals to PrEP and VMMC for those testing HIV-negative, and to TB clinics, family planning services, and harm reduction services for PWID (see "Targeted Testing Approaches" section).

Figure 1: Excerpt from Myanmar's National HTS Register

HTS Register

Date	Name	ID	Age	Sex		Pregnant Woman		Spouse of		Exposed child	Risk Categories					
				M	F	PP	MP	(+) woman	(-) woman		1	2	3	4	5	6

Risk Categories - HIV ပိုး ကူးစက်နိုင်သောအခွင့်အလမ်းအုပ်စု		
1	FSW (Female sex worker)	အမျိုးသမီးလိင်လုပ်သမား။
2	Client of FSW	လိင်အပျော်အပါးလိုက်စားသူ။
3	MSM (Man who has sex with man)	အမျိုးသားချင်းလိင်တူဆက်ဆံသူ။
4	IDU/ PWID (Intravenous Drug User/ people who inject drug)	မူးယစ်ဆေးသွေးကြောတွင်းထိုးသွင်းသူ။
5	Partner of Key Population (KP)	MSM, FSW, IDU စသောဦးတည်အုပ်စုများ၏လိင်ဆက်ဆံဖော်။ PLHIV ၏ခင်ပွန်း၊ ဇနီး။
6	Low Risk (not more than 10% of total)	HIV ပိုးကူးစက်ရန် အန္တရာယ်နည်းသော အုပ်စု (ကိုယ်ဝန်ဆောင်မိခင်၊ ကိုယ်ဝန်ဆောင်မိခင်၏ခင်ပွန်း ၊ Risk Categories အမှတ်စဉ် ၁ မှ ၅ အတွင်း) ခွဲခြားမထည့်နိုင်သော လူအားလုံး ။ **လူဦးရေစုစုပေါင်း၏ ၁၀% မကျော် ရှိ။**

Lastly, with the recommendation of retesting for verification prior to ART initiation, fields may need to be added to the HTS register to capture if someone is newly testing or coming in as a known positive (tested at another facility or self-tested), and whether retesting for verification was completed. This information will be essential to prevent double-counting of individuals previously tested within the facility or elsewhere.

Figure 2: Linkage to Care Field in Lesotho HTS Register

Linked to Care
(Y/N)
ART Unique No. Patient clinic #
(y)

Additional paper-based tools complementary to the HTS register.
In some contexts, additional tools may capture HTS information, either in parallel to the HTS register or without corresponding information recorded in an HTS register. This may include tools for KP prevention and testing services, antenatal clinic services, HIV-exposed infant services, partner notification, index testing, social network testing, and HIVST. Three key considerations regarding use of these tools for HTS are:

1) Guidelines on HTS reporting should be developed to clearly specify which tools are to be used to calculate aggregate HTS reporting indicators. Ideally, the HTS register should be used for reporting wherever possible.
2) For HIV prevention programs (such as PrEP and KP prevention outreach), registers should be designed to longitudinally track the re-testing of clients. This kind of system can be used to facilitate the generation of reminders to clients when re-testing is needed.
3) If these tools are used as the exclusive source document for HTS—i.e., if no HTS register is used to also record testing information—information to allow for relevant disaggregation for national/funder/implementer reporting (e.g., by age, gender, KP classification) should ideally be collected on a routine basis in these tools.

In addition, HTS programs may institute a separate referral register for tracking linkages to care among patients testing HIV-positive. Implementation of this type of register should include specific guidance on roles, responsibilities, and procedures for tracking linkages.

Electronic Data Systems. Utilizing or establishing an electronic system to capture HTS data and, in an automated fashion, continuously monitor HTS uptake and yield and linkage to treatment contributes to effective program monitoring and improvement efforts. This system may be designed to collect and manage aggregate data, for example from monthly HTS reports generated by facilities and from community testing; or client-level HTS data, such as data from a facility electronic medical record (EMR) or mHealth approaches such as tablet-based data collection.

For aggregate HTS data, an electronic system such as DHIS 2 (www.dhis2.org) may be used. DHIS 2 is open source, customizable, accessible from various types of devices, and is built around a structure that enables simple interoperability between it and other systems. This type of system can import data from other systems (for example national aggregate databases) and generate export data files for reporting to funders.

Patient-level databases, such as an EMR, offer many of the same features, and can provide several additional benefits:

- Support for routine program activities—for example, flagging clients who require follow-up HIV testing or who have not been linked to treatment services or other services, such as family planning or TB treatment
- If using a common identifier (e.g., national personal identification number or biometric data), linkage may be confirmed via referencing other existing patient-level databases such as for HIV care and treatment
- More flexibility in analyzing and summarizing HTS data

ii. Program Planning, Program Monitoring, and Data Use

Guidance on planning targeted testing, monitoring progress, and conducting program evaluations is described below.

Developing Targets. Programs should describe the specific population(s) that will be targeted in specific geographic areas and have a basis for how such targets will achieve programmatic goals. Associated testing targets need to be developed for each specific population and testing strategy. Background information and data needed to calculate targets and expected yield, including population size, prevalence estimates, surveys, and routinely collected data are drawn from published surveillance and peer-reviewed literature as well as programmatic data. An illustrative example of a targets table is shown in Table 2. The targets table includes the populations of interest, targets by geographical area, and HIV positivity targets (i.e., yield). Appropriate targeted testing approaches to meet targets are selected based on the target populations, geographic areas, population needs and preferences, and resources available.

Table 2: Illustrative Targets Table

Target Population	Region 1	Region 2	Region 3	Region 4	TOTAL to be Tested	Number Positive	HIV Positivity	Calculation Based on Assumptions	Assumptions	Source Information
MSM	3,050	1,954	700	1,696	7,400	1,480	20%	1) 13,602 total MSM in four regions 2) 80% to be reached: 10,882 3) Minus 15% with known HIV status: 9,250 4) 80% to accept HTS: 7,400	Proportion of male population that is MSM is 2.16%. Applied to population of regions based on Census data. Estimated number of MSM: 13,602 HIV prevalence among MSM ranges from 14% to 35%, depending on geographic area and data source.	• National Report on HIV-Related Risk Behaviors, HIV Prevalence, and Population Size Estimates of Key Populations • UNAIDS Global AIDS Response Progress Report • CDC Country Operation Plan (COP) 2016 • Census 2010
SW	1,387	842	N/A	N/A	2,229	892	40%	1) 4,976 total SW in two regions 2) 80% to be reached: 3,981 3) Minus 30% with known HIV status: 2,786 4) 80% to accept HTS: 2,229	Proportion of female population that is SW is 1.24%. Applied to population of regions based on Census data. Estimated number of SW: 4,976 HIV prevalence among SW ranges from 40% to 70% depending on geographic area and data source.	• National Report on HIV-Related Risk Behaviors, HIV Prevalence, and Population Size Estimates of Key Populations • CDC COP 2016 • Census 2010
Textile Workers	10,087	6,724	N/A	N/A	16,811	2,522	15%	1) 38,000 workers x 70%: 26,600 to be offered HTS 2) Minus 21% with known HIV status: 21,014 3) 80% to accept HTS: 16,811	Textile factories located in two regions Textile worker population estimated at 38,000 HIV prevalence among factory workers estimated at 20%	• Company employment records • Textile Association information • DHS 2014
Index-Client	9,099	9,615	2,275	8,285	29,274	2,342	8%	1) Newly enrolled on ART as per PEPFAR targets for 2017 and 2018: 21,925 2) 85% of families to be reached: 18,636 3) Times 2.1 to be tested (2 other household members per family plus neighbors) : 39,136 4) Minus 12% with known HIV status: 34,440 5) 85% to accept HTS : 29,274	Number newly initiated on ART from PEPFAR targets for 2017 and 2018 Estimated 12% HIV-positive	• MOH data • CDC COP 2016
Total	23,623	19,136	2,975	9,981	55,715	7,236	13%			

Monitoring Progress. As data are collected, programs must routinely review results, including target populations engaged, those HIV tested, those tested HIV-positive, and those linked to treatment or prevention services. Results must be compared to targets to determine if efforts have achieved the desired progress and where efforts may need to be refined or resources re-directed. HTS performance indicators should be aligned with country and funder reporting requirements. Illustrative HTS performance indicators are included in Table 3.

Table 3. Illustrative Recommended Indicators for Monitoring and Evaluation of HTS[1]

1. Number of individuals who received HTS and received their test results
2. Number and proportion of individuals who newly tested HIV-positive
3. Number and proportion of newly diagnosed HIV-positive individuals successfully linked to treatment
4. Number and proportion of newly diagnosed HIV-positive individuals linked to treatment who were retested for HIV prior to/at time of ART initiation
5. Proportion of family members/households identified through index patients and receiving HTS[2]
6. Number and proportion of identified KP hotspots reached through mobile HTS

[1]All indicators may be disaggregated as desired by sex, age, location, KP/priority population group, and testing strategy
[2]Assessed via quality assurance activities, as data will not be readily available from routine M&E systems

We note that data for indicators such as these may be generated on a routine basis by facilities providing HTS or, in some settings, it may be preferable to introduce certain data collection and aggregation efforts for limited time periods and/or within a subset of facilities or testing modalities (e.g., for a subset of indicators not able to be calculated using routine data). This latter approach may be useful for obtaining a basic understanding of how successful aspects of an HTS program have been within targeted locations, modalities, or populations.

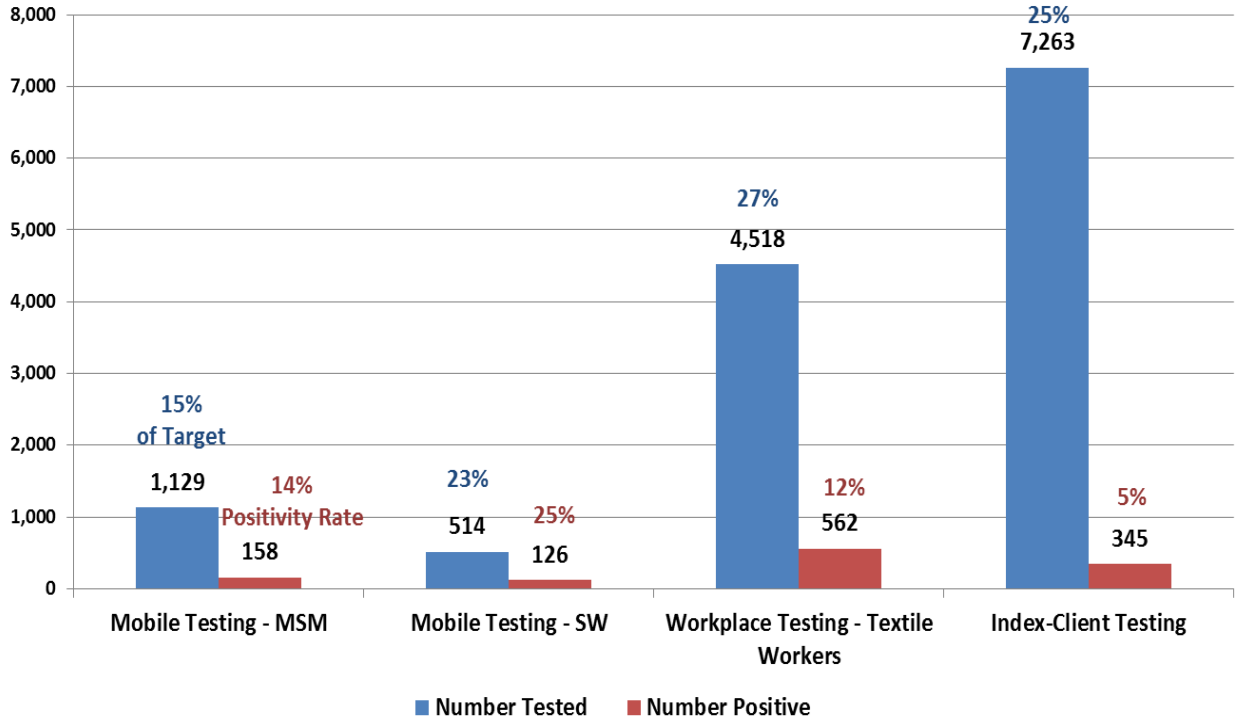
To utilize HTS data effectively, simple dashboards or interactive tools can be designed as part of the electronic HIS to summarize trends in testing coverage (if population denominators are available), trends in volume and yield across testing venues and types, and trends stratified by age, sex, key or priority population, and geographic region. Results can also be presented in a geographic context, incorporating regional background surveillance data (such as HIV prevalence and data on population sizes) where available.

Data summaries and maps of HTS results (see Figure 3) should be continuously monitored and, together with surveillance data, can be used to prioritize HIV testing efforts and testing methods (where needed) to populations and service points with a high yield or high background prevalence and low coverage or uptake.

Figure 3: Illustrative Map of HIV Positivity by Site (Swaziland)

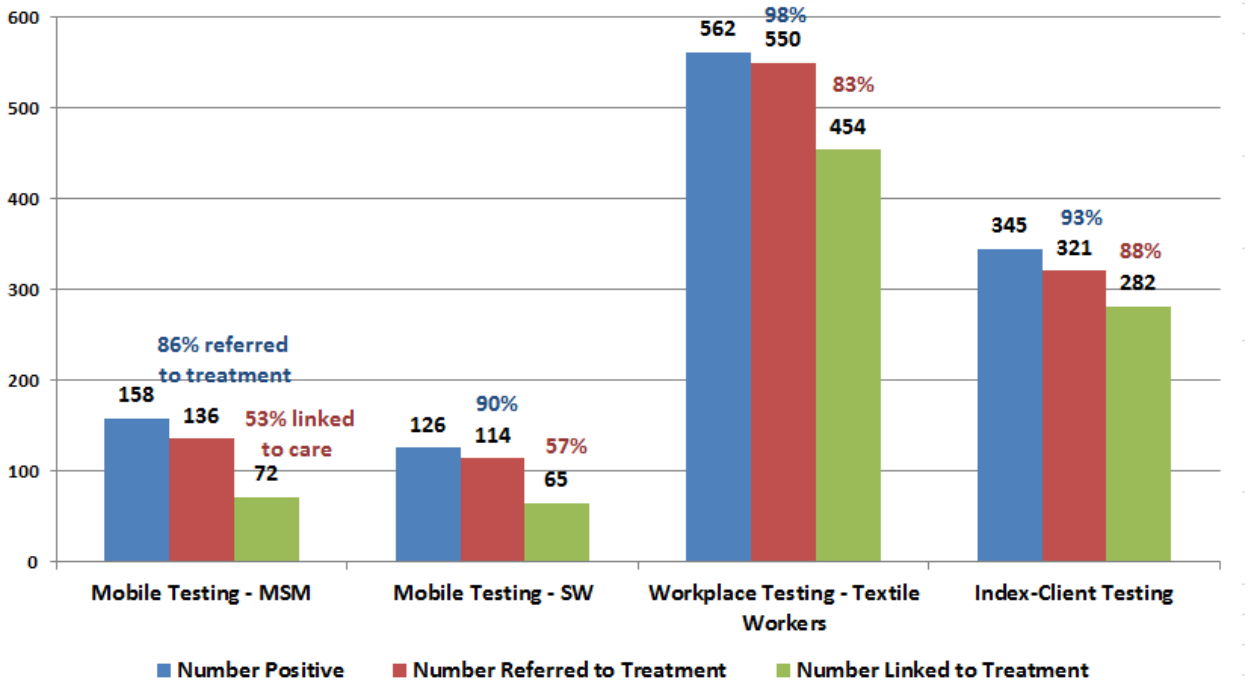
Figure 4 provides an example of how programs can visualize testing results. In this case, progress to targets (from the example in Table 2) is assessed after one quarter of implementation. Each targeted testing approach and associated target population is assessed for progress to annual target and positivity rate. Explanations for underperformance (i.e., <25% achievement of annual target) and lower-than-expected HIV positivity should be explored.

Figure 4: HIV Testing and Positivity Rate by Targeted Testing Approach, Quarter 1



The HIV testing cascade should also be evaluated to assess referrals and linkages to treatment and prevention services. Ideally, the cascade should start with an estimate of the size of the population at risk, or an estimate of the number of PLHIV in a population. Figure 5 provides an example of an HIV testing cascade for individuals testing HIV-positive by targeted testing approach. In this example, while referral to treatment is high, linkage to treatment is lower—particularly among MSM and SW identified through mobile testing. Linkage efforts should be re-evaluated and more resources may need to be directed toward linkage navigation. A continuous cycle of program planning, implementation, data collection, M&E, and adjustment of testing efforts should take place, with data review occurring on a quarterly basis at minimum.

Figure 5: HIV Testing Cascade, Quarter 1



B. Program Evaluation

Process and outcome evaluations should be conducted throughout the life of a program to determine progress toward the achievement of program objectives, to evaluate the relationship between testing strategies and key outcomes, and to inform mid-course modifications. Evaluation questions and design should be developed in consultation with the funder and other key stakeholders. Box 6 presents illustrative process and outcome evaluation questions.

Box 6: Illustrative Evaluation Questions

Process Evaluation/Monitoring Questions

1. To what extent have the planned program activities been implemented?
2. To what extent has targeted HIV prevention and HTS been scaled up to priority populations?

Outcome Evaluation Questions

1. What proportion of newly identified PLHIV have been linked to treatment within 90 days?
2. To what extent have national systems been developed for quality HTS and linkage to care and treatment?
3. To what extent has technical assistance supported the implementation of quality control and quality assurance activities, and built capacity to ensure high-quality test results?

C. Documenting Linkage to Care

Documenting linkage to treatment, prevention, and other services is critical to assessing the success of HTS. Information on referrals and linkage that should be documented includes:

1) Referrals made from HTS to services such as ART, PrEP, VMMC, TB, family planning, and harm reduction. This should be documented on the HTS register (as noted above) but also on a standardized referral form. This form may be adapted from national referral forms widely in use in many countries.
2) Confirmed linkage to these services. Approaches for documenting linkages for within-facility referrals may differ from approaches for documenting inter-facility or community-to-facility referrals. Linkages for referrals that are not within-facility will likely require more effort to confirm and document (e.g., needed procedures around use of a referral register, as described below).

A standard **referral protocol** at the national or regional level with accompanying referral tools, such as a standardized **referral form**, can guide and facilitate within- and inter-facility referrals, as well as referrals from community HTS to facility-based services. Detailed referral procedures should be in place and training on these procedures should be provided to health workers. A standardized **referral directory** should be established to facilitate referrals and follow-up. The directory should include all possible referral points for the area it covers, the services offered, provider names, service delivery hours, and contact information.

In addition to a standard referral form, a **referral tracking register** may be implemented within the context of standardized procedures,[15] in particular for referrals made to other facilities or from community HTS to facilities (see Figure 6). This register may be designed to include the sub-set of HTS clients who require specified type(s) of referrals and should capture relevant information such as patient contact information, referral type and location, dates of HTS staff follow-up with patient or facility, and documentation of confirmed linkage.

Figure 6: Illustrative Referral Tracking Register

Client contact information							Referrals																Notes
Date of referral	Client ID	Population group (see codes)	Name	DOB	Address/ Location	Mobile number	HIV clinic		PrEP		VMMC		TB clinic		Family planning		Harm reduction		Other:				
							Site referred to (see codes)	Linkage confirmed? (Y/N) Date of follow up	Site referred to (see codes)	Linkage confirmed? (Y/N) Date of follow up	Site referred to (see codes)	Linkage confirmed? (Y/N) Date of follow up	Site referred to (see codes)	Linkage confirmed? (Y/N) Date of follow up	Site referred to (see codes)	Linkage confirmed? (Y/N) Date of follow up	Site referred to (see codes)	Linkage confirmed? (Y/N) Date of follow up	Site referred to (see codes)	Linkage confirmed? (Y/N) Date of follow up		

Individual follow-up with patients to assess linkage to care can provide useful information to guide ongoing supportive services for clients, and can provide data for M&E of linkage. Individual follow-up can be extremely resource-intensive, however, and self-report of linkage may be unreliable. Therefore, universal tracking of linkage to services may only be feasible with implementation of a **national unique identification number**. If the identification number is not national, use or establishment of a local unique identification number (such as a medical record number) within facilities or within the context of a project conducted by a program implementer can facilitate tracking of patients across service points. Use of unique identifiers can be especially useful within the context of HIV prevention programs targeting discrete cohorts of clients, where numbers are used to track services provided over time (including follow-up HTS and linkage to prevention or

care). Also worth noting is that collection, management, and use of longitudinal information—especially outside of static locations such as clinics—is most feasible if implemented using electronic, client-level databases, as described above.

While perhaps not feasible for national-level implementation in many settings, an option for unique identification within a project context is **biometric data/biometric coding**, which collects unique data such as fingerprints and retinal or iris scans. The use of biometrics is an effective way of ensuring identification and preventing duplication and overestimation of patient volumes. It provides an extra layer of de-duplication in situations where patients may change their personal and demographic information and seek health care at multiple facilities. The risks and benefits of using biometric data over alphanumeric or other unique identifiers must be taken into consideration, and efforts are needed to ensure that such data are secure. For example, in situations where behaviors of KP are criminalized, a database with biomarkers of KP that may be accessible to the government may be unwise, scaring off the very population the project wishes to engage.

D. Data Security and Confidentiality

Maintaining the confidentiality and security of health data is critical for all health programs, especially for health conditions that are stigmatized (such as HIV) and for populations facing stigma and discrimination, including KP such as MSM, PWID, and SW.

It is therefore important for programs to establish standardized data security and confidentiality procedures in the collection, transport, storage, and use of data. Effective general standards for securing and protecting paper-based and electronic data have been described previously[16,17,18] and may be applied or adapted for use in a wide range of settings and populations.

In the context of HTS, services provided in community settings have special considerations in terms of data security and confidentiality. Health care workers and other data collectors will be in the community with paper or electronic records potentially containing personally identifiable health information, and will be transporting or transmitting that information to and from health facilities. It is essential that data security measures are in place both in community- and facility-based settings.

Paper records should be stored in a locked bag/container in the field when not in use, should not be left unattended, and should ideally be returned to the health facility or office on a daily basis to be stored in a locked and secured place. Health care workers and data collectors should not carry more health records/data than they need while in the field, and programs should not collect any personally identifying information on paper records that is not essential for program operations.

Using **electronic records** via devices such as smartphones and tablet computers for community-based HTS can help ensure confidentiality and security of client information. However, certain basic measures must be in place to ensure the security of these devices. For example, devices must be encrypted and password-protected. Data must be stored on a secure system (network or cloud) and data must be stored in accordance with in-country legal requirements. If possible, data should be uploaded to the server on a daily basis so that it is not stored locally on the electronic device for long periods of time. Mobile device management platforms for ongoing management of data collection devices should also be implemented, allowing for remote data protection on lost/stolen devices (including device lock, wipe, encryption, and password recovery). Lastly, protocol and procedures specifying user roles and ensuring that users do not share their passwords with anyone either intentionally or inadvertently (e.g., in the case of loss or theft) should be developed and implemented.

For partner notification programs, ensuring the security and confidentiality of client data and the personal and medical information of partners is essential to prevent harm and wrongful disclosure. A confidential and safe environment needs to be provided for PLHIV to identify sexual and drug-injecting partners. The index client's identity or HIV status must never be revealed to partners, and the outcome of partner testing services must never be shared with the index client.

E. Special Considerations for Specific Testing Approaches

While basic elements of M&E are fundamental to HTS, regardless of approach (i.e., collection of a minimum set of required information, facilitating reporting and data use, facilitating linkage to care, ensuring data security and confidentiality), certain modalities call for additional M&E-related considerations. For example, certain type of venues for HTS (e.g., mobile testing) are best suited for electronic data collection and others (e.g., workplace testing) may introduce particular concerns related to client data confidentiality.

Table 4 outlines key M&E considerations for each of the targeted testing approach discussed previously. When establishing M&E systems for particular testing approaches, the program must take into account the setting, population, and resources available.

Table 4: M&E Considerations for Specific Testing Approaches

Testing Approach	Key M&E Considerations
Mobile testing and venue-based testing	• HTS may need to be coordinated with prevention services activities and tools • Collection of KP classification as part of HTS • Standard tools are oriented to facilities and may not document sufficient information on location and venue • Documenting linkage to care, including to facilities other than the one supporting the testing activity. Referral tracking registers may be implemented. • Maintaining data security and confidentiality in the field • Use of mobile technology is ideal; however, aim to support national systems instead of creating parallel systems, so technology should incorporate data elements from national tools and facilitate routine HTS reporting • Testing events can be targeted based on number/percent yield and surveillance information
Integrated service delivery (one-stop model)	• Establishing procedures and tools to help ensure regular testing among populations at high risk for HIV • Consider incorporating unique IDs and establishing a client-level electronic system to track clients in need of follow-up testing and provide non-duplicated HTS data • Document linkage to care using MOH or clinic tools, depending on setting; specify roles and responsibilities for following up with patient or HIV clinic, and for documenting linkage
Workplace testing	• Concerns about confidentiality within the workplace setting. Ensure implementation of strong confidentiality and security guidelines and procedures, including training staff on confidentiality, limiting staff access to records, securing storage of records, and securing private spaces for HTS • If HIV testing is integrated into other health services, such as TB services, ensure that tools capture all key information (such as linkage for PLHIV)
Home-based testing	• Ensure security and confidentiality of client information • Document linkage to care • Use of mobile technology
Social network testing	• May need to establish special tools to track social network testing, including network trees, tools to track HTS provided to network members, and standardized aggregate reports
Index-client testing and partner notification services	• Partner and family testing tool for HIV clinic patients should be developed for clinical/quality assurance purposes • If implementing partner notification, an M&E system should be established for this (see Annex 3)

HIV self-testing	• M&E systems for scaled-up HIVST do not exist; identifying effective M&E systems for HIVST models should be a high priority • M&E needs and strategies will be highly dependent on the model (e.g., test kit distribution, support for linkage) • Ideally, HIVST data will be accessible for use in national efforts to assess coverage and yield
Health fairs and multi-disease screening campaigns/events	• M&E issues are similar to those for community-based mobile testing
Targeted PITC	• Ensure adequate information is collected and reported across testing points (e.g., age disaggregation in ANC testing) • Assess strategies for identifying testing uptake/coverage in clinics. Standard attendance and admissions registers do not collect information on HIV testing history, so cannot provide proper denominators to calculate testing coverage. If collected routinely, data from HIV test screening questions (such as those shown previously) can be used to compile numbers eligible for HTS within testing points • Testing can be targeted based on number/percent yield and through monitoring for low numbers tested
HIV birth testing for infants	• Existing national tools may not capture birth testing • National aggregate reports may be updated to summarize birth testing coverage, results, and ART initiation for HIV-positive infants

F. Summary

In order to reach the first of the global 90:90:90 targets, HTS coverage must increase within the geographic areas and populations where the HIV burden is highest, and in previously underserved areas and populations at risk for HIV. Innovative HIV testing approaches are required to meet this challenge, and M&E systems must evolve to provide the information to enhance and focus testing efforts.

Targeted testing approaches require robust M&E systems to monitor the number of individuals reached, testing yield, and linkage to treatment and prevention services, and to inform program planning. Paper-based systems and tools need to be modified or replaced by electronic HIS and tools that can more capably monitor HTS coverage and yield and permit thorough analysis of testing strategies. Registers and tools must collect information on key and priority populations reached and document referrals and linkage to treatment and other HIV-related services. Establishment of unique identifiers at the national level enables the universal tracking of linkage to care; however, implementation of unique identifiers on a smaller scale, such as within a facility or limited project, will help track patients longitudinally across service points. Ensuring data confidentiality and security is essential for the variety of HTS approaches discussed here.

While multiple targeted testing approaches may be employed, it is critical to conduct routine monitoring and periodic assessments to determine which approaches are the most effective at achieving the goals of coverage, quality, and yield. The approaches deemed most effective should be promoted and expanded to other populations and geographic areas, as appropriate.

Annex 1: Supporting Materials

To access these tools, copy and paste the URL below into your web browser. Note that not all hyperlinks will work directly from Word.

Birth Testing for HIV Diagnosis in Children: Considerations and Controversies
http://icap.columbia.edu/news-events/events/detail/icap-grand-rounds-webinar-birth-testing

ICAP Package of Care for People Living with HIV
http://icap.columbia.edu/resources/detail/icap-package-of-care-for-people-living-with-hiv

PEPFAR 3.0 Controlling the Epidemic: Delivering on the Promise of an AIDS-Free Generation
https://www.pepfar.gov/documents/organization/234744.pdf

WHO Guidelines on HIV Self-Testing and Partner Notification, Dec 2016
http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/

WHO Consolidated Guidelines on HIV Testing Services, July 2015
http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/

WHO Recommendations to Assure HIV Testing Quality: Policy Brief 2015
http://www.who.int/hiv/pub/toolkits/policy-hiv-testing-quality-assurance/en/

WHO Webpage on HIV Testing Services
http://who.int/hiv/topics/vct/en/

Annex 2: PEPFAR Key Population Classification Approach

Key Population Classification (core)	**6/14/2016**
This assessment was developed to be used in both community and facility health care settings for the purpose of helping providers identify the types of services needed by the client. The complete form should be offered to all clients, regardless of providers' assumptions about whether the client is a key population member or not. Note- all script in normal text should be read out loud to the client, italicized text is instruction to the provider. **Health Care Provider script to Client:** "I will be asking you about some sexual and drug using risk behaviors. Your responses will help me/us provide you with better care. Your answers to these questions will be kept in your confidential clinic record. Answering these questions is voluntary and you can refuse to answer any question and still receive the service you've come here for today."	
1. Do you consider yourself: male, female, transgender or other? □ MALE □ FEMALE □ TRANSGENDER (male to) FEMALE □ TRANSGENDER (female to) MALE □ _____OTHER □ REFUSE TO ANSWER	*If TRANSGENDER (male to) FEMALE: client was born a boy, but identifies as a woman* *If TRANSGENDER (female to) MALE: client was born a girl, but identifies as a man*
2. What was your sex at birth: male or female?	□ MALE □ FEMALE □ _____OTHER □ REFUSE TO ANSWER
3. Do you have sex with: men, women or both?	□ MEN ONLY □ WOMEN ONLY □ BOTH MEN AND WOMEN □ REFUSE TO ANSWER
4. Is selling sex your main source of income?	□ YES □ NO □ REFUSE TO ANSWER
5. In the last 6 months, have you injected illicit or illegal drugs?	□ YES □ NO □ REFUSE TO ANSWER

Source: PEPFAR Monitoring, Evaluation, and Reporting (MER 2.0) Indicator Reference Guide. https://www.pepfar.gov/documents/organization/263233.pdf

Annex 3: M&E of Partner Notification Services

As described previously in this document, introduction of partner notification services alongside HTS has been recommended by WHO. Data collected to monitor partner notification services should include the number of partners elicited, notified, and tested for HIV. Specifically, the HTS register or partner notification tool should include information on:

- PLHIV who are offered partner notification services
- PLHIV who accept partner notification services
- PLHIV screened for intimate partner violence for each partner*
- Partners identified per HIV-positive client
- Physical location of identified partners
- Type of partner (sexual or drug-injecting)
- Identified partners who were notified
- Type of partner notification (passive, contract, dual, provider)
- Partners who accept HTS
- Partners who test HIV-positive
- HIV-positive partners linked to care and treatment
- Adverse events occurring to HIV-positive clients following partner notification

**If intimate partner violence is identified, partner notification is deferred*

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