World Health Organization

SUPPLEMENT

GUIDELINES ON

HIV SELF-TESTING AND PARTNER NOTIFICATION

SUPPLEMENT TO CONSOLIDATED GUIDELINES ON HIV TESTING SERVICES

DECEMBER 2016

HIV TESTING SERVICES

World Health Organization

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#Test4HIV

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ABBREVIATIONS

AIDS	acquired immune deficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral (drug)
CDC	United States Centers for Disease Control and Prevention
GDG	Guideline Development Group
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIV	human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV testing services
ICER	incremental cost-effectiveness ratio
IPV	intimate partner violence
NGO	nongovernmental organization
PEP	post-exposure prophylaxis
PICO	population, intervention, comparison, outcome
PrEP	pre-exposure prophylaxis
QA	quality assurance
RDT	rapid diagnostic test
RR	relative risk
STI	sexually transmitted infection
TB	tuberculosis
TWG	Technical Working Group
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VMMC	voluntary medical male circumcision
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.

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

Assisted partner notification services: refer to when consenting HIV-positive clients are assisted by a trained provider to disclose their status or to anonymously notify their sexual and/or drug injecting partner(s) of their potential exposure to HIV infection. The provider then offers HIV testing to these partner(s). Assisted partner notification is done using contract referral, provider referral or dual referral approaches.

Concentrated epidemic: refers to when 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.

Confirm: to issue a report on HIV status. Initially reactive test results, including reactive self-test results, need to be confirmed according to the national validated testing algorithm.

Contract referral: an assisted partner notification service approach in which HIV-positive clients enter into a contract with a trained provider and agree to disclose their status and the potential HIV exposure to their partners by themselves, and refer their partners to HIV testing services (HTS) within a specific time period. If the partner(s) of the HIV-positive individual does not access HTS, or contact the health provider, within that period, then the provider will contact the partner(s) directly and offer voluntary HTS.

Dual referral: an assisted partner notification service approach in which a trained provider accompanies and provides support to HIV-positive clients when they disclose their status and the potential exposure to HIV infection to their partners. The provider also offers voluntary HTS to the partner(s).

Directly assisted HIV self-testing (HIVST): refers to when individuals who are self-testing for HIV receive an in-person demonstration from a trained provider or peer before or during HIVST, with instructions on how to perform a self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer-supplied instructions for use and other materials found inside HIVST kits.

Generalized epidemic: refers to when HIV is firmly established in the general population. Although subpopulations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain the epidemic. Numerical proxy: HIV prevalence is consistently over 1% in pregnant women attending antenatal clinics.

Harm or social harm: any intended or unintended cause of physical, economic, emotional or psychosocial injury or hurt from one person to another, a person to themselves, or an institution to a person, occurring before, during or after testing for HIV.

HIV self-testing: a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts.

HIV status: is the final report that is given to the patient; it is the final interpretation of the patient disease state and is based on a collection of testing results generated from one or more assays. HIV status may be reported as HIV-positive, HIV-negative or HIV-inconclusive.

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

Index testing: often referred to as index case, index patient or index partner HIV testing. This is a focused HTS approach in which the household, family members (including children) and partners of people diagnosed with HIV are offered HTS. For additional details on index partner testing, see definitions on assisted partner notification, contract referral, dual referral, partner notification services, passive referral and provider referral.

In vitro diagnostic 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 diagnosis, monitoring or determining compatibility. For example, an in vitro diagnostic medical device can be used for: diagnosis, as an aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status.

Intimate partner violence: behaviour within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship, including acts of physical violence, sexual violence, emotional or psychological abuse and controlling behaviours.

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

Lay provider: any person who performs functions related to health-care delivery and has been trained to deliver these services but has no formal professional or para-professional certification, nor a tertiary education degree.

Negative predictive value: the probability that a person with a negative test result is not infected with HIV, that is, that he or she is *truly negative*.

Non-reactive test result: a test result that does not show a reaction indicating the presence of analyte, which in the context of HIV refers to HIV-1 p24 antigen or HIV-1/2 antibodies.

Partner notification services: also known as disclosure or contact tracing; is defined as a voluntary process whereby a trained provider asks people diagnosed with HIV about their sexual partners and/or drug injecting partners, and then, if the HIV-positive client agrees, offers these partner(s) HTS. Partner notification is provided using passive or assisted approaches.

Passive referral: is a partner notification service in which HIV-positive clients are encouraged by a trained provider to disclose their status to their sexual and/or drug injecting partners by themselves, and to also suggest HTS to the partner(s) given their potential exposure to HIV infection.

Point-of-sex testing: refers to when individuals use an HIV rapid diagnostic test for self-testing to screen potential sex partners and determine his or her own HIV status and their partner(s)' HIV status.

Positive predictive value: the probability that a person with a positive test result is infected with HIV, that is, that he or she is *truly positive*.

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

Provider referral: an assisted partner notification service approach in which, with the consent of the HIV-positive client, a trained provider confidentially contacts the person's partner(s) directly and offers the partner(s) voluntary HTS.

Quality assurance: part of quality management focused on providing confidence amongst stakeholders that quality requirements will be fulfilled.

Quality control: is the set of procedures designed to monitor the test method and results to ensure appropriate test system performance. It includes testing control materials, charting the results and analysing them to identify source of error, and evaluating and documenting any remedial action taken as a result of this analysis.

Quality improvement: an element of quality management focused on increasing the ability to fulfil quality requirements.

Quality management system: a system to direct and control an organization with regard to quality. Systematic and process-oriented efforts are essential to meet quality objectives. Principles of quality management include categories such as documents and records, organization, personnel, equipment, purchasing and inventory, process control, information management, occurrence management, assessments – external and internal, process improvement, customer services and facilities and safety.

Rapid diagnostic test: in vitro diagnostic medical device of immunochromatographic or immunofiltration format for the detection of HIV-1/2 antibodies and/or HIV p24-1 antigen in the context of HIV.

Reactive test result: a test result that shows a reaction indicating the presence of analyte, which in the context of HIV includes HIV-1 p24 antigen or HIV-1/2 antibodies.

Repeat testing: a situation in which additional testing is performed for an individual immediately following a first test, during the same testing visit, due to HIV-inconclusive status or discordant test results. The same assay(s) is used and, where possible, the same specimen.

Retesting: refers to certain situations in which individuals should be retested after a defined period of time: (1) HIV-negative people with recent or ongoing 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 errors and ruling in or ruling out seroconversion.

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

Seroconversion: is when an individual's immune system produces a quantity of HIV-1/2 antibodies sufficient to be detectable on a given HIV serology assay.

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

Serology assay: refers to an assay that detects the presence of antibodies in human specimens. Such assays typically use serum or plasma, but also capillary/venous whole blood and oral fluid. For example, rapid diagnostic tests, immunoassays and certain supplemental HIV assays are serology assays.

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

Task sharing: the rational redistribution of tasks and the increased scope of work among different cadres of health-care providers, including trained lay providers.

Test for triage: an HIV testing approach whereby a trained provider or self-tester performs a single HIV rapid diagnostic test. Individuals with a reactive test result are encouraged by a trained provider, or by written or pictorial information, to link to a facility for further HIV testing to confirm their status, and if confirmed HIV-positive, to prevention, treatment, care and other support. Individuals with a non-reactive test result are advised to link to appropriate HIV prevention services and retest if they tested within six weeks of possible HIV exposure or are at ongoing HIV risk.

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

Testing strategy: describes a testing sequence to attain a specific objective. In the context of HIV, a testing strategy takes into consideration the presumed HIV prevalence in the population being tested, either high HIV prevalence (5% and above) or low HIV prevalence (below 5%).

Unassisted HIV self-testing: refers to when individuals self-test for HIV using only a self-test kit that includes manufacturer-provided instructions for use. As with all self-testing, users may be provided with links or contact details to access additional support, such as telephone hotlines or instructional videos.

Window period: the period between HIV infection and the detection of HIV-1/2 antibodies using serology assays, which marks the end of the diagnostic window period and the end of seroconversion.

EXECUTIVE SUMMARY

Purpose

To achieve the United Nations (UN) 90–90–90 global HIV targets – and specifically the first target of diagnosing 90% of all people with HIV – the World Health Organization (WHO) released the *Consolidated guidelines on HIV testing services* in 2015 *(1)*.

This document presents new WHO recommendations and guidance on:
1. HIV self-testing
2. Partner notification

In that first edition of the guidelines, WHO synthesized the existing guidance on HIV testing services (HTS) and issued a new recommendation to support trained lay providers to deliver HTS using rapid diagnostic tests (RDTs). In addition, the guidelines emphasized the need for strategic approaches to deliver HTS. In particular, they highlighted the potential of HIV self-testing (HIVST) to increase HTS access, especially among men, key populations[1] and young people. They also highlighted the need to improve the uptake of couples and partner testing services, including by offering HTS to the partners of people with HIV *(1)*. Moreover, the guidelines noted that there was a growing unregulated market for HIVST in low- and middle-income settings, where products of unknown quality were often being used. Since the release of the 2015 guidelines, a growing number of countries have recognized the need to support HIVST in a more regulated way and to use HIV RDTs for self-testing that are approved by the relevant regulatory authority, or following results of an international regulatory review.

WHO has recommended partner testing since 2012 *(2)*. Although there has been some progress in including partner testing in national testing policies (especially for partners of women attending antenatal clinics), implementation of partner testing in most countries remains low *(3)*.

Since the release of the consolidated guidelines in 2015, new evidence has emerged. Consequently, in an effort to further support countries, programme managers, health workers and other stakeholders seeking to achieve national and international HIV goals *(4)*, this 2016 supplement issues new recommendations and additional guidance on HIVST and assisted HIV partner notification services.

These new guidelines aim to:

- Support the implementation and scale-up of ethical, effective, acceptable and evidence-based approaches to HIVST and assisted HIV partner notification.
- Support the routine offer of voluntary assisted HIV partner notification services as part of a public health approach to delivering HTS.

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 the WHO *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* (http://www.who.int/hiv/pub/guidelines/keypopulations).

- Provide guidance on how HIVST and assisted HIV partner notification services could be integrated into both community-based and facility-based HTS approaches and be tailored to specific population groups.
- Support the introduction of HIVST as a formal HTS intervention using quality-assured products that are approved by WHO and official local and international bodies.
- Position HIVST and assisted HIV partner notification services as HTS approaches that will contribute to closing the testing gap and achieving the UN's 90–90–90 and 2030 global goals.

These new guidelines include issues related to offering HIVST and assisted HIV partner notification services to the following population groups:

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

Guideline development methodology

In response to the availability of new evidence on the potential benefits of HIVST and assisted HIV partner notification services, external experts and stakeholders proposed supplement to the WHO *Consolidated guidelines on HIV testing services (1)*. As a result, from November 2015 to August 2016, the WHO HIV Department led the development of new guidance with the WHO Guideline Steering Group and an independent Guideline Development Group (GDG) made up of a geographically and gender-balanced group of external experts, including academics, researchers, programme managers, implementers and representatives of community networks and organizations. The HIV Department, Guideline Steering Group and GDG formulated the population, intervention, comparator, outcome (PICO) questions that were used to outline the new guidelines. Support was also provided by the HIVST Technical Working Group (TWG), which is co-convened by the WHO HIV Department and the Prequalification of In Vitro Diagnostics Programme, as well as the External Review Group.

From January to April 2016, WHO convened four virtual meetings of the GDG and the WHO Guideline Steering Group. During those meetings, the WHO HIV Department provided an overview of the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) process *(5–7)*, and the two groups reviewed and finalized the PICO questions, outcomes and stratifications for each of the systematic reviews. Using an electronic survey, the groups then ranked the importance of each systematic review outcome using the GRADE rating scale (1–9) *(5)*.

From April to July 2016, the WHO HIV Department convened four virtual meetings and one in-person meeting of the HIVST TWG. During those meetings, an overview of the proposed standards for WHO prequalification of HIV RDTs for self-testing was provided,

the evidence on the performance of HIV RDTs used for self-testing was reviewed, and the defining of a risk/benefit-based approach for assessing HIV RDTs used for self-testing was considered. Based on this review of evidence and other information considered at these expert-level meetings, WHO formulated a set of technical specifications for HIV RDTs for self-testing. These specifications are available on the WHO prequalification of In vitro Diagnostics Programme website: http://www.who.int/diagnostics_laboratory/guidance/en/

The GDG and WHO Guideline Steering Group reviewed and provided inputs into the development of new or updated definitions needed to inform the new guidelines and complete additional background work, including: an accuracy and performance review, cost-effectiveness analysis, risk/benefit analysis, country policy analysis, values and preferences reviews and surveys and social harm review.

In July 2016, WHO organized an in-person meeting of the WHO Guideline Steering Group and GDG to review the final results of the GRADE systematic reviews and other background work. The HIVST TWG was also convened at this meeting and participated in discussing implementation considerations and mapping of implementation and research gaps. Based on the evidence provided, the GDG made recommendations to WHO on HIVST and assisted HIV partner notification services.

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

Recommendations

The box below summarizes the recommendations presented in these new guidelines:

NEW

Recommendations

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

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

The new recommendation on HIVST is in line with existing WHO recommendations supporting task sharing, the utilization of trained lay providers in the health sector and the *test for triage* approach *(1)*. Using the GRADE method, the GDG determined the evidence to be of moderate quality and, based on this evidence, made a strong recommendation to WHO that HIVST be offered as an additional HTS approach.

The recommendation on assisted HIV partner notification is in line with and builds on existing WHO recommendations supporting couples and partner testing, including offering HIV testing to the households, family members and partners of people who are HIV-positive *(1,2)*. Using the GRADE method, the GDG deemed the evidence to be of moderate quality and, based on this evidence, made a strong recommendation to WHO that voluntary assisted HIV partner notification services be offered as part of a comprehensive package of testing and care offered to people with HIV.

Implications for programming

These guidelines aim to support countries to provide two additional HTS options in order to reach people who may not otherwise test for HIV.

Closing the HIV testing gap and diagnosing 90% of all people with HIV by 2020 is critical to the success of the global HIV response. These WHO guidelines aim to support countries to provide two additional HTS approaches that can be utilized to reach people, particularly those at high HIV risk who may not otherwise test. They also aim to enable countries and programmes to strategically expand coverage in areas and among populations in greatest need and to increase access to services, thereby contributing to the achievement of global HIV targets.

To accomplish these goals, countries need to assess their specific situations, taking into account their particular epidemiological contexts and the populations most in need in different settings. It is also important that the programme approaches adopted adhere to the WHO 5Cs of HTS: **C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results and **C**onnection *(1)*. Moreover, approaches need to address country- and population-specific social and legal barriers to the access and uptake of HTS.

INTRODUCTION

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1.1 Progress and challenges with HIV testing services

People's knowledge of their own, and their partner's, HIV status is essential to the success of the global HIV response. The overarching goals of providing HIV testing services (HTS) are to deliver a diagnosis and effectively facilitate access to and uptake of HIV prevention, treatment and care, including antiretroviral therapy (ART), voluntary medical male circumcision, services for prevention of mother-to-child transmission, male and female condoms and lubricants, contraception, harm reduction services for people who inject drugs, pre-exposure prophylaxis and post-exposure prophylaxis. These high-impact interventions have the potential to reduce HIV transmission and HIV-related morbidity and mortality *(1,8–10)*.

Over the past decade, the global scale-up of HTS has been substantial. In 2005 it was estimated that only 10% of people with HIV in Africa were aware of their HIV status and that, globally, only 12% of people who wanted to test for HIV were able to *(11)*. In contrast, in 2015 it was estimated that 55% of all people with HIV in Africa and 60% of people with HIV globally knew their status *(12)* and that more than 600 million people received HTS in 122 low- and middle-income countries in the years 2010–2014 *(13)*. These achievements have been possible largely because of the scale-up and use of effective HIV treatment and the wide availability of low-cost rapid diagnostic tests (RDTs). The growing availability and use of RDTs has made it possible to increase task sharing. This has enabled HTS to also be delivered by trained lay providers and to be implemented in more settings, ranging from routine testing in facilities to community-based outreach.

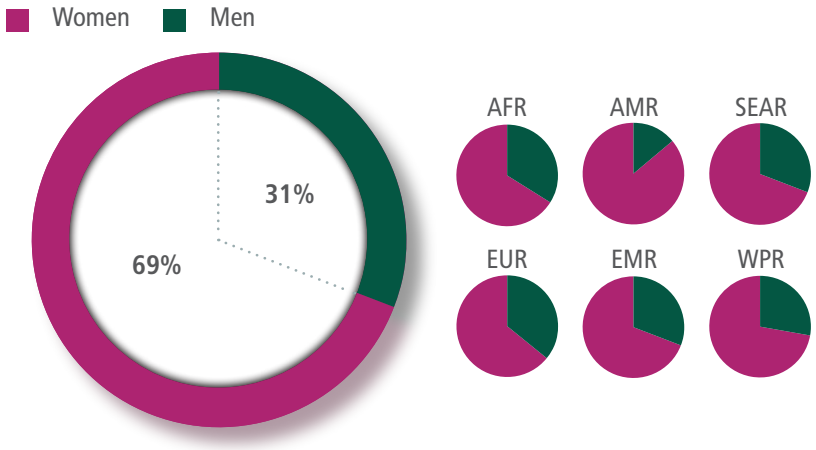
Many of those at highest risk of HIV remain unreached.

In spite of these achievements, a substantial testing gap remains. According to recent estimates, 77% of all people diagnosed with HIV are on ART; however, 40% of all people with HIV remain undiagnosed *(12)*. Furthermore, despite the annual increases in HIV tests and HIV testing coverage *(13)*, in many settings HTS is not sufficiently focused. Many of those at highest risk, such as men, partners of people with HIV, adolescents and young people in high HIV prevalence settings and key populations worldwide, remain unreached.

1.1.1 Men continue to lag behind

Globally, HTS uptake and coverage for men continues to be lower than for women *(3)*. Nearly 70% of adult HIV tests reported in 76 low- and middle-income countries in 2014 were conducted for women (see Fig. 1.1) *(13)*. Global reporting suggests this is because HIV testing has been successfully integrated into reproductive health services, including antenatal care, but not consistently into other relevant clinic settings. Also, male partner testing is not widely implemented or, where offered, taken up *(3)*. As of June 2014 only half of 58 low- and middle-income countries surveyed had policies supporting couples HTS *(14)*. Fewer still reported couples HTS rates over 20% in antenatal care settings, with the offer of partner testing being even less likely outside of these settings *(14)*; more than half of countries did not have policies recommending the offering of partner testing in all settings (see Annex 24 for details).

Fig. 1.1. Men and women as a proportion of people older than 15 years who received HIV testing services in low- and middle-income countries, by WHO region, 2014



AFR = African Region; AMR = Region of the Americas; SEAR = South-East Asia Region; EUR = European Region; EMR = Eastern Mediterranean Region; and WPR = Western Pacific Region.

Source: WHO, 2015 *(13)*.

Barriers hindering men's access to and uptake of HTS are often due to their perceptions that health services, particularly antenatal care settings, are not friendly to men *(15)*. Other socio-cultural beliefs and behaviours are also contributing factors. As a result, many men remain untested, and those who are HIV-positive continue to be undiagnosed and, therefore, linked to treatment and care late. Consequently, in many settings, males have a higher HIV-mortality rate than their female peers *(16)*.

Strategies are needed to increase men's uptake of HTS, including providing HTS in more accessible settings. Also needed are ways to encourage more testing of male partners in high prevalence settings and testing of male partners of women with HIV in all settings. As reported in recent systematic reviews, assisted HIV partner notification services, HIVST, male-focused interventions and outreach such as mobile or home-based HIV testing are particularly promising, having increased uptake of HTS among men in several settings *(17,18)*.

1.1.2 Adolescents are also underserved

Adolescents, particularly girls, are also at significant risk of HIV infection. Risk is highest in sub-Saharan Africa, where nearly 90% of the world's HIV-positive adolescents (10–19 years of age) are estimated to be living *(19)*. Additionally, an analysis across 19 countries in sub-Saharan Africa reports that, regardless of gender, adolescent orphans are more likely to be HIV-positive than other adolescents *(20)*.

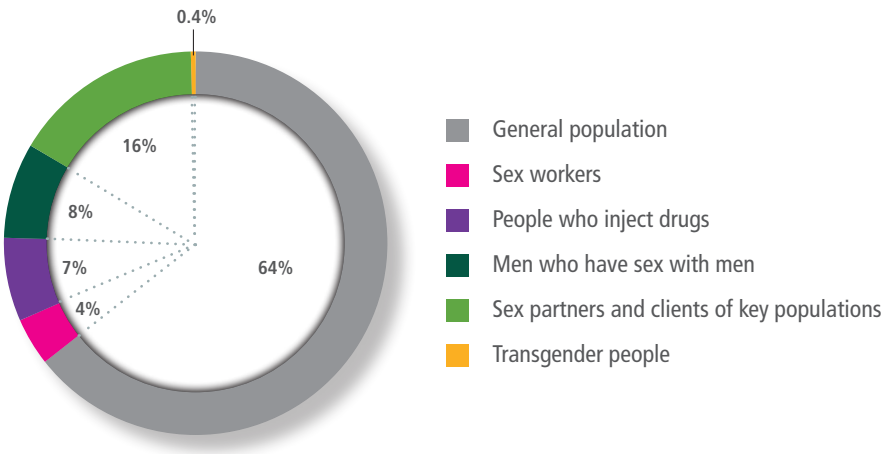
Despite the need for HIV testing among adolescents, coverage and uptake remain poor. In the WHO Africa Region it is estimated that fewer than one in every five girls (15–19 years of age) are aware of their HIV status *(21,22)*. Poor access and uptake are often due

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

1.1.3 Increasing access for key populations

Key populations are also disproportionately affected by HIV. They comprise approximately 36% of the 1.9 million new adult HIV infections that occur each year *(8,12)* (see Fig. 1.2). Although countries are increasingly including key populations in their national HTS guidelines, implementation remains limited, and coverage continues to be low in most settings *(13)*.

Fig. 1.2. Global distribution of new HIV infections by population group, 2014



Source: UNAIDS, 2016 *(12)*.

Poor coverage and low uptake of HTS among key populations is not only related to availability but also to acceptability of services. Low acceptability frequently reflects unfriendly services, fear of stigma, discrimination, and punitive laws and practices that criminalize behaviours and, thereby, discourage access to health services, including HTS *(8)*.

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

1.2 Guidelines rationale

These 2016 guidelines aim to address gaps in the WHO *Consolidated guidelines on HIV testing services* by providing recommendations and guidance on HIV self-testing (HIVST) and assisted HIV partner notification services. Countries are particularly seeking WHO guidance on HIVST because HIVST kits are increasingly available through informal channels, such as private pharmacies and the Internet, with products frequently of unknown quality *(24–26)*. Likewise, although several countries have policies on HIV partner notification, it remains poorly implemented in practice – even though partner notification is simple, effective and can lead to the diagnosis of high proportions of persons with HIV infection. Furthermore, concerns about potential social harm, including violence resulting from partner notification, have not been borne out in the scientific studies conducted to date. While programme implementers should be sensitive to the potential for harm arising from disclosure of HIV status, this should be balanced against the benefit of diagnosing HIV infection and linking people to treatment. Offering voluntary assisted partner notification services for sexual and drug injecting partners of people with HIV will expand the number of people who are aware of their exposure to HIV infection.

Countries and other key stakeholders have indicated the importance of this new guidance to enable them to make decisions about whether, or how, to adopt these two approaches to HIV testing so as to enhance their ability to strategically focus on and scale up HTS, with a view to achieving the UN 90–90–90 goals and fast-tracking the end of HIV by 2030 *(4)*.

1.3 Scope of guidelines

These new guidelines present two approaches to testing that were not covered in the 2015 *Consolidated guidelines on HIV testing services (1)*. In particular, they present and discuss guidance to support the most ethical, acceptable and effective implementation of HIVST and assisted HIV partner notification services. The detailed methodology used to develop the guidelines is described in Annex 16. Chapter 2 details the guidance and recommendations on HIVST, while Chapter 3 details the guidance and recommendations on assisted HIV partner notification services. These guidelines are also available in the 2015 consolidated guidelines as Chapters 10 and 11. They are also available as abridged policy briefs: http://www.who.int/hiv/pub/guidelines/.

1.4 Using the guidelines

These guidelines are intended to help countries implement a strategic combination of HTS approaches that address each specific epidemiological context in an appropriate way. They are aligned with a public health approach to HTS and are guided by the human rights principles outlined in the WHO 5Cs for HIV testing (see section 1.7).

The background documents developed to support these guidelines and the systematic reviews and Grading of Recommendations, Assessment, Development and Evaluation tables for new recommendations appear in the annexes listed in the table of contents, which are available on the Internet (http://www.who.int/hiv/pub/guidelines/).

1.5 Goal and objectives

The primary goal of these guidelines is to better support and complement existing HTS approaches in order to reach people who may not otherwise test.

The primary goal of these 2016 guidelines is to supplement the existing WHO *Consolidated guidelines on HIV testing services* and, thereby, better support countries and national programmes seeking to reach people who may not otherwise test.

Specific objectives in support of this goal include the following:

- Strengthen existing guidance on HIVST, which encourages countries to conduct pilot services and demonstration projects.
- Support the routine offering of voluntary assisted HIV partner notification services as part of the public health approach to delivering HTS.
- Strengthen existing guidance to promote couples and partner HTS, in particular offering voluntary HTS to the partners of all people diagnosed with HIV.
- Support the implementation and scale-up of HIVST and assisted HIV partner notification in the most ethical, effective, acceptable and evidence-based manner.
- Provide guidance on how HIVST and assisted HIV partner notification services should be integrated into existing community-based and facility-based HTS approaches and tailored to specific population groups.
- Position HIVST and assisted HIV partner notification services as part of the strategic combination of HTS approaches that will contribute to closing the testing gap and achieving the UN's 90–90–90 global goals.

1.6 Target audience

These guidelines are intended for national and sub-national HIV programme managers, particularly within ministries of health, who are responsible for the national health sector response to HIV, including HTS and prevention, care and treatment services, as well as officers at the national level responsible for other communicable diseases, especially other forms of sexually transmitted infections, tuberculosis and viral hepatitis.

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

1.7 Guiding principles

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

It is important to deliver HTS with a public health and human rights-based approach that highlights priority areas, including universal health coverage, gender equality and health-related human rights such as accessibility, availability, acceptability and quality of services. For all HTS, regardless of approach, the public health benefits must always outweigh the potential harm or risk. Moreover, the main reasons for testing must always be to both benefit the individuals tested and to improve health outcomes at the population level. HTS should be expanded not merely to achieve a high rate of testing uptake or to meet HIV testing targets, but primarily to provide access for all people in need to appropriate, quality HTS, which is linked to prevention, treatment and care services. HIV testing for diagnosis must always be voluntary, and consent for testing must be informed by pre-test information.

All forms of HTS, including HIVST and HIV partner notification services, should adhere to the WHO 5 Cs: **C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results and **C**onnection (linkage to prevention, care and treatment services) *(1)*. Coerced or mandatory testing is never appropriate, whether that coercion comes from a health-care provider or from a partner, family member, or any other person.

WHO 5 Cs of HIV testing services

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

- **Consent:** People receiving HTS must give their 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. It should not be assumed that people who request, or report, self-testing for HIV are giving or have implicitly given their consent. It is important that all people who self-test are informed that mandatory or coercive testing is never warranted.

  Informed consent is necessary when programmes adopt assisted HIVST approaches. In addition, it is essential that all people with HIV are informed that assisted partner notification is voluntary, and that partners of HIV-positive clients are also made aware that HIV testing is voluntary, not mandatory.

- **Confidentiality:** HTS must be confidential. Discussions held between the HTS provider and the client should not be disclosed to a third party without the express consent of the person being tested. Although confidentiality must be respected, it should never be used to reinforce secrecy, stigma or shame. Counsellors should always ask clients, among other things, who they 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 to HIV-positive clients.

- **Counselling:** Pre-test information and post-test counselling can be provided in a group setting if appropriate; however, all persons should have the opportunity to ask questions in a private setting if they request it. All HTS must be accompanied by appropriate and high-quality post-test counselling, based on HIV test results. Quality assurance (QA) mechanisms, as well as supportive supervision and mentoring systems, should be in place to ensure the provision of high-quality counselling.

  In the context of HIVST, it is important to note that pre-test information and post-test counselling can be provided using a directly assisted approach (for example, in-person demonstration and explanation by a trained provider or peer) or using an unassisted approach (for example, use of manufacturer provided instructions), as well as a number of other support tools, such as brochures, links to Internet- or computer-based programmes or videos, or telephone hotlines or mobile phone applications or text message services.

- **Correct test results:** Providers of HTS should strive to provide high-quality testing services and QA mechanisms that ensure people receive a correct diagnosis. QA may comprise both internal and external measures and should include support from the national reference laboratory.

  A single reactive self-test result *does not* provide an HIV-positive diagnosis. It should be followed by further testing and confirmation by a trained provider. Additionally, all people who receive a positive HIV diagnosis should be retested to verify their diagnosis before initiation of ART or HIV care. Interpretation of a non-reactive self-test result will depend on the ongoing risk of HIV exposure. Individuals at high ongoing risk, or who are using anti-retroviral drugs for treatment or prevention, should be encouraged to retest.

- **Connection:** Linkage to prevention, treatment and care services should include the provision of effective and appropriate follow-up. Providing HTS in situations where there is no access or poor linkage to care, including ART, has limited benefit for those with HIV.

  In the context of HIVST, connection also includes linkage to further HIV testing in a stigma-free community- or facility-based setting, where test results can be confirmed and an HIV diagnosis given by a trained provider.

HIV SELF-TESTING

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2 HIV SELF-TESTING

KEY POINTS

- **HIV self-testing (HIVST)** refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts. As with all approaches to HIV testing, HIVST should always be voluntary, not coercive or mandatory. Although reported misuse and social harm are rare, efforts to prevent, monitor and further mitigate related risks are essential.
- A **reactive (positive) self-test result** always requires further testing and confirmation from a trained tester starting from the beginning of a validated national testing algorithm. Clear messages are essential to ensure users understand that HIVST does not provide a definitive HIV-positive diagnosis, and they are aware of what to do after a reactive self-test result.
- **Interpretation of a non-reactive (negative) self-test result** will depend on the ongoing risk of HIV exposure. Individuals at high ongoing risk, or who test within 6 to 12 weeks of possible HIV exposure, should be encouraged to retest. HIVST is not recommended for users with a known HIV status who are taking antiretroviral drugs, as this may lead to an incorrect self-test result (false non-reactive).
- **HIVST is acceptable** to many users across different contexts and can, therefore, **increase uptake and frequency of HIV testing**, particularly among populations at high ongoing risk of HIV, who may be less likely to access testing or test less frequently than recommended.
- **HIV rapid diagnostic tests (RDTs) used by self-testers can perform as accurately as when used by a trained tester**, provided the HIVST products meet quality, safety and performance standards. In-person demonstrations and other support tools, such as videos, may also enhance the performance of HIVST.
- **HIVST can be delivered through various approaches** in the public and private sectors, including community-based, facility-based and Internet-based channels. Approaches may also offer the option of using an oral fluid or blood-based HIV RDT for self-testing. As such, different populations can benefit from a range of choices when self-testing for HIV.

NEW

Recommendation

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

2.1 Background and rationale

HIV self-testing (HIVST) is an empowering and innovative way to help achieve the first of the United Nations 90–90–90 treatment targets *(1)* – for 90% of all people with HIV to know their status by 2020. HIVST will contribute to this global target by reaching first-time testers, as well as by creating demand for and enabling more people to receive HIV testing, particularly those with undiagnosed HIV or who are at high ongoing risk and in need of frequent retesting *(2)*.

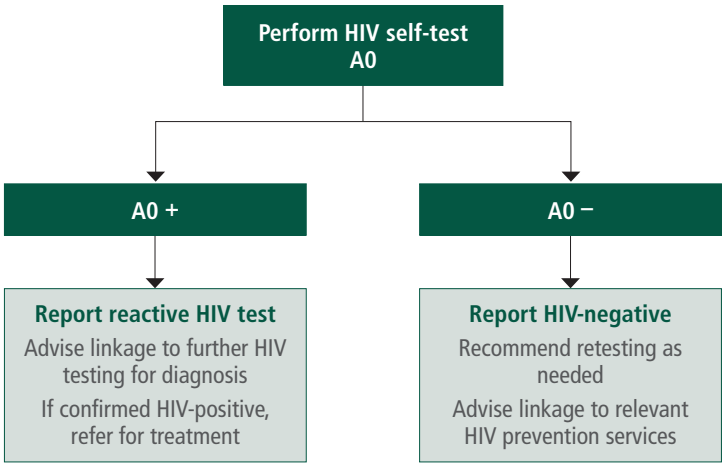
HIVST specifically refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts *(2)*. Self-testing is not a new concept; it is used in the diagnosis and management of other health conditions, such as pregnancy and diabetes, as well as colon cancer. In this way, HIVST represents another step in line with efforts to increase patient autonomy, decentralize services and create demand for HIV testing among those unreached by existing services.

HIVST is a convenient and discreet approach, which has many possible advantages for users who may prefer additional ways to test for HIV. HIVST has proven to be highly acceptable among various groups of users in diverse settings *(2–7)*, particularly: key populations *(4,8,9)*, men *(10,11)*, young people *(10,12,13)*, health workers *(7,14)*, the general population *(10,15,16)*, pregnant women (*17)* and their male partners *(18,19)*, and other couples and partners *(14,20)*. Since the early 2000s, health workers in high HIV prevalence African settings *(14,21–23)*, as well as other populations *(24,25)*, have been known to self-test for HIV by accessing test kits of unknown quality through informal channels, including private pharmacies and the Internet.

A reactive self-test result always requires further testing and confirmation by a trained tester.

HIVST does not provide a definitive HIV-positive diagnosis. This is because, as with all HIV testing, a single rapid diagnostic test (RDT) is not sufficient to make an HIV-positive diagnosis. Thus, HIVST is considered to be a *test for triage (2,6)*, which requires individuals with a reactive test result to receive further testing from a trained tester using a validated national testing strategy (see Fig. 2.1). Further guidance on HIV testing strategies and algorithms for diagnosis are available in Chapter 7 of the World Health Organization (WHO) *Consolidated guidelines on HIV testing services (2)*.

Fig. 2.1. HIVST testing strategy



A0 = Assay 0 (test for triage).

Programmes distributing HIV RDTs for self-testing should inform users about the performance and limitations of the product. Also, programmes should advise all users with a non-reactive self-test result to retest if there is a possibility that they were exposed to HIV in the preceding 6 to 12 weeks, or if they are at high ongoing HIV risk. Any person who is uncertain about how to correctly perform the self-test or interpret the self-test result should be provided with the necessary contact details and information about HIV testing services (HTS) and encouraged to access facility-based or community-based HTS *(2)*.

HIVST may increase the efficiency and effectiveness of a health system by focusing health services and resources on those with a reactive self-test result in need of further testing, support and referral, thereby directing services more appropriately. Individuals with a reactive self-test result who disclose their result to a provider should be advised and supported to link to clinical services for additional HIV testing, and if the HIV-positive diagnosis is confirmed, linked to treatment and care. Individuals with a non-reactive self-test result who disclose their result to a provider will usually not require further testing, unless they tested within 6 to 12 weeks of possible HIV exposure or are at high ongoing risk of acquiring HIV *(2)*.

HIVST may be particularly appropriate for people with high ongoing risk of HIV, such as key populations and serodiscordant couples, who could benefit from more frequent testing without having to increase facility visits. In this way, HIVST would lessen the time and burden of HIV testing on health services and reduce the costs of frequent testing incurred by the individual. Nevertheless, it is important that self-testers are aware of the limitations of HIV RDTs for self-testing in relation to the window period between HIV infection and the detection of HIV-1/2 antibodies. In most cases, higher-risk users who have a non-reactive self-test and disclose their result to a provider should be referred and, if necessary, linked to additional testing as well as HIV prevention services (such as

condoms and lubricants, voluntary male medical circumcision (VMMC), harm reduction and post-exposure prophylaxis (PEP). Referral for further testing and receipt of a confirmed HIV-negative status by a trained tester will be required before initiation of pre-exposure prophylaxis (PrEP) *(26)*.

WHO has outlined various public and private sector channels through which HIV RDTs for self-testing could be distributed, including approaches that are community-based, facility-based, over-the-counter and Internet-based *(2)* (see also section 2.3.1). Approaches also vary in terms of the level and type of support provided – such as, directly assisted and unassisted methods (see Box 2.1).

Box 2.1. Definitions of assisted and unassisted HIVST

Directly assisted HIVST refers to trained providers or peers giving individuals an in-person demonstration before or during HIVST of how to perform the test and interpret the test result.

Unassisted HIVST refers to when individuals self-test for HIV and only use an HIVST kit with manufacturer-provided instructions for use.

Both **directly assisted HIVST** and **unassisted HIVST** may supply additional support tools, such as telephone hotlines, mobile phone text messages, videos, social media and Internet-based applications, which provide technical support, counselling and referrals for further HIV testing services, HIV prevention, care and treatment and other services.

Country policies on HIVST

Globally, HIVST policy is at varying stages.In a WHO review of country policies and an analysis of country reporting, 23 countries reported having a policy supportive of HIVST *(27)*.

HIV RDTs for self-testing that are approved by local regulatory authorities are legally available in France, the United Kingdom and the United States *(28)*. Several other countries have introduced national HIV testing policies or strategic plans that permit or support HIVST. However, as yet, many do not have a regulated or approved product for HIVST *(27)*.

Many countries report HIVST is increasingly available informally through private pharmacies and the Internet – with specific reports on this from Australia *(29)*, China *(24)*, Namibia *(25)*, Peru *(9)*, South Africa *(30)*, Philippines *(31)* and Malaysia *(32)*. Although there is limited information, it is likely that much of this informal and unregulated sale may include the use of products of unknown quality, safety and performance.

2.2 Review of the evidence

2.2.1 Grading of Recommendations, Assessment, Development and Evaluation (GRADE) systematic review on HIVST

Since 2014, WHO has encouraging countries to implement pilot HIVST programmes to evaluate this potential approach. In this 2016 guideline, WHO has issued a strong recommendation that HIVST should be offered as an additional approach to delivering HTS. The Guideline Development Group (GDG) has determined the evidence reviewed on HIVST to be of moderate quality.

Discussion of this recommendation follows, along with a summary of the results of two systematic reviews and a literature review of values and preferences of self-testers and potential self-testers, as well as providers and key stakeholders, on HIVST.

In accordance with the GRADE methodology, this review prioritized randomized controlled trials that directly compared HIVST to existing and standard HIV testing approaches (for example, facility-based or community-based HTS). Other studies, including trials and observational studies that reported outcomes of interest (such as uptake, positivity or linkage) but did not directly compare HIVST to standard HTS, were not included in the GRADE analysis and were summarized instead. Any study reporting on values and preferences, cost or cost-effectiveness related to HIVST was also summarized. See Annexes 17 and 19 for detailed information on the methodology and evidence from the systematic review.

The searches yielded 638 citations. After removing duplicate studies, reviewers considered 496 unique records and initially excluded 317 of these. After reviewing the remaining 179 records in full text, an additional 174 records were excluded because they did not meet the inclusion criteria. Ultimately, five randomized controlled trials were identified and included in the review. All five were conference abstracts, and additional study details were retrieved by directly contacting the authors.

The five randomized controlled trials *(33–37)* took place in four countries. All of them focused on reaching men. Two took place in Kenya, where women distributed HIVST kits to their male partners. This approach was compared with using letters or referral cards to invite their male partners for HIV testing at a clinic *(35,36)*. The remaining studies were among men who have sex with men and took place in Australia *(34)*, Hong Kong SAR of the People's Republic of China *(37)* and the United States of America *(33)*; all of these studies compared the offer of HIVST with facility-based HTS.

All five randomized controlled trials offered free, oral fluid-based HIV RDTs for self-testing with the manufacturer's instructions for use, but they differed in terms of the number of kits available to participants and the level of assistance. In the United States, men who have sex with men had continuous access to HIVST kits; in Australia, participants had continuous access and received four HIVST kits at enrolment *(34)*. In Kenya, women were provided with two HIVST kits at enrolment (one for themselves and one for their male partner) *(35,36)*. In Hong Kong SAR, men who have sex with men were provided with only one HIVST kit at enrolment *(37)*. Two randomized controlled trials provided unassisted HIVST: in addition to the test kit, participants were given a video link *(34,37)* and, in one of the trials, telephone-based motivational interviewing and social media-based pre- and post-test counselling *(37)*. The other three randomized controlled

trials provided direct assistance, including an in-person demonstration on how to self-test *(33,35,36)*; in two of these trials, women were provided with the demonstration so they could show their male partners how to self-test *(35,36)*.

Box 2.2. Main outcomes of randomized control trials used in GRADE review

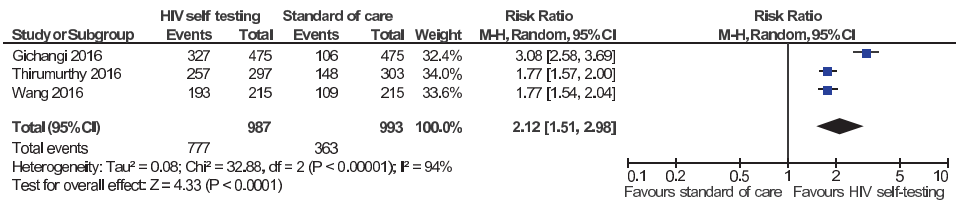
In general, the five randomized controlled trials concluded that, when compared to standard facility-based testing, HIV self-testing (HIVST):

- Increased the uptake of HIV testing among male partners of pregnant or postpartum women and men who have sex with men.
- Increased the uptake of couples HIV testing among male partners of pregnant or postpartum women.
- Increased the frequency of HIV testing among men who have sex with men by approximately two times in a year.
- Did not increase HIV risk behaviours (such as condomless anal intercourse) or the number of bacterial sexually transmitted infections (STIs).
- Did not decrease the uptake or frequency of testing for STIs.
- Did not increase social harm or other adverse events (only one case of social harm was reported and was not directly related to HIVST).

Uptake of HIV testing

HIVST increased the uptake of HTS. Three *(35–37)* of the five randomized controlled trials reported on uptake of HIV testing. A meta-analysis of these results indicated that HIVST doubled the uptake of HIV testing compared to standard HTS (Relative Risk (RR) = 2.12; 95% CI: 1.51, 2.98) (see Fig. 2.2). (See Annex 17 for further details.)

Fig. 2.2. Meta-analysis of HIV testing uptake at three and six months



M-H: Mantel-Haenszel; CI: Confidence interval.

The two studies, in Kenya where women distributed HIVST kits to their male partners, also reported an increased uptake of couples testing when compared with the approach of giving male partners letters or vouchers inviting them to test at a clinic *(35,36)*.

Among men who have sex with men in Hong Kong SAR, one study *(37)* reported that uptake of HIV testing was higher in the HIVST group compared to the facility-based HIV testing group, both in the sub-groups of recent testers (>1–3 tests in 3 years)

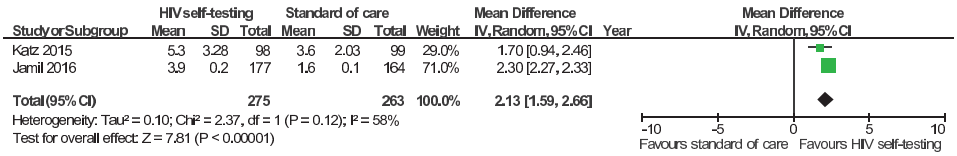
(RR = 1.75; 95% CI: 1.46, 2.08) and non-recent testers (0 tests in 3 years) (RR = 2.22; 95% CI: 1.61; 3.08). Analysis of uptake in this study also showed that the men who have sex with men who reported condomless anal intercourse at enrolment were also more likely to test if they were in the HIVST group compared to the standard HTS group (RR = 1.75; 95% CI: 1.26, 1.81) *(37)*. These results suggests that higher risk men who have sex with men may be more likely to take up HIVST than standard facility-based HTS.

These findings are consistent with results from other systematic reviews *(4,6,38)*, trials and observational studies from Kenya *(39,40)*, Lesotho *(41)*, Malawi *(10,42)* and Zimbabwe *(16)*, which report similar increases in the uptake of HIV testing following the offer of HIVST. For instance, a two-year cluster randomized trial in Malawi reported uptake of directly assisted community-based HIVST among the general population at approximately 76.5% (crude uptake: 84%, 14 004/16 660) when adjusted to account for population turnover *(10)*. Over the two-year period, the study reported that 44% were first-time testers. Uptake was consistently high in years one and two among adolescents (16–19 years of age) (95%; 2374/2502 and 2405/2502), young people (16–29 years of age) (90%; 8333/9315 and 8503/9315), women (85%; 6835/7802 and 6445/7802) and men (68%; 5902/8643 and 5924/8643) *(10)*. Likewise, studies among key populations, primarily men who have sex with men and female sex workers, also report high uptake of HIV testing when HIVST is offered *(4,5)*.

Frequency of HIV testing

HIVST increased the frequency of HIV testing among men who have sex with men. Two of the five randomized controlled trials reported on frequency of HIV testing among men who have sex with men *(33,34)*. Across both studies, men in the HIVST group had a mean of two more tests in a 12–15 month period than those in the facility-based HTS group (mean difference = 2.13; 95% CI: 1.59, 2.66) *(33,34)* (see Fig. 2.3).

Fig. 2.3. Meta-analysis of mean number of tests among men who have sex with men in 12–15 month period



M-H: Mantel-Haenszel; SD: Standard deviation; CI: Confidence interval; IV: Independent variable.

In Australia, among non-recent testers (0 tests in >2 years or never tested) HIVST substantially increased the frequency of HIV testing compared to standard testing *(33,34)*. The rate ratio for this sub-group showed that men in the HIVST group had a testing rate 5.54 times higher in a 12-month period than men in the standard HIV testing group (Rate Ratio = 5.54; 95% CI: 3.15, 9.74).

In the United States, HIVST was also shown to increase the uptake of quarterly HIV testing among men who have sex with men (76%; 74/98) compared to those receiving standard HTS (54%; 53/99) *(33)*.

Although the results considered above are from a small number of studies, the reported increases in the frequency of HIV testing could have important public health

implications, particularly when reaching people with undiagnosed HIV infections and those at high ongoing risk who are not accessing existing services. Sustained increases in frequency of HIV testing among higher risk populations of this magnitude or more, facilitated by HIVST, could identify a greater number of infections and result in a reduction in HIV incidence if individuals are effectively linked to prevention and treatment services *(43,44)*.

HIV risk behaviour following HIVST

There was no increase in HIV risk behaviour identified following HIVST. One of the five randomized controlled trials reported on risk behaviour following HIVST *(33)*. In this study, men who have sex with men in the HIVST group did not increase condomless anal intercourse compared to those receiving standard HTS, as reported at a nine-month follow-up (RR = 0.94: 95% CI: 0.55, 1.61). In this same study, men in the HIVST group acquired fewer bacterial sexually transmitted infections (STIs) than those in the standard HIV testing group (RR = 0.41; 95% CI: 0.15, 1.13).

Additionally, in Australia, HIVST was found to neither decrease nor increase the frequency with which men who have sex with men tested for STIs *(34)*.

Although not reported in the reviewed randomized controlled trials, other observational studies suggest some users may be interested in using HIVST to screen potential sex partners *(11,18,45,46)*. Studies have shown this could prevent users with a reactive self-test result from engaging in condomless sex *(18,45)*. This evidence also suggests HIVST could be used to serosort (select a sex partner based on their self-reported HIV status) and to inform decisions about behaviour, including on using HIV prevention, such as condoms *(18,45)*. In many of these studies, however, users were unaware that current HIVST technologies have a three-month window period and do not identify acute or early HIV infection.

While the decision to not use condoms may be appropriate in longer term relationships, where both partners have low ongoing risk, serosorting following HIVST is not recommended in population groups with high HIV incidence (for example, sex workers and men who have sex with men) *(47)*. Clear messages about the potential risks of using HIVST to make decisions about risk behaviour and use of HIV prevention need to be communicated, particularly to key populations who may be at high ongoing risk of HIV.

Social harm

Only one instance of harm, which was not directly related to HIVST, was identified in the review *(35)*. In that randomized controlled trial, there was one report of intimate partner violence (IPV) in both the HIVST group and the standard HIV testing group (1/297 in the HIVST group; 1/303 in the control group) *(35)*. In the HIVST group, the harm was not directly related to HIVST: the female participant reported that the occurred because she took part in the study without consulting her husband *(35)*. The participant reported leaving home for approximately three weeks, before returning. At a two-month follow-up visit, she informed researchers that she and her husband had reconciled. In the standard HIV testing group, one female participant also reported IPV *(35)*.

These results suggest that HIVST may not directly influence the risk of IPV, but that these risks largely depend on the setting, context and relationship dynamics of couples and partners. Such findings are consistent with those reported by systematic reviews

assessing harm across all forms of HTS *(48)*, couples HTS *(49)*, and self-testing for HIV and other conditions and diseases *(50)*, as well as other observational studies. In an urban setting in Malawi, results from a two-year cluster randomized trial reported no cases of IPV, self-harm or suicide resulting from HIVST or other HIV testing in the community *(10)*. In the United States, a study reported that, out of 124 events where men offered HIVST to their male sexual partners, 7 resulted in a verbal confrontation and none resulted in physical violence *(45)*.Several studies have also shown that some initial reports of "coercion" to test were rather "persuasion" or "encouragement" to test *(10,20,51)*. For example, in Malawi, it was primarily men who self-tested with their female partner who reported being coerced to test; of whom 94.4% (252/267) also said they would recommend HIVST to friends and family, and 92.2% (130/141) said they were highly satisfied with HIVST *(10)*.

Nevertheless, while most users consider HIVST to be empowering *(20,51)*, a study in Malawi on couples who received HIVST kits reported that two of 17 couples felt pressured by their partner to self-test and found dealing with serodiscordant results challenging *(20)*. Likewise, in Kenya, four of 265 HIV-negative pregnant and postpartum women and female sex workers who distributed HIVST kits to their male partners and clients reported instances of IPV; two were among postpartum women and two were among female sex workers *(18)*. It was unclear if these cases were directly linked to HIVST since prior to the intervention 41% of all female study participants said they had experienced IPV in the preceding 12 months. The two women in postpartum care who reported experiencing verbal abuse in a confrontation with their husbands said this was regarding a reactive test result *(18)*. Both women left their homes but later returned and reconciled with their husbands. One woman reported that her husband (who was diagnosed HIV-positive) has since enrolled in care and that they are now using condoms during sex *(18)*. Of concern are the two cases among female sex workers who distributed HIVST to their clients and experienced physical violence; one reported forced condomless sex *(18)*, suggesting that not all testing approaches are appropriate for all contexts, and that caution may still be needed among vulnerable populations.

While the overall results are encouraging, it is critical for programmes to recognize the importance and complexity of monitoring, reporting, evaluating and assessing social harm in relation to HIVST. As recommended with all HTS, programmes need to consider context-specific approaches to implementing HIVST in ways that are ethical, safe and acceptable. In addition, risk mitigation in relation to social harm and the establishment of active monitoring and reporting systems are important.

HIVST positivity

A major aim of any HTS approach is to be as efficient and effective as possible in reaching people with undiagnosed HIV. One of the five randomized controlled trials reported on HIV positivity *(33)*, and indicated that men who have sex with men in the HIVST group were twice as likely to have an HIV-positive test than those in the standard care group (RR = 1.97; 95% CI: 0.37, 10.52).

No other randomized controlled trials included in the GRADE analysis reported on HIV positivity, that is, the proportion of people with a reactive and confirmed positive HIV self-test result. However, several other studies on HIVST, which do not make a direct comparison with standard HTS, report HIV positivity ranging from 3–14% among the general population in sub-Saharan Africa and from 1–30% among key populations (see Table 2.1).

Table 2.1. Summary of HIV positivity studies implementing HIVST

Study/setting	HIVST approach	Population	Reported HIV positivity[a]	Estimated HIV prevalence[b]
Thirumurthy et al., 2016 *(18)*; Kenya	Partner distributed	Men (18+ years of age)	3% (4/144)	4.8%
Choko et al., 2015 *(10)*; Malawi	Community-based	General population	11.8% (1257/10 614), 95% CI: 11.2–12.5%	9.1%
Choko et al., 2015 *(10)*; Malawi	Community-based	Men (40–49 years of age)	22.5%, 95% CI: 19.4–25.8%	7.1%
Choko et al., 2015 *(10)*; Malawi	Community-based	Adolescents (16–19 years of age)	2.5%, 95% CI: 1.9–3.2%	1.8–3.2%
Napierala Mavedzenge et al., 2016 *(52)*; Zimbabwe	Community-based	General population	8% (47/590)	14.7%
Sibande et al., 2016 *(16)*; Zimbabwe	Community-based	General population	14.3% (1153/8095)	14.7%
Zhong et al., 2016 *(53)*; China	Other/social entrepreneur model	MSM	4.5% (8/178)	0.037%[c]
Tao et al., 2014 *(54)*; China	Community-based	MSM	15% (33/220)	0.037%[c]
Green et al., 2016 *(55)*; Viet Nam	Community-based	MSM, TG, PWID	7% (24/344)	0.5%
Thirumurthy et al., 2016 *(18)*; Kenya	Partner distributed	FSW partners/ clients	14% (41/298)	4.8%
Cowan et al., 2016 *(56)*; Zimbabwe	Facility-based	FSW	30% (98/325)	14.7%
Medline et al., 2015 *(57)*; United States	Internet-based	MSM	3.5% (2/57)	0.6%[d]
Katz et al., 2015 *(58)*; United States	Community-based	MSM	6.1% (12/197)	0.6%[d]
Mayer et al., 2014 *(59)*; United States	Other directly assisted	MSM	1.2% (2/161)	0.6%[d]

[a] Estimated HIV positivity based on reports of reactive HIV self-test results and confirmed HIV-positive diagnosis.
[b] Estimated national HIV prevalence, UNAIDS, 2016, http://aidsinfo.unaids.org/, accessed 10 August 2016.
[c] Estimated HIV prevalence in China in 2015, UNAIDS, 2016, http://www.unaids.org/sites/default/files/country/documents/CHN_narrative_report_2015.pdf, accessed 23 August 2016.
[d] Estimated HIV prevalence in the United States in 2012, http://www.avert.org/professionals/hiv-around-world/western-central-europe-north-america/usa, accessed 23 August 2016.
MSM = men who have sex with men.
TG = transgender people.
PWID = people who inject drugs.
FSW = female sex workers.

Despite the lack of a comparison with standard HTS, these studies describe HIV positivity on a par with that reported in many other HTS approaches in similar populations and settings *(38)*.

It is important to note that, as HTS coverage increases, the proportion of HIV-positive tests and new diagnoses will likely decrease across all approaches. Thus, more strategic and focused methods will be required in order to continue to achieve similar, or greater, levels of HIV positivity for all HTS approaches, including HIVST.

2.2.2 Additional considerations

Linkage to further HIV testing and HIV prevention, treatment and care services

One of the five randomized controlled trials reported on linkage to further testing following HIVST *(36)*. In that study, 72% (n=396) of male partners of pregnant women who received an HIVST kit reported attending a facility for further HTS *(36)*. This outcome could not be compared with standard facility-based HTS because only HIVST requires linkage to further testing.

No other studies included in the GRADE analysis reported on linkage to further HTS or HIV prevention, treatment and care services. Therefore, the findings from additional trials and observational studies, which did report on outcomes related to linkage to care, were summarized. An overview of these findings is included here.

Across general populations in sub-Saharan Africa, linkage to care was 50–56%. Among the general population in Malawi, community-based HIVST together with home-based assessment and initiation of treatment led to a threefold increase in linkage to care compared with standard HTS and facility-based care (181/8194, 2.2% vs. 63/8466, 0.7%; RR = 2.94; 95% CI, 2.10, 4.12; $p < 0.001$) *(60)*. Also in Malawi, a two-year cluster randomized trial with the same assisted community-based HIVST approach but which utilized clinic referral cards to facilitate linkage estimated that 56.3% (524/930) of people diagnosed as HIV-positive after HIVST were linked to care *(10)*. In a cohort study in Kenya, linkage to care was similar, with 50% (2/4) of women in antenatal care or postpartum care reporting that their male partner linked to care within three months of self-testing and being diagnosed HIV-positive *(18)*.

Among key populations, linkage to care was approximately 20–100%. Two observational studies in the United States reported 100% linkage to care among four men who have sex with men, two in each study, who self-tested and were confirmed HIV-positive *(59,61)*. In Hong Kong SAR, 20% (2/10) of men who have sex with men who were uncertain of their self-test result, or had a reactive self-test result, linked to further HIV testing or sought medical advice, while the majority (8/10) used another HIVST kit to retest *(62)*. In Viet Nam, a pilot study of community-based HIVST among men who have sex with men, transgender people and people who inject drugs reported that 100% of those self-testing for HIV received confirmatory testing and were linked to care *(55)*. In Kenya, 88% (23/26) of female sex workers reported that their male partners or clients who self-tested HIV-positive enrolled in HIV care *(18)*. In Zimbabwe, 99% (97/98) of female sex workers with a reactive self-test result who were confirmed HIV-positive linked to care *(56)*.

Although these findings are based on a small number of cases, they suggest that, as with all HTS approaches, linkage rates are often suboptimal unless an evidence-based linkage intervention is utilized. However, results also suggest that HIVST plus home-based assessment or treatment may be a particularly effective approach, as well as other assisted community-based strategies, couples and partners HIVST, and facility-based HIVST approaches.

Implementing these linkage services requires trained personnel to provide follow-up services. Further evaluation of strategies and approaches that can facilitate linkage to care, as well as prevention, following HIVST are needed, particularly for key populations, who may be less likely to link to services, especially in settings with restrictive laws and policies.

(See section 2.3.1 on planning for service delivery for further information on linkage to care.)

2.2.3 Values and preferences on HIVST

In the process of identifying studies for the GRADE analysis, 125 studies which reported on some aspect of values and preferences and feasibility in relation to HIVST among actual or potential self-testers, health workers, policy-makers or other key stakeholders were identified. Study locations were: across the Americas – Brazil *(63–66)*, Canada *(67–69)*, Mexico *(70)*, Peru *(9,71)*, Puerto Rico *(72)*, the United States *(12,45,58,61,73–104)*; Africa – Ethiopia *(22)*, Kenya *(14,18,23,39,40,105–112)*, Lesotho *(41)*, Malawi *(10,19,20,42,51,113,114)*, Nigeria *(115)*, South Africa *(116–121)*, Zambia *(15,122,123)*, Zimbabwe *(16,52,56,124,125)*; Asia and the Pacific – Australia *(8,29,126–130)*, China *(24,53,54,62,131–140)*, India *(17,141)*, Singapore *(142)*, Viet Nam *(55)*; Europe – France *(143–145)*, Italy *(146)*, the Netherlands *(147–149)*, Spain *(150–153)*, the United Kingdom *(11,154)*; and other multi-country studies *(21,46,155–158)*. One of the randomized controlled trials also reported on values and preferences on HIVST among men who have sex with men in Australia *(34)*. Several systematic reviews also assessed values and preferences in relation to HIVST *(4–7)*, including a qualitative synthesis *(159)*.

In addition, a qualitative values and preferences study among fishing communities, sex workers, general populations and health workers in Uganda, and young key populations in Indonesia, Pakistan, Philippines and Thailand, was conducted to inform these guidelines *(160,161)*.

An overview of the results of these studies are presented here according to key population, general population, couples and partners, young people (15–24 years of age), and health workers and other key stakeholders.

Key populations

Acceptability and willingness to use HIVST is generally high among key populations *(4,18,56,112,131,132)* despite some reported concerns about the potential lack of support, possible social harm, the level of accuracy of test results, and the related costs which could hinder access *(4,72,80)*. Overall, the benefits of HIVST most commonly cited by key populations were convenience and privacy, followed by HIVST being an easy and painless testing option *(4,80)* as well as not needing a facility visit *(112)*.

Some studies among men who have sex with men and female sex workers reported preferences for oral fluid-based RDTs for HIVST because this is a painless testing option. In contrast, other users said they preferred fingerstick/whole blood-based RDTs for HIVST as they considered them to be more accurate *(11,55)*. For example, a study in Viet Nam reported that people who inject drugs preferred HIVST using a fingerstick/whole blood-based RDT, whereas more men who have sex with men and female sex workers said they favoured oral fluid-based RDTs *(55)*.

Although there are many possible ways and channels for distributing HIVST, some studies suggest that men who have sex with men, transgender women and female sex workers prefer HIVST to be available over-the-counter at pharmacies and other locations or through the Internet *(4)*. Several studies in Australia, China, Brazil, Peru, the United Kingdom and the United States reported that a high proportion of men who have sex with men and transgender women were comfortable accessing HIVST through the Internet and online gay dating sites, which mail a kit to their home or a location of their choice *(4,9,57,66,100,154)*. Other options, such as vending machines and distribution at events, have also been shown to be acceptable among men who have sex with men and

Case example: "A hora é agora" ("The time is now"): an internet-based HIV self-testing strategy in Brazil

"A hora é agora" ("The time is now"), is a comprehensive programme to increase HIV testing and linkage to care among men who have sex with men in the city of Curitiba, Brazil. The programme uses a secure web-based platform (www.ahoraeagora.org/) and both iOS and Android apps to offer men who have sex with men free oral-fluid HIV self-testing (HIVST) (up to two kits every six- months), as well as condoms and lubricants, and support to promote linkage to care.

Men can access video tutorials and multimedia instructions on how to correctly use the HIVST kit and interpret the results; they can receive additional support through a 24/7 telephone hotline. Individuals with a reactive or inconclusive self-test result are instructed to seek confirmatory testing at Curitiba's HIV counselling and testing centre (COA), where those with a reactive self-test are given confirmatory testing and if confirmed HIV-positive then supported to link to treatment and care. This programme is actively promoted using virtual and mobile media (social networking, dating websites), as well as face-to-face peer interventions at social/sexual gatherings.

As of 31 January 2016, the programme distributed over 4,000 HIVST kits, the majority of which were sent by mail. 17% (432/2527) of men who have sex with men who requested a HIVST kit self-reported their test results through the web-based platform. Out of these, 4% (19/432) reported having a reactive self-test result. Overall, 81% (30/37) of men who have sex with men who reported self-testing and received confirmatory testing at the COA were confirmed HIV-positive.

Source: Annex 21.

transgender people *(98,99,101)*. In Kenya, female sex workers reported preferences for accessing HIVST kits at pharmacies or private clinics rather than obtaining them at public sector clinics *(112)*, as well as a willingness to distribute HIVST to their peers, social network, primary partners and clients *(18)*.

General populations

In the studies considered, HIVST was viewed to be highly acceptable by the general adult population, where there was strong support to promote and use HIVST.

In many African countries, interest in HIVST was consistently high. In Zimbabwe, a cross-sectional study among 289 adults found 80% would self-test, and nearly 90% would self-test if the cost was low *(124)*. Likewise, in Zambia, 76% (1216/1600) said if HIVST were available they would definitely use it *(122)*. In Kenya, a synthesis of several studies reported that privacy and personal empowerment were key motivations to self-test for HIV and that users would like to access HIVST kits at clinics or pharmacies *(111)*. In-depth qualitative interviews in South Africa also indicated high acceptability of HIVST, as it was perceived to be a way to overcome barriers to existing HTS, such as lack of trust in health workers and the health system *(117)*.

In Europe and the region of the Americas, similar levels of high acceptability were identified among general populations *(76,150,153,154)*. In the United States, in 2006, prior to the availability of HIVST, 56.2% (95% CI: 54.7, 57.7) of adults who participated in a telephone survey indicated HIVST as acceptable *(76)*, and two thirds of at-risk populations expressed a desire to use HIVST *(76)*. In Spain, 80% (2699/3373) of individuals attending a street-based HTS site were in favour of making HIVST available *(153)*. Additionally, 84% (174/207) of those accessing unassisted HIVST using fingerstick/whole blood-based RDTs in Spain said they were motivated to self-test for HIV in the future *(150)*. In the United Kingdom, among 555 users who self-tested using a fingerstick/whole blood-based RDT, 98% said they would use it again and reported it was easy to perform *(154)*.

Potential barriers to HIVST among the general population included concerns about the risk of violence, self-harm or suicide; misuse of HIVST kits; accuracy; lack of support; and potentially high costs. For example, in Kenya, 61% (n=1133) of people said HIVST kits might be misused, and there were also concerns about suicide or non-disclosure of self-test results *(110)*. In Zambia, similar concerns were reported, albeit on a smaller scale: although 35% (n=1617) of respondents said they had concerns about HIVST, 98% of them said these concerns were minor and could be addressed *(122)*. Concerns about the accuracy of HIVST were generally in relation to how to perform the test correctly and whether fingerstick/whole blood-based RDTs or oral fluid-based RDTs were more accurate *(122)*. In one qualitative study in South Africa, a proportion of male respondents indicated they would prefer HIVST using fingerstick/whole blood-based RDTs because they perceived them to be more accurate *(117)*.

Although concerns were raised about social harm in several of the studies, it is important to note that nearly all of those studies were conducted among individuals who had never self-tested for HIV. In contrast, in the studies in which HIVST was implemented, reports of social harm were rare (see section 2.2.1). Furthermore, in the studies considered, despite the various concerns raised by users, there was a consistently high level of interest and desire for HIVST to be readily available.

Couples and partners

In the studies considered, couples and partners from the general population and key population groups in Kenya *(14,18,40,105)*, Malawi *(20,51)* and the United States *(45,58,92,94,95,102,162)* reported a high level of acceptability and interest in using HIVST.

Men who have sex with men in the United States, particularly those with casual partners and who do not use condoms, reported that they were interested in using HIVST as a form of harm reduction by screening potential sex partners *(45,92,95,102,162)*. In two related studies, high-risk men who have sex with men suggested HIVST could improve honesty in disclosure of HIV status *(102)* and reported that, after their partner had a reactive self-test result, they provided emotional support and linked their partner to care *(92)*. Service providers also report that couples-based HIVST could be a health promotion approach for men who have sex with men *(102,162)*.

Among heterosexual cohabiting couples, HIVST may be a preferred approach to both determine one's HIV status and strengthen a relationship. In Malawi, HIVST was seen as an enabling, innovative way to test with a partner, strengthen a relationship bond and address concerns about suspected infidelity *(20,51)*. Among women, in Malawi, the motivation to self-test as a couple was reportedly driven by long-term goals of health and "togetherness", while men reported that they needed persuasion to self-test (although this was perceived as beneficial) and viewed HIVST as more flexible and less intimidating than HTS at a facility *(20)*. HIVST also provided a way for couples to disclose a previously concealed HIV-positive status, alleviating internal conflict *(20)*. Studies in Malawi and Kenya also demonstrated that distribution of an HIVST kit to a partner was perceived to be both safe and acceptable *(19,105)*.

In Kenya, HIVST was highly acceptable among serodiscordant couples who were aware of their partner's status and were using PrEP *(40)*. According to a cross-sectional study among 120 couples, 92.5% of couples found HIVST easy to use and nearly 40% self-tested with their partner *(40)*.

As with all HTS, it is important to consider the potential risks, as well as benefits, to couples and partners. While studies to date, and the evidence summarized above, indicate that there are many benefits and that the risk of harm is minimal, it remains true that coercion or IPV are possible, depending on the context, setting and relationship dynamics. Coping with serodiscordant results can be challenging, whichever way HIV testing is performed or delivered. Some partners who self-test together and have non-reactive test results may forgo condoms, which could lead to the acquisition of HIV or other STIs if they have additional sexual partners. However, other couples who self-test together and have a reactive or serodiscordant result could be more likely to use condoms and support each other in linking to further HIV testing and HIV prevention and treatment services – bringing multiple benefits, including the prevention of future HIV transmission. Like other forms of couples and partner HTS, HIVST may not be appropriate for individuals or couples who report IPV in their current relationship *(49)*. Thus, clear messages and information need to be delivered to couples and partners to mitigate potential risks and maximize benefits. (See section 2.2.1 above and Chapter 4 for additional information, as well as section 5.4 in Chapter 5 of the *Consolidated guidelines on HIV testing services*.)

Young people (15–24 years of age)

Although the number of existing studies that look at young people's (15–24 years of age) willingness to use HIVST kits are few, they report considerable interest in accessing HIVST in Canada *(68)*, France *(143)*, South Africa *(116)* and the United States *(12,80,103,104)*.

In Canada, a survey of university students reported that 81% thought unassisted HIVST using an oral fluid-based RDT was acceptable, despite some concerns about accuracy and linkage to care *(68)*. Similar findings were identified among South African university students *(116)*, who also suggested HIVST was empowering, could "normalize" HIV, and that subsidized or free test kits may help people access HIVST.

In the United States, three studies reported high willingness to use HIVST kits among high-risk young people *(12,103,104)*. One of these studies suggested the key motivations to self-test for HIV were ease of access, no need for a clinic visit, quick results, and the fact that HIVST kits could be used in non-monogamous relationships *(104)*. However, the study noted that young people lacked information about the window period *(104)*. Another study among young African Americans also indicated HIVST as preferable to facility-based HTS because it provides privacy and increases convenience, whilst reducing stigma and normalizing HTS *(12,103)*. However, young people expressed concerns about accessing confirmatory testing, coping with a reactive self-test result, and whether people with a low socio-economic status would be able to understand the instruction materials provided *(12,103)*. Similar preferences were reported among young people in France, especially if HIVST were available free of charge or came with the option of having assistance *(143)*.

Health workers and other key stakeholders

HIVST is highly acceptable to health workers in high HIV prevalence settings for testing themselves, particularly those who have never tested before. The rate of informal HIVST among health workers is high in Ethiopia, Kenya, Malawi, Mozambique and Zimbabwe *(7)*, where health workers view HIVST as a way to reduce stigma and discrimination around HIV testing and as a way for their family members to test *(7)*. In Ethiopia, 70% (n=307) of health workers reported they had self-tested for HIV informally *(22)*. Of those who self-tested, 82% said they did so for greater confidentiality and 14% said they self-tested because they lacked the time to receive standard HTS *(22)*. In Kenya, a feasibility study reported that, following distribution of HIVST kits and provision of an information session, 89% (680/765) of survey respondents said they would recommend HIVST to fellow health workers *(14)*.

Health workers and key stakeholders who provide or support the delivery of HTS report HIVST to be highly acceptable when implemented appropriately, using accurate and easy-to-use RDTs, and when there is linkage to care *(69,157,158)*. In two studies in Canada, key stakeholders and health workers said HIVST should be made available nationally *(67,69)*. One of the studies in Canada showed that one third of providers wanted further education on HIVST and preferred a more community-based approach for distributing HIVST kits *(67)*. In Zimbabwe, focus groups revealed that, while health workers perceived HIVST to be a way to reach people with undiagnosed HIV, particularly men and those

living in areas where there is limited access to HTS, they had concerns about how HIVST could impact their jobs and the jobs of other health workers *(125)*.

(See Annex 17 for the full GRADE systematic review, including values and preferences in relation to whether HIVST should be offered as an additional HTS approach.)

2.2.4 Cost and cost-effectiveness

The potential cost of implementing HIVST, or buying RDTs for self-testing, is a concern for both policy-makers and end users. Three studies *(163–165)* and one report *(28)* identified in the review process included information on cost and cost-effectiveness.

The UNITAID/WHO assessment of the market landscape estimated that in high-income settings HIV RDTs for self-testing are directly available to consumers for approximately US$ 7.50–43 and in low- and middle-income countries (in the context of research) for US$ 3–16 *(28,31)*. Due to the cost of additional packaging and modifications to the test kit, as well as a number of market uncertainties, the prices for HIV RDTs for self-testing are currently higher than those for professional use (US$ 0.50–11 per test kit) *(28)*.

When assessing the cost of HIVST, it is important to not only consider the unit price per test kit, but also the financial impact of different HIVST approaches in varying settings and among various populations.

In the United States, the distribution of unassisted HIVST through a gay dating application reported that total programme costs of distributing 455 kits were high (US$ 17 600), but that this was driven by the cost of the test kit (US$ 26). The cost of personnel and advertising made up only 25% of the total programme costs. Using a lower-cost test kit would make this unassisted HIVST approach substantially more cost-effective *(163)*.

As illustrated by a costing study of assisted community-based HIVST in Malawi, where trained provider were available and supported self-testers as needed, the mean health provider cost per participant tested through community-based HIVST, at US$ 8.78, was comparable to the cost per participant of testing through facility-based HTS, at US$ 7.53–10.57 *(165)*. When HIVST was considered on the basis of cost per HIV-positive case identified, community-based HIVST was associated with a higher mean health provider cost, at US$ 97.50, than facility-based HTS, at US$ 25.18–76.14 *(165)*. These findings are reflective of lower HIV prevalence among those reached through community-based HIVST as well as an HIVST approach in which personnel and monitoring systems were more expensive and accounted for a greater proportion of total costs compared with facility-based HTS. These costs would likely be much lower if approaches were more focused and used methods that reduced the level of direct assistance, such as by giving group HIVST demonstrations or using social media or videos to provide instructions and support. Costs would also be lower if less expensive but effective monitoring and evaluation systems were utilized and if the unit price of HIVST kits decreased.

According to a mathematical model based on data from Zimbabwe, HIVST can be cost-effective if test kits cost US$ 3 per unit and there is a moderate (20%) increase in HIV testing due to HIVST *(164)*. In this context, the community-based HIVST model would save US$ 75 million in health-care costs and avert approximately 7000 disability-adjusted life years over 20 years *(164)*. Using available data, this mathematical model was updated to assess the cost-effectiveness of different HIVST approaches in Zimbabwe (community-based, partner-distributed and pharmacy-based). It was found that, given the high testing coverage and that approximately 85% of people with HIV know their status, the majority of all other additional HTS approaches would be less cost-effective than HIVST. HIVST, however, was shown to be cost-effective (considering a US$ 500 cost-effectiveness threshold) when it was utilized in secondary distribution to reach male partners, distributed through pharmacies and to female sex workers in the community *(166)*.

It is likely that HIVST will be more cost-effective in settings with lower testing coverage if linkage to care following self-testing increases, and if HIV-negative individuals link to HIV prevention such as PrEP and VMMC, and if individuals at high ongoing risk of HIV increase their frequency of testing. As more countries move toward implementing 'treat all' policies, implementing HIVST will likely become more cost-effective since all persons diagnosed HIV-positive will be eligible for antiretroviral therapy (ART), which will result in additional health benefits. Further, while current HIVST kits are more costly than professional-use RDTs, many efforts are underway to develop new products and decrease prices.

2.2.5 Systematic review and meta-analysis on performance of HIV RDTs for self-testing

This section summarizes results of a systematic review on the performance of HIV RDTs used for self-testing. (See Annex 19 for more detailed information.)

To identify evidence on the performance of HIV RDTs for self-testing, reviewers searched three electronic databases and six conference databases, covering the period up to the end date of 1 April 2016. Additional gray literature was searched through Google Scholar. Studies were included if they were conducted among individuals who self-tested using an HIV RDT and reported on the concordance or the sensitivity and specificity of these RDTs compared to testing performed by a trained health worker.

From an initial screen of 2332 titles, 25 studies were included in the review, including two randomized controlled trials *(167,168)*; the remainder were observational studies. The 25 studies were diverse in terms of design, but all reported on concordance between the result of an HIV RDT used by a self-tester compared to the result obtained by a trained health worker. The studies were primarily in urban settings (n=20), with only four in rural settings *(17,167,169,170)* and one reporting on both settings *(168)*. Fifteen studies used oral fluid-based HIV RDTs only *(10,17,42,68,96,108,131,167,168,170–175)*, six used fingerstick/whole blood-based RDTs only *(142,150,169,176–178)* and four used both oral and blood specimens *(84,85,179,180)*. Eleven studies provided direct assistance to self-testers *(10,17,42,68,85,131,167,170,175,176,178)*, thirteen were unassisted *(68,84,96,108,142,168,169,172–174,177,179,180)*, and one study provided both approaches *(150)*.

Box 2.3. Overview of study results on the performance of HIV RDTs for self-testing

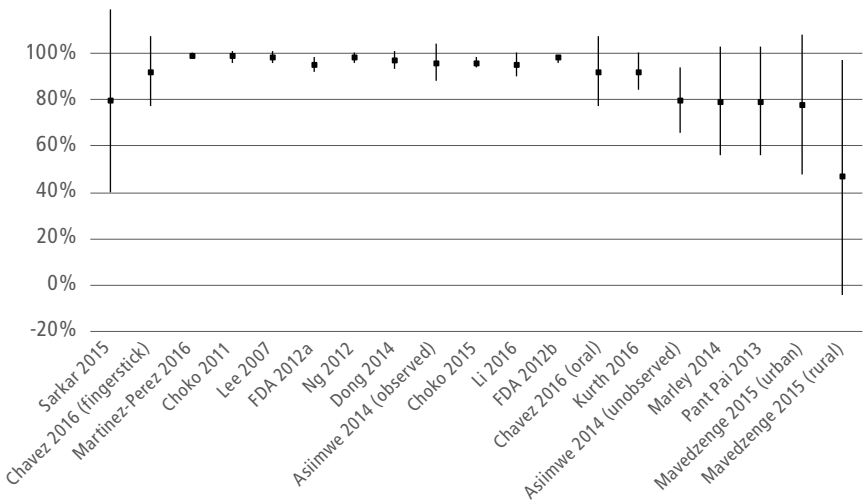
In general, the studies reviewed concluded that:

- An HIV rapid diagnostic test (RDT) used and interpreted by a self-tester can perform as well as an HIV RDT used and interpreted by a trained health worker.
- HIV RDTs used by self-testers can achieve acceptable sensitivity and specificity, especially when appropriate and quality products are utilized and when a demonstration or other support tools, such as instructions for use and videos, are provided.

Performance of HIV RDTs for self-testing

An HIV RDT used and interpreted by a self-tester performs as well as an HIV RDT used and interpreted by a trained health worker. Across 16 studies using directly assisted or unassisted HIVST, and one study reporting on both, kappa agreement between self-testers and trained health workers was almost perfect (see Fig. 2.4). No differences in concordance between self-testers and trained health workers were identified by type of approach, observation, type of specimen or HIV positivity (directly assisted: 0.98, 95% CI: 0.96–0.99 vs. unassisted: 0.98, 95% CI: 0.96–0.99; I^2 33%, 95% CI: 19.5–98.1).

Fig. 2.4. Concordance of test results performed by self-tester compared to trained health worker (measured by Cohen's kappa) (n=16)



Source: Figueroa et al, 2016 *(181)*.

HIV RDTs used by self-testers can achieve high sensitivity and specificity. While there was a wide range in reported sensitivity, only two of 20 studies reported sensitivity of less than 80%; one of these studies did not provide sufficient information on how to interpret faint positive lines *(175)*, and the other study suggested lengthy instructions were a barrier among participants in the rural arm, where literacy levels were low *(52)*. Excluding these two studies with sensitivity less than 80%, sensitivity and specificity estimates were higher for fingerstick/whole blood-based RDTs *(84,142,169,177)* compared to oral fluid-based RDTs *(10,17,42,108,131,167,168,170,171,173–175)* (sensitivity 96.2–100% vs. 80–100%; specificity 99.5–100% vs. 95.1–100%). However, overall, there was no difference in sensitivity or specificity between approaches that offered direct assistance compared to those that did not *(181)* (see Table 2.2).

Table 2.2. Sensitivity and specificity of RDTs used for self-testing by type of approach (n=16)

Studies	Sensitivity estimate (95% CI)	TR/(TR+FN)	Specificity estimate (95% CI)	TN/(TN+FR)	HIV positivity	Type of population
TYPE OF APPROACH						
Directly assisted						
Pant Pai 2013	66.7% (29.9, 92.5)	6/6+3	100% (98.5, 100)	242/242+0	3.6% (9/251)	Health care workers (100%)
Sarkar 2015	100% (15.8, 100)	2/2+0	100% (98.1, 100)	197/197+0	0.9% (2/202)	Pregnant women (100%)
Choko 2011	97.9% (88.9, 99.9)	47/47+1	100% (98.3, 100)	210/210+0	16.9% (48/283)	GP (100%)
Choko 2015[a]	93.6% (88.2, 97.0)	132/132+9	99.9% (99.6, 100)	1507/1507+1	8.6% (141/1649)	GP (100%)
Marley 2014[b]	100% (54.1, 100)	6/6+0	98.6% (95.9, 99.7)	209/209+3	5.8% (13/222)	GP (100%)
Asiimwe 2014 (observed arm)	100% (75.3, 100)	13/13+0	99.1% (95.0, 100)	109/109+4	10.6% (13/122)	GP (100%)
Asiimwe 2014 (unobserved arm)	90.0% (68.3, 98.8)	18/18+2	95.1% (89.0, 98.4)	98/98+5	17.2% (20/116)	GP (100%)
Martínez-Perez 2016	98.8% (96.9, 99.7)	323/323+4	100% (99.8, 100)	1860/1860+0	14.9% (327/2187)	GP (100%)
Unassisted						
Gras 2014	96.2% (80.4, 99.9)	25/25+1	n/a	n/a	100% (26/26)	PLHIV (100%)
Lee 2007	98.8% (93.5, 100)	83/83+1	99.6% (97.9, 100)	260/260+1	24.3% (84/345)	GP (90%) and KP (10%)
Dong 2014	97.7% (88.0, 99.9)	43/43+1	99.5% (97.1, 100)	186/186+1	19.0% (44/231)	GP (100%)
Chavez 2016 (FWB arm)	100% (54.1, 100)	6/6+0	100% (99.2, 100)	486/486+0	1.7% (9/515)	KP (100%)
Chavez 2016 (oral fluid arm)	88.9% (51.8, 99.7)	8/8+1	100% (99.3, 100)	501/501+0	1.7% (9/515)	KP (100%)
Li 2016	94.4% (84.6, 98.8)	51/51+3	99.3% (96.1, 100)	139/139+1	28.9% (55/190)	KP (100%)
Kurth 2016	89.7% (72.6, 97.8)	26/26+3	99.4% (96.8, 100)	173/173+1	14.3% (29/203)	GP (100%)
FDA phase III 2012	91.7% (84.2, 96.3)	88/88+8	100% (99.9, 100)	4902/4902+1	1.9% (96/4903)	GP (86.9%) and KP (13.1%)
Mavedzenge 2015 (rural arm)	66.7% (9.4, 99.2)	2/2+1	94.7% (85.4, 98.9)	54/54+3	8% (5/62)	GP (100%)
Mavedzenge 2015 (urban arm)[c]	80.0% (28.4, 99.5)	4/4+1	97.8% (88.5, 99.9)	45/45+1	9% (16/172)	GP (100%)
Ng 2012	97.4% (94.0, 99.1)	186/186+5	99.9% (99.3, 100)	791/791+1	19.3% (192/994)	GP (63.7%), PLHIV (20%), and KP (16.3%)
FDA phase IIb 2012	97.9% (96.2, 99.0)	470/470+10	99.8% (98.8, 100)	472/472+1	51.9% (526/1013)	GP (42.4%), PLHIV (51.3%), and KP (6.3%)

n/a non available; **TR** true reactive; **FR** false reactive; **FN** false non-reactive; **TN** true non-reactive; **FWB** Fingerstick/whole blood; **GP** general population; **KP** key population; **PLHIV** people living with HIV

[a] Four participants were on ART; they tested negative via self-test and positive in confirmatory testing.

[b] This study assessed accuracy in sub-sample of participants (229/800).

[c] One participant was on ART; this person tested negative via self-test and positive in confirmatory testing.

Heterogeneity: sensitivity I^2 55.1%; specificity I^2 78.7%. Spearman correlation coefficient -0.259, p=0.285

Fingerstick/whole blood-based Oral fluid-based

Although sensitivity and specificity were typically high, common errors in performing the self-test or misinterpreting the self-test results were identified, such as errors in collecting the specimen (finger-prick or oral-swab) *(42,131,168,178)* and incorrect use or spilling of the buffer *(42,168,170,171,174)*. Some of these errors resulted in invalid self-test results, such as errors in collecting the specimen, and others resulted in reduced test sensitivity. Studies using fingerstick/whole blood-based RDTs *(84,85,150,169,178,180)* reported a greater proportion of invalid results compared to studies using oral fluid-based RDTs (0.4–9.5% vs. 0.2–4.5%) *(17,42,84,85,131,167,168,170,171,173,174,179,180)*.

In Zimbabwe, a study among a rural population with low literacy levels, which reported poor test sensitivity (66.7% 95% CI 9.4, 99.2), suggested user errors performing the self-test and interpreting the results were likely due to difficulties in reading and comprehending the instructions for use *(168)*. Also, several studies that included people with known HIV-positive status reported that these users may have been more likely to make errors in performing a self-test or interpreting the self-test result *(171,177)*.

HIV RDTs for self-testing among individuals on antiretroviral (ARV) drugs

Three of the 25 studies included in the review reported on whether or not participants were taking ARV drugs for treatment or prevention, including studies among participants with known HIV-positive status. These studies used an oral fluid-based RDT; in two of them, participants taking ARV drugs had a non-reactive self-test result and were later confirmed HIV-positive using a validated testing algorithm *(10,168)*, whilst in the third study, both the HIVST and confirmatory test results were non-reactive because the reference standard was the same oral fluid-based RDT *(179)*. While there is limited evidence on the impact of ARV drugs on the performance of HIV RDTs, several studies suggest they may be more likely to cause false non-reactive test results when using serology (antibody) tests because HIV antibodies are suppressed and remain undetected *(2,182)*. This may be a risk for all serology tests, particularly oral fluid-based RDTs. (See Chapter 7 of the *Consolidated guidelines on HIV testing services*.) Therefore, it cannot be ruled out that studies reporting low sensitivity may have included populations taking ARV drugs.

Although HIVST can be highly accurate – as high as 100% sensitivity and 100% specificity, particularly with validated tests and instructions for use *(181)* – as with all HIV testing, a single reactive HIV RDT result is not sufficient to provide an HIV-positive diagnosis. All reactive self-test results must be confirmed by a trained tester starting from the beginning of a validated national testing algorithm *(2)*. Currently, it is not recommended for individuals to attempt their own confirmatory testing through HIVST.

(For more detailed information on this systematic review on the performance of HIV RDTs for self-testing, please refer to Annex 19.)

2.2.6 Recommendation

After reviewing the evidence presented in two systematic reviews, a review of studies reporting on values and preferences, feasibility, and resource use, and a review of national policies, the Guideline Development Group (GDG) came to a consensus and decided to make a recommendation on HIVST.

Using the GRADE method for rating the quality of the evidence provided, the GDG determined this evidence to be of moderate quality. After taking into consideration all the evidence and the potential public health benefits and risks, the GDG deemed that the benefits of HIVST strongly outweighed the potential risks. Thus, the GDG came to a consensus and advised that WHO make a strong recommendation to support the availability of HIVST as an additional HTS approach.

NEW

Recommendation

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

2.3 Continuum of approaches for successful HIVST implementation

To maximize the benefits of HIVST, it is important to not only consider the quality-assured product but also the components of a successful programme, including service delivery approaches, ways to facilitate linkage to care, and monitoring and reporting systems.

Programmes that have all these components will be more successful when developed in collaboration with the Ministry of Health and other relevant governmental and non-government agencies, such as community-based organizations, networks of people living with HIV, key population groups and communities affected by HIV, as well as researchers.

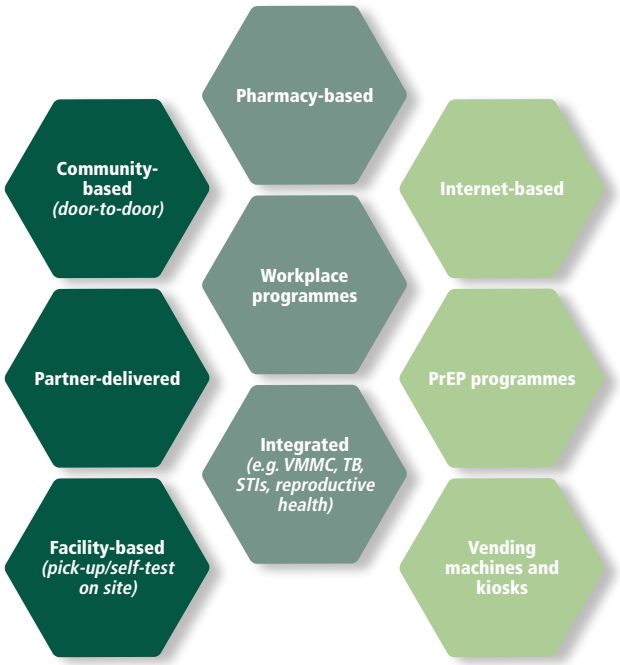
2.3.1 Strategic planning for HIVST service delivery

When planning an HIVST programme, it is important to first analyse and evaluate the existing HTS programme and determine where and how to implement HIVST so that it is complementary to other HST approaches and addresses any gaps in current coverage. In this way, HIVST may contribute to the enhanced efficiency of the health system. It is also important to monitor and evaluate the impact and outcomes of implementing HIVST, as well as to conduct further research, in order to identify the most effective and acceptable approaches for different settings and populations (see Box 2.4).

HIVST is particularly appropriate for reaching people at high risk of HIV who are unable to access or have difficulty accessing existing services. In low prevalence settings, this may include partners of people with HIV and key populations. In high prevalence settings, this may include men, serodiscordant couples and partners, adolescents and young people, key populations and other vulnerable groups – as defined by country context.

A continuum of different HIVST service delivery approaches can be considered, depending on the context, setting and population that the programme is trying to reach. Approaches can be largely facility-based or community-based, implemented through secondary distribution (for example, delivered by sexual partners), integrated with other related health programmes and interventions, or provided through pharmacies, vending machines, the Internet or other public and private sector channels (see Fig. 2.5).

Fig. 2.5. Different HIVST service delivery approaches



Box 2.4. Summary of HIV self-testing service delivery approaches

Community-based distribution. In Malawi, the implementation of community-based HIV self-testing (HIVST) among the general population resulted in a 77% uptake of HIVST. Of those self-testing, 44% were first-time testers. The highest rate of uptake was among adolescents and young people. Among those self-testing, 11.8% were confirmed HIV-positive; 56.3% of these persons were linked to care *(10)*.

Couples and partners testing. In Kenya, providing women in antenatal or postpartum care and sex workers at drop-in centres with HIVST kits to distribute to their male partner(s) and social networks led to a 98% HIVST uptake among male partners and facilitated a 51–83% uptake of couples testing among male partners *(18)*.

Facility-based distribution. HIVST may provide a way to improve HIV testing coverage and efficiency within clinics, particularly for generalized epidemic settings, where it is recommended that all individuals presenting to clinics receive an HIV test. Individuals presenting to facilities could be offered an opportunity to self-test for HIV while waiting for other services or be provided with an HIVST kit to take home for self-testing or sharing with a partner. This approach is currently being evaluated in Malawi, Zambia and Zimbabwe *(183)*.

Integration of services and outreach. In Zimbabwe, community- and facility-based distribution of HIVST to men is being evaluated as part of an outreach

Box 2.4. Summary of HIV self-testing service delivery approaches (continued)

strategy to facilitate uptake of voluntary medical male circumcision *(183)*. Integration with other models across existing public health programmes, such as those targeting tuberculosis, bacterial sexually transmitted infections, viral hepatitis and providing contraception, should also be considered.

Internet-based outreach to key populations. Several studies report that men who have sex with men obtain HIVST through the Internet and social networking applications. In China, a programme offering free HIVST online and mailing kits was able to reach high-risk men, 15% of whom had a reactive self-test result; all of these men were then linked to confirmatory testing *(54)*. In Brazil, a website is providing men who have sex with men with information and free HIVST kits for pick-up at a pharmacy or via the post *(66)*. In the United States, marketing HIVST through the Internet, social media networks, vending machines and voucher programmes has proven to be acceptable and has facilitated HIVST uptake among men who have sex with men *(91,98,100)*.

Pharmacy-based distribution. HIVST is available formally over-the-counter through pharmacies and other retail venues in France, the United Kingdom and the United States. In addition, it is available informally in many other countries *(2)*. In Kenya, a randomized trial distributing HIVST through pharmacies is underway and will evaluate acceptability, uptake, HIV positivity and linkage to care *(39)*.

PrEP programmes. Because HIVST reaches people at high risk of HIV, it may be an important entry point for pre-exposure prophylaxis (PrEP). With the use of appropriate technology, it may be possible to include HIVST in PrEP programmes. For example, a study in Kenya among serodiscordant couples using PrEP reported a 90% HIVST uptake, and 69% of participants shared results with partners (all users were confirmed HIV-negative) *(40)*. This approach may help to reduce the costs of retesting between facility visits *(184)* as well as encourage PrEP uptake *(2)*. The potential for HIVST within PrEP services is an important area for implementation research. However, until there has been adequate evaluation of the use of HIV rapid diagnostic tests (RDTs) for self-testing by PrEP users, this approach should be adopted with caution since it is possible that the performance of HIV RDTs in this context may be suboptimal.

Workplace programmes. HIVST may provide an opportunity to introduce HIV testing within workplace wellness and occupational health initiatives. Such approaches could reach men, including populations at high risk in some settings such as miners, fisherfolk and truck drivers, as well as health workers and their partners, with a view to facilitating the uptake of HIV prevention. For example, HIVST may be appealing to health workers who are hesitant to access existing HIV testing services and post-exposure prophylaxis, following a potential HIV exposure, because they fear stigma and discrimination from other health workers *(14)*. Workplace programmes should identify options that employees find suitable and discreet enough to enable them to access HIVST kits, including through pharmacies, the Internet, mobile phone applications and dispensers in offices. Information should also be provided on HIV prevention, treatment and care, including where and how users can discreetly access these services and confidential telephone hotlines that provide counselling.

Directly assisted and unassisted HIVST approaches

Depending on the population, interventions may vary in terms of the intensity and technologies used to support self-testers. The support that is offered can be either directly assisted or completely unassisted (see Table 2.3). For example, populations with disabilities, low literacy levels, and some rural communities may require direct assistance in the form of in-person demonstrations and explanations before, during and after self-testing. However, no matter the type of approach, users with access to the Internet and social media, as well as frequent and repeat testers, may be able to conduct the test using the instructions alone or accessing further assistance through telephone hotlines, text message services, videos and other support tools provided with the test kit.

Table 2.3. Support tools for directly assisted and unassisted HIVST approaches

Support tools	Directly assisted	Unassisted
Brief in-person, one-on-one or group demonstrations on how to correctly use the kit and how to interpret the results	✔	
Internet-based, virtual or social media demonstrations on how to correctly use the kit and how to interpret the results	✔	✔
In-person assistance during self-testing procedure	✔	
Instructions for use: • Pictorial/written • Brochures or flyers that include information on local HIV services and contact details, for example, health clinic, 24hr hotline • Multimedia instructions	✔	✔
Remote support via telephone, social media, text message, QR code, Internet-based or mobile messaging applications	✔	✔

Linkage to further HTS and HIV prevention, treatment and care

In addition to identifying the best approach for delivering HIVST, programmes need to consider how to facilitate linkage to prevention, treatment and care following HIVST. Further research, monitoring and evaluation of strategies that facilitate linkage to care following HIVST are needed. Box 2.5 summarizes the approaches to linkage currently being implemented that can be considered.

Box 2.5. Summary of linkage strategies following HIV self-testing

Proactive, community-based follow-up by peer and/or outreach workers (in-person or via telephone/text message/social messaging platforms). Particularly in instances where trained community-based workers are responsible for HIV self-testing (HIVST) kit distribution, these workers can offer follow-up and additional post-test counselling, as well as assistance and/or accompanied referral to confirmatory testing services.

Home-based treatment assessment and initiation, with support and active follow-up through community-based networks. This approach has proven to be an effective way to support linkage to care in Malawi among the general population, including young people *(10,60)*. The same approach has been used effectively among key populations in Viet Nam *(55)*.

Brochures and flyers distributed together with HIVST kits, containing information on HIV testing services (HTS) and HIV prevention, treatment and care, as well as information on other diseases such as tuberculosis, bacterial sexually transmitted infections and viral hepatitis.

Telephone hotlines that users call before or after self-testing to obtain psychosocial and/or technical support can also provide referrals and linkage to HTS and other HIV services, as well as to nonmedical services such as legal support and violence support programmes.

Mobile phone text messages services can provide information, reminders, videos and messages that encourage linkage following HIVST.

Internet- and computer-based programmes and applications can provide linkage information in a variety of ways. Some approaches used to date have included live, online two-way text, audio or video counselling services and programmes that offer step-by-step instructions on what to do following a reactive self-test result.

Vouchers, coupons or rebates may facilitate linkage, particularly among populations facing structural barriers to accessing services, such as long distance and costly transportation.

Appointment cards and referral slips given to clients may facilitate linkage by including the day and time of an appointment or the name and phone number of a contact person and facility where services can be sought.

Couples and partner HIVST can promote linkage in the way demonstrated by a study in Kenya, where women delivered HIVST kits to their male partners, who then linked to care *(18)*.

Monitoring and reporting systems

Monitoring and reporting systems are critical for all approaches to HTS, including HIVST. Because of the discreet, private nature of HIVST, there may be particular challenges with collecting information on how effective an HIVST programme is, or monitoring the experiences of users and tracking possible social harm. Although the instances of harm reported to date have been few, it is essential for programmes to utilize or adapt existing systems to monitor and report on social harm or other adverse events, as well as corrective action and follow-up, in order to address harm if and when it occurs.

In order to track programmatic outcomes, monitoring and evaluation of HTS indicators may need to be adapted to include HIVST. Many HTS programmes are starting to use a combination of the tools described in Box 2.6 to improve monitoring of HIVST.

Box 2.6. Summary of monitoring and reporting tools

Monitoring and analysis of **calls to HIV self-testing (HIVST) hotlines and text message services**, including pictures of self-test results that are shared, which can be used to estimate the number of reactive test results and identify reports of test kit failures, adverse events or social harm.

Community-based surveillance systems and household/population-based surveys, health impact assessments and behavioural surveys can be modified to include HIVST, by collecting data not only on the uptake of HIV testing but also on the mode of testing in order to be able to assess what proportion of all diagnoses are identified through HIVST and record instances of social harm and adverse events.

Site-level and facility-level logbooks/testing registers can be modified to include HIVST, for example by noting if clients have self-tested before attending an HIV testing service facility and recording the reported self-test result. These registers can also be used to monitor linkage to prevention, treatment and care.

Internet and mobile phone surveys and tools can be used to encourage users to provide feedback on their experiences, including test kit failures and social harm or adverse events.

Existing post-market surveillance systems can be adapted to identify and report on problems related to the rapid diagnostic tests used for HIVST.

E-readers and **mobile applications** that assist users in interpreting self-test results can be linked to health information systems. Thereafter, test results or other patient information and health outcomes can be sent electronically to facilities that monitor the impact of the HIVST programme and the performance of HIVST kits used by self-testers.

Financial or **in-kind incentives** can be utilized to encourage users to report and share information about their HIV self-testing experience.

2.3.2 Key messages for users and implementers

Any HIV RDT for self-testing, either oral or blood, which is procured or used for HIVST should be approved by the relevant regulatory authority, or the results of an international regulatory review may be used.

Appropriate, validated, clear and concise instructions for the use of HIVST kits are critical to minimize errors and maximize the performance of HIV RDTs used for self-testing. Printed instructions – written and/or pictorial – are essential to support correct use and interpretation. In-person demonstrations of how to use an HIVST kit, along with additional population-specific information, can be very useful, particularly for rural settings or where literacy and formal education levels are low *(10,17,42,68,85,131,167, 170,175,176,178)*. Other support tools, such as telephone-based or Internet-based messaging services, which provide information on HIVST and answer questions about how to perform a self-test and interpret a self-test result, may also be appropriate and potentially improve performance for some populations *(181)*.

Pre-test information and post-test counselling messages should be readily accessible and available – for instance, through package inserts or brochures, hotlines, text message services, in-person demonstrations, counselling delivered by trained providers, volunteers or peers, Internet- or computer-based programmes, or videos posted on the Internet.

Clear messages are needed to ensure that users understand that a reactive test result must be confirmed through further HIV testing by a trained tester. Additionally, **messaging on what to do after a reactive self-test result is crucial**, including where to go to access stigma-free HTS, HIV prevention, treatment and care and other support services. **Messages and information on tuberculosis, STIs and viral hepatitis are also beneficial**, since individuals with HIV are at high risk of co-infection.

A non-reactive self-test result does not usually require further HIV testing. However, **clear messages are needed to ensure that users understand that a non-reactive test result does not always indicate an HIV-negative status**. The accuracy of results can depend on the test used, possible errors in performing the self-test or interpreting the results, as well as the limitations of testing in the window period before an HIV infection is detectable. As with all HIV testing, **individuals with known or possible HIV exposure in the 6 to 12 weeks prior to testing should be advised to retest or seek facility-based testing** at an appropriate interval based on the client's risk and the type of test used.

Providers and users should be aware that **HIVST is not recommended for people with a known HIV status who are taking ARV drugs for treatment or prevention**, as this may lead to an incorrect self-test result (false non-reactive), particularly when using oral fluid-based RDTs.

Clear messages are also needed to ensure that users understand that **HIV self-test results should not be used to serosort or to justify in HIV risk behaviour** such as condomless sex following a negative self-test result. Since a negative self-test result does not always indicate that a person is HIV-negative, **users should be encouraged to utilize existing HIV prevention options**, such as condoms and PrEP, regardless of their self-test result.

As with any HIV testing, there is a need for information and tailored **messaging on disclosure in order to mitigate the risk of social harm** and help couples and families to cope with a reactive self-test result or serodiscordant self-test results. Individuals or couples who report IPV in their current relationship should be counselled to disclose or undergo couples testing only if the safety of both partners can be assured. Linkages to further testing, prevention, treatment and care, as well as services for domestic abuse and gender-based violence, should be offered as part of HIVST services, either during the counselling in directly assisted approaches or in the package inserts/instructions in unassisted approaches *(2,49)*.

Educating the community – including networks of people with HIV, such as key and affected populations, trained testers and health workers – **about HIVST is critical** in order to increase the uptake of self-testing and minimize the risks of misuse. It is also important to communicate to providers that HIVST can serve as a tool to create demand for existing services and, thereby, enhance their role in delivering HTS. Information tools such as brochures, job aids and standard operating procedures can also be useful in increasing understanding and raising awareness, especially when combined with training and information sessions.

Integrating HIVST into comprehensive sexual health service programmes is critical in settings where there is a rising incidence of STIs. Although HIVST is an innovate way of encouraging greater uptake of HIV testing among clients who might otherwise not know their HIV status, enabling individuals to test without having to attend a sexual health clinic can mean some users may access other health services, such as STI testing, less frequently. Even if high-risk clients have a non-reactive HIV self-test result, they **should be provided with information on further HIV testing and treatment, as well as on other STIs and viral hepatitis**, and be encouraged to access comprehensive sexual health services.

E-readers and/or mobile applications may be available in the future to assist HIVST users in interpreting test results, or identifying errors, in performing the test. A number of these tools are under development, both by test manufacturers and external agencies. There are, however, numerous challenges still to be resolved regarding the use of these tools, including data security, accuracy and equity in access (for example, access to mobile and smart phone technology varies across settings and populations, and applications require that smart phones meet specific technical standards to function correctly).

2.3.3 Policy and regulatory frameworks

Currently, HIVST is taking place in many countries that do not have formal policies fully regulating the quality, sale, distribution or use of HIVST kits. To optimize implementation of HIVST, a number of policies and regulations will likely need to be adapted, developed and harmonized. In particular, policy-makers, regulators and implementers should work together to consider the following *(185)*:

Laws and regulations permitting the sale, distribution, advertisement and use of in vitro diagnostics for HIVST will generally need to be adapted or developed. Countries must provide clear pathways for national validation and registration of HIVST kits. Countries where RDTs for HIVST are informally available may need to develop additional

systems to address this issue by informing consumers about how to identify quality-assured HIVST kits and by taking legal actions to prevent products of unknown quality from reaching the market.

Policies on access to HIV testing may need to be adapted or developed to enable populations to self-test for HIV. In particular, **age of consent** policies may need to specifically address HIVST so that adolescents can self-test for HIV and be linked to additional services. This should include policies protecting the testing of minors without the consent of guardians, for example in schools.

Laws, policies and regulations that address misuse and abuse (such as coercive testing, violence, discrimination and prosecution) may need to be developed or adapted to protect people who self-test. It may be important, also, to develop channels through which misuse or abuse can be reported, monitored and addressed.

Healthcare and managerial policies and regulations, national testing strategies and validated testing algorithms may need to be adapted or developed to incorporate HIVST. This may involve reviewing existing policies to ensure that HIVST is recognized as a *test for triage* and that it does not replace first-line assays. Also, this review may involve revisiting policies about who can perform an HIV test and who can interpret an HIV test result. Health workers and other personnel, and national programmes, are likely to need guidance, technical support and training on the integration of HIVST into existing HTS frameworks.

Quality assurance systems for HTS may need to be reinterpreted and adapted to include HIVST. **Post-market surveillance systems**, if not already in existence, may need to be established and/or adapted to identify and report problems related to RDTs used for HIVST. In addition, **community-based monitoring systems** and other tools can be used to document, monitor and address potential social harm.

Legal issues concerning disclosure of HIVST results to others (including sexual partners) must be reviewed in countries where the current legislation requires disclosure of known HIV-positive status. It should be made clear that HIVST does not provide a definitive HIV-positive diagnosis and, therefore, disclosure of a reactive result may not be relevant until confirmed by a trained provider. Messaging and other information on HTS should address this issue and clarify the legal implications of HIVST for disclosure, keeping in mind that disclosure should be encouraged when it is safe and beneficial but should not be required.

Further reading

- Technical specifications for WHO prequalification - Human immunodeficiency virus (HIV) rapid diagnostic tests for professional and/or self-testing. Geneva: World Health Organization; 2016 (http://www.who.int/diagnostics_laboratory/ guidance/en/).
- Operational research note on HIV self-testing. Geneva: Global Fund; 2016 (http://www.theglobalfund.org/documents/core/infonotes/Core_OpResearchImplementationHIVSelfTesting_BriefingNote_en/).
- Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2015 (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/).
- March 2014 supplement to the consolidated HIV guidelines on the use of antiretroviral therapy – a public health approach. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_march2014/en/).
- A short technical update on HIV self-testing. Geneva: Joint United Nations Programme on HIV/AIDS; 2014 (http://www.unaids.org/sites/default/files/media_asset/JC2603_self-testing_en_0.pdf).
- WHO/UNITAID HIV self-testing technology landscape – 2nd edition. Geneva: UNITAID; 2016 (http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_rapid_diagnostic_tests_for_self-testing.pdf).

HIV PARTNER NOTIFICATION SERVICES

3

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3 HIV PARTNER NOTIFICATION SERVICES

KEY POINTS

- HIV partner notification is a **voluntary process** where trained health workers, including lay providers, ask people diagnosed with HIV about their sexual partners or drug injecting partners, and **with the consent of the HIV-positive client**, offer these partners voluntary HIV testing. Partner notification is provided using passive or assisted approaches.
- Assisted partner notification services (such as provider, contract or dual referral) **increase the uptake of HIV testing among partners of HIV-positive clients**, and **high proportions of HIV-positive people are diagnosed** and linked to care and treatment.
- **Reports of social harm or other adverse events following voluntary HIV partner notification have been rare.** Trained providers should offer partner notification services appropriately and safely. Associated counselling and support services, such as helplines and intimate partner violence screening tools, can also be utilized to reduce the potential risk of harm.
- **HIV-positive clients should be offered multiple options for assisted partner notification** (such as contract referral, provider referral or dual referral), and the approach selected should be based on client preferences. Clients should also be given the opportunity to decline.
- **Partner notification services should always be voluntary.** Mandatory or coercive approaches to partner notification are never justified. People should always be counselled about the benefits and risks so that they can make safe and informed choices.
- **Notification should only be delivered to partners of HIV-positive people, no one else.** Criminal justice, law enforcement or other non-health-related service providers should not be involved in partner notification services, especially in instances where the behaviour of key population groups is criminalized.
- **Supportive policies are essential for effective and safe HIV partner notification programmes.** Countries should review their laws and policies in order to consider how they could be more supportive of people with HIV, for example revising mandatory or coercive partner notification practices that may stigmatize, criminalize or discriminate against people from key population groups and people with HIV.

NEW

Recommendation

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

3.1 Background and rationale

It is estimated that, as of the end of 2015, over 36 million people worldwide had HIV and of these 40% remained undiagnosed *(1)*. To address this gap in knowledge of HIV status and to achieve UN testing and treatment goals – in particular, the first of the 90–90–90 goals, to diagnose 90% of people with HIV infection by 2020 *(1)* – new approaches are needed that enhance the efficiency and coverage of testing. HIV partner notification is an approach that has the potential to improve coverage while also identifying people with undiagnosed HIV infection.

Assisted partner notification has been an important public health approach in infectious disease management for decades, including in programmes targeting sexually transmitted infections (STIs) and tuberculosis (TB). STI partner notification approaches have been shown to be effective in diagnosing and treating STIs and preventing recurrent infection *(2)*. Likewise, active tracing of contacts and the voluntary screening of household members of people with active TB is an effective and standard approach that has been used successfully in communities with high HIV and TB prevalence *(3)*.

The sexual partners and drug injecting partners of people diagnosed with HIV infection have an increased probability of also being HIV-positive *(4–10)*. However, partner testing services, including partner notification, for people diagnosed with HIV have not been routinely offered or implemented, therefore, uptake and coverage remains low *(11)*. The benefits of partner and couples HTS have been well documented, including mutual support to access prevention, treatment and care services, as well as improved adherence and retention in treatment and prevention of mother-to-child transmission programmes *(12,13)*. Partner testing also allows those in serodiscordant partnerships to prioritize effective HIV prevention, such as the use of condoms, immediate antiretroviral therapy (ART), medication adherence by HIV-positive partners, and pre-exposure prophylaxis (PrEP) for HIV-negative partners *(12,13)*.

In 2012 WHO developed guidance recommending couples and partner HTS, including support for mutual disclosure, with a special focus on testing the partners of people diagnosed with HIV infection in all epidemiological settings *(12)* (see Box 3.1). In 2013, WHO also issued recommendations on community-based HIV testing, including guidance to offer home-based HTS to the households and family members of people diagnosed with HIV (see Box 3.1).

Box 3.1. Existing WHO recommendations on HIV testing services

- HIV testing services for couples and partners, with support for mutual disclosure, should be offered to individuals with known HIV status and their partners *(strong recommendation, 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).*
- WHO recommends community-based HIV testing services, with linkage to prevention, treatment and care services, in addition to routinely offering PITC *(strong recommendation, low quality of evidence for all populations in generalized epidemics and for key populations in concentrated epidemics).*

Source: WHO, 2015 *(14)*.

Several studies *(5–7,9,11,14–16)*, systematic reviews *(2,17)*, and cost-effectiveness studies and models *(18–21)* have pointed to the benefits of offering HTS to the partners of people diagnosed with HIV. Assisting people who are HIV-positive in contacting and offering HTS to their people is a way of facilitating partner testing and overcoming the current failure to reach people who could benefit from the full range of HIV services. Those partners who are diagnosed with HIV can be linked to treatment services, and those with a HIV-negative result can be linked to appropriate and effective prevention. Despite the WHO recommendation to offer partner and couples testing, and its inclusion in the HIV polices of many countries, it has not often been actively prioritized or widely implemented.

Box 3.2. Definitions of passive and assisted partner notification

Partner notification, or disclosure, or contact tracing, is defined as a voluntary process whereby a trained provider asks people diagnosed with HIV about their sexual partners and/or drug injecting partners and then, if the HIV-positive client agrees, offers these partners HTS. Partner notification is provided using passive or assisted approaches.

Passive HIV partner notification services refer to when HIV-positive clients are encouraged by a trained provider to disclose their status to their sexual and/or drug injecting partners by themselves, and to also suggest HTS to the partner(s) given their potential exposure to HIV infection.

Assisted HIV partner notification services refer to when consenting HIV-positive clients are assisted by a trained provider to disclose their status or to anonymously notify their sexual and/or drug injecting partner(s) of their potential exposure to HIV infection. The provider then offers HIV testing to these partner(s). Assisted partner notification is done using contract referral, provider referral or dual referral approaches.

Contract referral: HIV-positive clients enter into a *contract* with a trained provider and agree to disclose their status and the potential HIV exposure to their partner(s) by themselves and to refer their partner(s) to HTS within a specific time period. If the partner(s) of the HIV-positive individual does not access HTS or contact the health provider within that period, then the provider will contact the partner(s) directly and offer voluntary HTS.

Provider referral: With the consent of the HIV-positive client, a trained provider confidentially contacts the person's partner(s) directly and offers the partner(s) voluntary HTS.

Dual referral: A trained provider accompanies and provides support to HIV-positive clients when they disclose their status and the potential exposure to HIV infection to their partner(s). The provider also offers voluntary HTS to the partner(s).

Country policies on HIV partner notification

Currently, 67 countries have policies for HIV partner notification.

Globally, policy development on HIV partner notification services varies. In all WHO regions, some countries have partner notification policies related to HIV testing. Based on a 2016 review of publicly available national HTS policies, 54% (67/123) recommend HIV partner notification services; however, only 20 of these policies stipulate that this approach is currently being implemented *(22)*. Identified policies recommend partner notification for multiple populations, including couples, adolescents, pregnant women and people who inject drugs, although only 43% (29/67) recommend notification for all sexual partners (see Figure 3.1a) *(22)*. In general, policies most commonly describe a combination of passive referral followed by provider referral, with few countries mentioning provider or contract referral alone (see Figure 3.1b). None of the identified policies mentions legal provisions to protect HIV-positive individuals against potential harm following disclosure of their HIV status and partner notification. Nineteen countries do not mention informed consent for HTS in their policies, and 21 countries have some form of mandatory partner notification. Mandatory partner notification is not supported by WHO. These guidelines provide alternative approaches to ensure voluntarism, with informed consent and the explicit right to decline.

Fig. 3.1a. Groups for whom HIV partner notification is recommended in 67 national policies

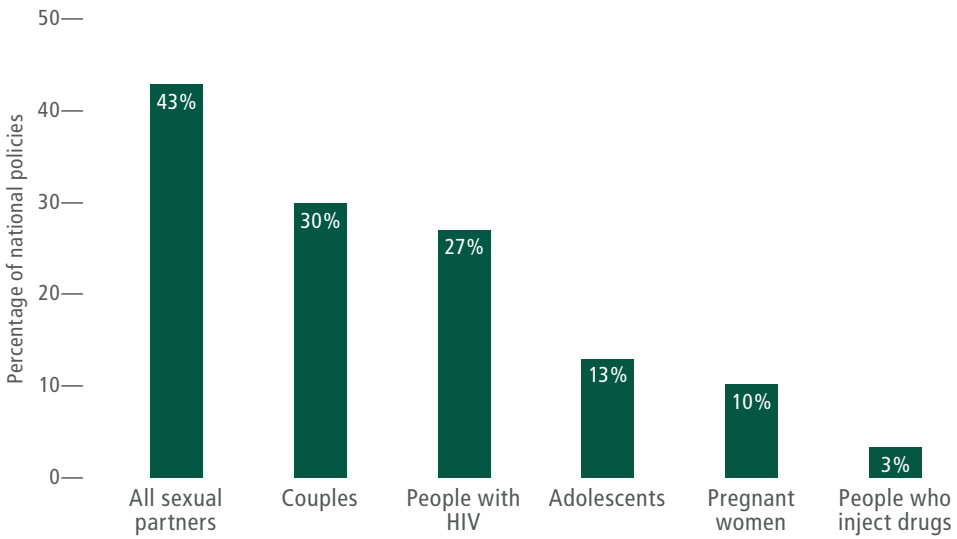
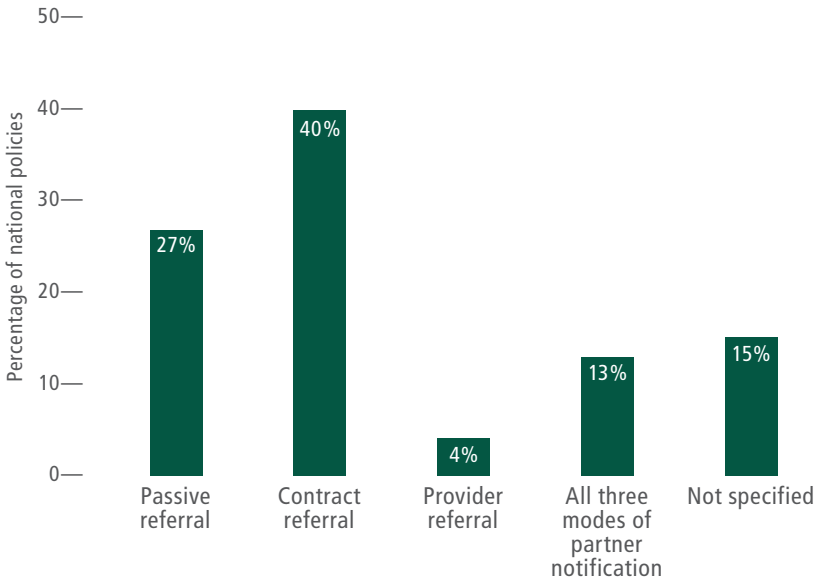


Fig. 3.1b. Partner notification approaches described in 67 national policies



Note: Some countries described multiple approaches.

3.2 Review of the evidence

3.2.1 Grading of Recommendations, Assessment, Development and Evaluation (GRADE) systematic review on HIV partner notification services

Since 2012, WHO has recommended offering HTS to the partners of all people diagnosed with HIV *(12,13)*. In this 2016 guideline, WHO has issued a strong recommendation on the inclusion of voluntary assisted HIV partner notification services as part of a comprehensive approach to improving the coverage of HTS. The Guideline Development Group (GDG) has determined that the evidence reviewed on partner notification services is of moderate quality.

Discussion of this recommendation follows, along with a summary of the results of a systematic review and literature review on values and preferences of providers and recipients of partner notification. In accordance with the GRADE methodology, this review prioritized randomized controlled trials and studies that directly compared assisted partner notification services (provider referral, contract referral or dual referral) to no referral or passive approaches. (See Annex 18 for detailed information on the methods and evidence from the systematic review.)

The searches yielded 1742 citations. After removing duplicates, there were 1407 unique records. A total of 1057 of these records were excluded in the initial screening, as were 340 additional records in a second screening, because they did not meet the inclusion criteria: four were reviews or commentaries, 46 were feasibility studies, four were related to cost, 56 presented end-user values and preferences, and 230 presented no

relevant information. Therefore, a total of four randomized controlled trials were deemed eligible and included in the review. (See Annex 18 for further details.)

The three individually randomized controlled trials and one cluster randomized controlled trial included in the review were conducted in Kenya *(9)*, Malawi *(5,7)*, and the United States *(6)*. Three compared assisted partner notification services (provider or contract referral) with passive approaches, while the fourth compared immediate with delayed partner notification. One study also offered invitation letters in the passive referral arm *(7)*. The study populations included pregnant women attending antenatal care, patients from STI clinics, clients from an HIV testing centre, and patients in a county health department, including women, men who have sex with men, and people who inject drugs. Six observational studies conducted among the general population in Cameroon *(23)*, Mozambique *(24)*, Spain *(15)*, Taiwan *(26)*, the United Republic of Tanzania *(25)* and the United States *(27)* were also included, as they reported on outcomes following the offer of different HIV partner notification options (provider, contract and passive referral) to HIV-positive clients.

Box 3.3. Main outcomes of studies used in GRADE review

In general, the four studies concluded that:

- Assisted partner notification services (provider or contract referral) can increase uptake of HIV testing services among partners of HIV-positive individuals.
- Assisted HIV partner notification services can result in high proportions of HIV-positive people being diagnosed.
- Assisted HIV partner notification services can result in increased linkage to care among partners of HIV-positive individuals.
- Reported social harm and other adverse events following HIV partner notification using passive or assisted approaches have been rare.

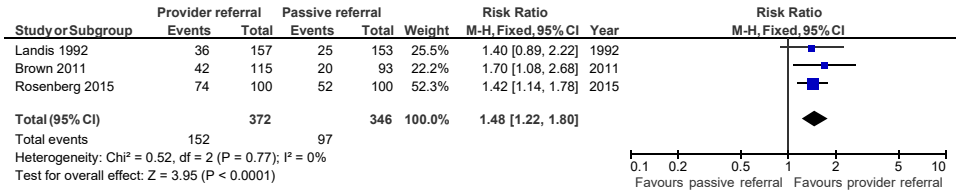
HIV testing service uptake among partners of HIV-positive clients

Assisted partner notification services can increase uptake of HTS among the partners of HIV-positive individuals. All three randomized controlled trials and the cluster randomized controlled trial included in the GRADE review noted that assisted partner notification services resulted in: higher uptake of HIV testing among partners of people with HIV than passive referral methods in both general populations and key populations; identification of high proportions of HIV-infected persons; and increased linkage to care through the referral of newly identified HIV-infected partners to ART services.

Meta-analysis of the three individually randomized controlled trials demonstrated that assisted partner notification services via a provider resulted in a 1.5-fold increase in the uptake of HIV testing among the partners of HIV-positive individuals (Relative Risk (RR) = 1.48; 95% CI: 1.22–1.80; Chi^2 for heterogeneity = 0.52; I^2 = 0%) compared with passive referral *(5–7)* (see Fig. 3.2). Results of sensitivity analyses, using only partners who could be located as the denominator, found similar results (RR = 1.39; 95% CI: 0.93,

2.06). When the cluster randomized controlled trial was included in the meta-analysis, a similar beneficial effect was found, although the result was less precise (RR = 1.91; 95% CI: 0.93, 3.93). Using the rate ratio to indicate the average rate of testing or return of partners to the clinic per index patient, a meta-analysis of all four of the included trials demonstrated a rate in the provider-assisted partner notification group twice that of in the passive referral group (rate ratio = 2.04; 95% CI: 1.11, 3.77).

Fig. 3.2. Meta-analysis of HIV testing uptake among partners of HIV-positive individuals



M-H: Mantel-Haenszel; CI: Confidence interval.

Source: WHO, 2016 *(9)*.

One study *(5)* also showed increased uptake of HIV testing among couples and primary partners. In the cluster randomized controlled trial in Kenya, immediate assisted partner notification substantially increased uptake of HIV testing among partners of HIV-positive clients who were new testers compared with delayed referral (14.7%, 81/550 vs. 0.7%, 4/569; Incidence Rate Ratio = 14.80; 95% CI: 5.35, 40.93).

A single trial *(5)* compared contract referral to passive referral. It showed that assisted partner notification services using contract referral resulted in a two-fold increase in HIV test uptake among the partners of HIV-positive individuals (RR = 2.08; 95% CI: 1.33, 3.25) compared with passive referral. Results of sensitivity analyses, using only partners who could be located as the denominator, found similar results (RR = 2.1; 95% CI: 1.36, 3.23).

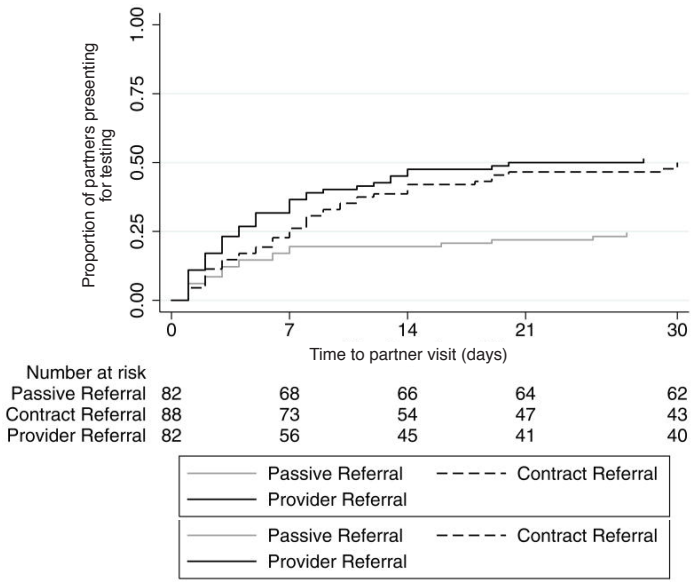
Across all six observational studies, assisted partner notification was associated with increased uptake of HIV testing among partners who were notified compared with passive referral *(15,23–27,29)*. In a study from the United Republic of Tanzania, 93% of HIV-positive individuals preferred passive approaches over contract or provider referral, and among partners who were notified this way, 96% (232/242) accepted testing, while 100% (7/7) accepted testing with assisted approaches *(25)*.

Two randomized controlled trials in Malawi reported that the difference in notification rates between passive and provider-assisted partner notification methods became more pronounced over time (*5,7)*. In the first week following the HIV-positive diagnosis of a client, similar numbers of partners in both passive and assisted approaches returned to clinics for HTS. However, after one week, provider-assisted methods resulted in higher numbers of partners returning for HTS than passive referral (see Fig. 3.3a, 3.3b) *(5,7)*. The cluster randomized controlled trial in Kenya, which compared a delayed and an immediate provider-assisted approach, showed significant increases in uptake of HTS in the immediate arm (71.3%, 392/550 vs. 14.9%, 85/569; IRR = 4.83; 95% CI: 3.66, 6.39) *(9)*. In an observational study from the United Republic of Tanzania, 70% of partners of HIV-positive individuals notified within seven days of their diagnosis were successfully

referred for HTS *(25)*. Although taken from a small number of studies, these results suggest that HIV-positive individuals who do not inform their partners of their status within the first week of diagnosis may be less likely to do so later. Across all studies, high proportions of partners returned for HTS when contacted by a provider, whichever method was used.

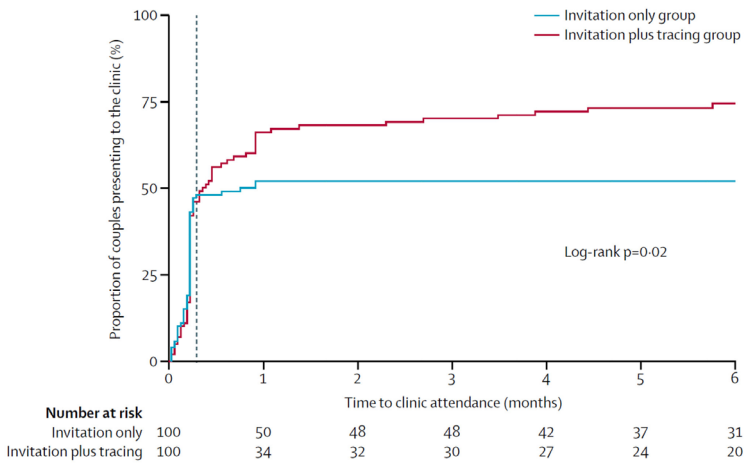
Fig. 3.3. Time to presentation at clinics for partners of HIV-positive clients associated with passive and assisted partner notification methods in two trials in Malawi

Fig. 3.3a.



Source: Brown et al., 2011 *(5)*.

Fig. 3.3b.



Note: The vertical dotted line at 8 days shows the time when notification by a provider was supposed to be initiated.
Source: Rosenberg et al., 2015 *(7)*. Reprinted with permission from Elsevier (The Lancet HIV, 2015, 2(11), e483-e491).

HIV testing service uptake with passive referral

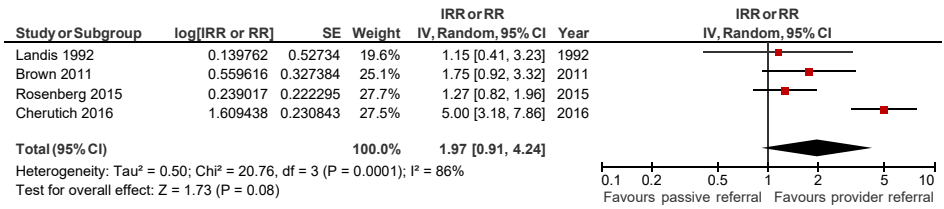
In all six observational studies that were reviewed, assisted partner notification approaches resulted in higher HIV test uptake among notified partners. Five of these studies showed higher proportions of partners testing HIV-positive, and two studies that reported on linakge to care demonstrated improvements to care over passive referral approaches. However, in both the randomized trials and observational studies, passive referral also resulted in uptake of HIV testing among partners (2–65%) *(5–7,15,24,25)*. In some of the observational studies the level of HIV test uptake with passive referral was similar to that seen in assisted approaches used in other studies. Two studies with very low HTS uptake with the passive referral groups were conducted in the United States before triple therapy was available (3%) *(6)* and when implementation of partner notification reporting appeared to be low (2%) *(27)*. Other studies reported HTS uptake with passive referral between 20–65% *(5,7,15,24–26,29)*. Therefore, the simple act of offering partner notification services to a person who is HIV-positive, whether verbally during counselling, or through written invitation letters or referral cards, is likely beneficial and could be considered while assisted approaches are being scaled up.

New HIV diagnoses among partners of HIV-positive clients

The percentage of people *newly* diagnosed with HIV infection following assisted partner notification is typically high. The three randomized controlled trials and the cluster randomized trial demonstrated that the proportion of partners of people with HIV who were also HIV-positive was high (up to 72% in one trial among partners of pregnant HIV-positive women) *(5–7,9)*. In a meta-analysis of the three individually randomized controlled trials, the proportion of all identified partners who were HIV-positive following testing was 1.5 times higher with the assisted partner notification approach than with the passive approach (RR = 1.47; 95% CI: 1.12, 1.92; Chi^2 for heterogeneity = 0.14; I^2 = 0%). In sensitivity analyses, the results were similar, using locatable partners as the denominator (RR = 1.49; 95% CI: 1.14, 1.95). Data including the cluster randomized controlled trial showed a similarly beneficial effect in favour of provider-assisted partner notification (RR = 1.97; 95% CI: 0.91, 4.24 (see Annex 18).

The percentage of partners newly diagnosed with HIV, when considering partners who could be located, was higher in the provider-assisted partner notification group (RR = 1.37; 95% CI: 0.98, 1.93). Data from a meta-analysis including the cluster randomized controlled trial showed a similarly beneficial effect in favour of provider-assisted partner notification (RR = 1.97; 95% CI: 0.91, 4.24; Chi^2 for heterogeneity = 20.76; I^2 = 86%) (see Fig. 3.4).

Fig. 3.4. Proportion of newly identified HIV-positive partners following testing of all locatable partners



RR: Relative risk; IRR: Incidence rate ratio; SE: Standard error; IV: Independent variable; CI: Confidence interval.

As with HTS uptake, only one individually randomized controlled trial *(5)* assessed the proportions of partners who tested HIV-positive, comparing contract referral with passive referral. It demonstrated that assisted partner notification services using contract referral resulted in an almost two-fold higher proportion of HIV-positive partners (RR = 1.91; 95% CI: 1.07, 3.18) compared with passive referral. Results of sensitivity analyses, using only partners who could be located as the denominator, found similar results (RR = 1.8; 95% CI: 1.02, 3.18).

Across the observational studies, 0-86% of partners of HIV-positive individuals were newly diagnosed with HIV *(15,24,25,27,29)*. Feasibility studies among general and key populations, particularly in studies among men who have sex with men and people who inject drugs, also identified a high proportion of HIV-positive partners (5–80%) *(16,30–51)*.

Linkage to HIV care and treatment among partners of HIV-positive clients

Compared with passive referral, assisted HIV partner notification services can increase linkage to care. In a meta-analysis of two trials reporting this outcome, linkage to care of HIV-positive partners was more than three times greater in the provider referral arm than in the passive arm (rate ratio = 3.76; 95% CI: 2.41, 5.86) *(7,9)*. A randomized controlled trial in Malawi also demonstrated that partners of recently diagnosed HIV-positive individuals who received provider referral were more likely to have a clinical assessment within one month than those who received passive referral (45.5%, 15/33 vs. 19.2%, 5/26) *(7)*.

In addition to the randomized controlled trials included in the GRADE analysis, five feasibility studies also reported that a high proportion of partners newly diagnosed with HIV were linked to clinical assessment or ART (84–100%) *(23–25,29,37,40)*.

Social harm following partner notification

Across studies reviewed, no physical violence or intimate partner violence resulted from HIV partner notification services.

Reported social harm and other adverse events following HIV partner notification, using passive or assisted approaches, have been rare. Concerns exist about the possible harm that could result from disclosure of HIV-positive status *(52)*, particularly for key populations and other vulnerable groups. Fears about social harm are of particular concern in situations where certain behaviours associated with HIV infection are criminalized, such as among people who inject drugs, or where one partner is economically dependent on the other and fears losing social and financial support. However, although these concerns have been raised *(53,54)* where hypothetical questions on the social impact of disclosure or partner notification have been assessed, when adverse events have actually been measured, very few have occurred *(5–7,9)*.

All three randomized controlled trials and the cluster randomized controlled trial reported few instances of violence or harm *(5,7,9)*. Reported incidents of harm in randomized controlled trials in Kenya and Malawi appeared not to be associated with HIV partner notification services, as they occurred prior to the intervention *(7,9)*. Some studies screened for intimate partner violence (IPV) and excluded those with a history of

IPV, which could put them at risk of harm following disclosure. In a meta-analysis of two individually randomized controlled trials and the cluster randomized controlled trial, the adverse events assessed with IPV or abandonment were not different between assisted partner notification and passive referral approaches (RR = 1.86; 95% CI: 0.37, 9.50; Chi^2 for heterogeneity = 1.17; I^2 = 0%).

Similarly, observational studies did not identify any physical violence or IPV resulting from partner notification *(23,29,55)*. A single study in Mozambique reported that three HIV-positive individuals were left by a partner, out of 173 partners notified; two instances were HIV-related, and of these, one resulted in financial loss *(29)*. However, these results on measured harm were obtained from a limited number of studies undertaken in the United States and Africa; further studies in other world regions are needed.

While programme implementers should be sensitive to the potential for harm arising from disclosure of HIV status, this should be balanced against the benefit of diagnosing HIV infection and linking people to treatment. Recognizing that physical and emotional violence can occur between couples and partners worldwide, those offering partner notification services should discuss potential risks with HIV-positive clients and, if the safety of the client is not compromised, offer voluntary partner notification services in order to reach partners, who can, thereafter, benefit from HTS and, if necessary, life-saving ART. Screening for IPV among HIV-positive clients, having open discussions about potential notification approaches and outcomes during counselling sessions, and having referral resources such as counselling, helplines or safe places are some ways of approaching this issue. Confidentiality and voluntariness are vital. Partner notification should only occur with the express consent of the HIV-positive client and be made to their partner(s) alone, and to nobody else.

3.2.2 Values and preferences of persons using partner notification services

Fifty-six studies coded as relevant for values and preferences reported on aspects of partner notification services among general and key populations, HIV-positive individuals and their partners, health workers and other key stakeholders involved in delivering partner notification services. Study locations were across Africa – Botswana *(56)*, Cameroon *(40, 57)*, Ethiopia *(58)*, Kenya *(9)*, Malawi *(59)*; the Americas – Barbados *(60)*, Canada *(61–64)*, Guatemala *(65)*, Peru *(66–68)*, the United States *(8,69–94)*; Europe – Denmark *(95,96)*, Estonia *(97)*, Italy *(98,99)*, the Netherlands *(100)*, Spain *(101)*, the United Kingdom *(102–105)*; and Asia and the Pacific – Australia *(106)*, Singapore *(107)*. Two systematic reviews of qualitative literature on partner notification were also completed; one with a focus on the United States *(17)* and the other with a global scope *(108)*. In addition, qualitative values and preferences studies among fishing communities, sex workers, general populations and health workers in Uganda, and young key populations in Indonesia, Pakistan, Philippines and Thailand, was conducted to inform these guidelines *(109,110)*.

Partner notification among key populations

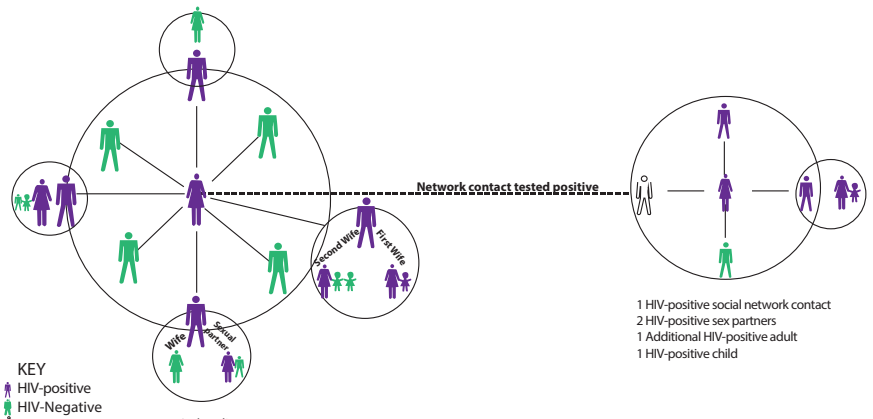
Studies on partner notification have been conducted among key populations including men who have sex with men, sex workers, transgender people and people who inject drugs. As

with studies among the general population, assisted partner notification services resulted in higher uptake of HTS compared to passive referral, and a high proportion of partners diagnosed as HIV-positive and linked to treatment or care. One of the challenges reported across key populations has been that people may be less able or willing to identify partners *(81)*. Although this also occurred among the general population, particularly among people with casual partners *(111)*, recall of and contact information for partners was better among heterosexual women than among men who have sex with men or people who inject drugs *(55)*. Therefore, providing partner notification services to key populations may require more intensive efforts to locate partners, including the assurance of confidentiality and anonymity for HIV-positive clients.

Preferences for partner notification approaches were similar among key population groups, with studies finding that healthcare provider referrals (either contract or provider referral) were favoured. Men who have sex with men in a study in the United States reported that provider referral protected against blame, violence and stigma *(108)*. A study in Peru among men who have sex with men and transgender women found that, although 93% of survey respondents considered it very important to notify regular partners, 74% thought that few of their peers would actually do so; similarly, although 73% found it very important to notify casual partners, 85% did not believe their peers would *(68)*. In Singapore, men who have sex with men preferred the use of email for partner notification significantly more than did heterosexual respondents *(107)*.

One study among female sex workers in Guatemala found partner notification to be generally acceptable and feasible, especially for regular partners (>90% intention to refer for the last client, casual clients and regular clients) *(65)*. These women preferred notification to be by passive referral (85%) rather than by a letter or phone call from a health clinic (51%) *(65)*.

Fig. 3.5. Example of assisted HIV partner notification of a young woman who engaged in transactional sex



Note: All HIV-positive individuals are enrolled in care.
Source: LVCT Health Kenya.

Partner notification among adolescents and young people

Three studies assessed partner notification among young people. A study in Singapore found that significantly more respondents who were younger than 32 years of age preferred to notify partners by text message than did older adults *(107)*. Focus groups in Canada revealed that older adults favoured using online partner notification methods like e-mail, whereas younger people preferred mobile phone text messaging, and each group perceived their chosen method to be more serious and private *(64)*. Moreover, in another Canadian study, online services appealed to the needs of young people for reasons of convenience (bypassing clinic visits) and privacy and were thought to reduce anxiety as compared to face-to-face notification *(62)*. Of note, the young people surveyed appeared to have a relatively low tolerance for technologies that they perceived to be antiquated or outdated. The results of these studies highlight some important factors that should be considered when designing a partner notification programme, in order to ensure the approaches adopted are appropriate for the groups being reached.

Box 3.4. Assisted partner notification considerations for adolescents and young people

- Adolescents should not be excluded from partner notification services. The ability to access earlier HIV testing services and linkage to antiretroviral therapy (ART) is of benefit to all persons with undiagnosed HIV. Assisted partner notification services are a way of increasing HIV testing of people at risk of infection, especially those who may be unaware of their possible exposure to HIV infection, or who might welcome support and a prompt to test.
- Receiving information about potential HIV exposure may be more emotionally challenging for adolescents.
- Providers should consider appropriate means of contact with adolescents to enable the provision of support services, should they be required.
- The potential loss of social and economic support, or the loss of a partner, may be especially difficult for adolescents, particularly if the partner is older and/or has more power in the relationship.
- Adolescents may feel especially vulnerable to intimate partner violence (IPV) and abuse based on their situation.
- Partners of adolescents may be more difficult to locate.
- Providers may encounter situations where the age of consent for HIV testing, or for sexual intercourse with adults, is in conflict with national policies. However, the provision of health services to adolescents in a safe environment, without the involvement of law enforcement, is important to enable this vulnerable group to access lifesaving ART if diagnosed HIV-positive or prevention services if HIV-negative.
- Partner notification for adolescents, whether they be the HIV-positive client or the partner being informed of exposure to HIV infection, requires the provider to engage sensitively and non-judgementally in a discussion about sexual partner(s), how to facilitate mutual disclosure and how to recognize and minimize risks of IPV.

Facilitators and barriers to assisted HIV partner notification

Across all studies and population groups, the main motivation for notifying partners was reported to be social responsibility, namely, the personal and public health benefits of identifying people with HIV in order to link them to lifesaving care and treatment and also to prevent further HIV transmission. This motivation was particularly strong among men who have sex with men and transgender women, who saw it as imperative to notify partners and facilitate partner access to testing and treatment *(68,104,108)*.

In hypothetical situations, despite strong motivations, concerns about embarrassment, guilt, shame, the loss of autonomy and emotional support, as well as fears of stigma, rejection, abandonment and relationship break-up, were key barriers that individuals suggested would hinder them from notifying partners *(57,60,66,101,103,105)*. However, as indicated earlier (see section on social harm following partner notification, p. 51), these fears have not been borne out by partner notification services that have been implemented and reported on in the scientific literature to date. A further reported barrier to notifying partners was not knowing a partner, not having their contact details, or not being able to locate them. These reasons were cited as a barrier to notifying non-primary and casual partners *(101,110)* and may particularly affect key populations and their willingness and ability to notify partners *(81)*.

Preferred HIV partner notification approaches and contact methods

Existing literature indicates that no one method of partner notification is universally preferred. Preferences differ by population, age (specifically young people) and partner type (primary or non-primary). Some studies indicated that clients and providers preferred passive referral (73–96%) *(76,101,103,109)*. However, in other studies, clients preferred assisted approaches and found provider referral acceptable (11–71%) *(8,59,83, 99,105)*. In one study in Barbados, HIV-positive individuals preferred contract referral to other assisted or passive approaches because it addressed the potential delay in notifying partners *(60)*. Studies suggest that provider referral may be particularly useful for notifying non-primary partners *(101,103,105,109)*. In Uganda, a qualitative study to assess hypothetical partner notification preferences found that female sex workers and fishermen preferred contract or provider referral approaches for notifying non-primary and casual partners but favoured passive referral for primary partners *(109)*. Among men who have sex with men and female sex workers, contract or provider referral was also perceived to be protective against potential blame, violence and stigma *(108,109)*. One study among people who inject drugs reported that, given the option between passive or provider referral by an outreach worker, 71% of HIV-positive individuals selected provider referral *(8)*.

Partner notification services are acceptable and can be delivered through many channels.

There are many contact methods through which passive or assisted partner notification services can be delivered. Passive approaches could occur in the context of post-test counselling, where the counsellor encourages the newly diagnosed person to disclose their status to all their sexual and drug injecting partners, or by providing a referral letter, appointment card or other written or electronic invitation to an HIV-positive client (whether newly diagnosed or in care and treatment) to give to their partner(s).

Assisted partner notification methods could include face-to-face conversations with partners, letters, phone calls, text messages, videos, emails and Internet-based messaging systems. Care is needed when using methods such as phone calls and text messaging to ensure that the correct person receives the message and that the anonymity of both the HIV-positive client and notified partner is maintained. Where available, partner notification via Internet applications and text messages may be more acceptable to young people *(64,107)* and to men who have sex with men than other groups, particularly when individuals do not have other contact information for their sex partners *(78,104)*. However, in both general and key populations, preferences varied depending on the type of partner and relationship. Among some men who have sex with men, notifying non-primary and casual partners through technologies such as text message, e-mail, the Internet and mobile apps was considered acceptable *(101)*. Although clients accessing STI services in Canada who reported having multiple partners were also more likely to prefer e-mail or text message notification methods, they expressed the desire to notify some partners themselves and to have a nurse or provider notify others *(61)*. Studies in Singapore and the United States indicated that individuals preferred in-person notification over the telephone or using text message options *(88,107)*.

3.2.3 Cost and cost-effectiveness

The potential cost of implementing HIV partner notification services is a concern for policy-makers because locating and contacting partners requires training and additional provider time and health system resources.

Overall, studies suggest HIV assisted partner notification services can be cost-effective. In Japan, a setting with a very low HIV prevalence, assisted partner notification was cost-effective, with an incremental cost-effectiveness ratio (ICER) of US$ 4930 per life year gained, lower than that estimated for other HIV interventions in Japan *(112)*. In a recent study among men who have sex with men in Europe, HIV assisted partner notification services were found to be cost-effective, with the ICER estimate more favourable when the analysis was considered over a longer time horizon of 20 years *(21)*. In an urban STI clinic in Malawi, where HIV prevalence was particularly high, assisted partner notification services had an ICER of US$ 3560 per HIV transmission averted for contract referral compared with passive referral, and an ICER of US$ 4106 per HIV transmission averted for provider referral compared to passive referral *(20)*. In the study in Malawi, the costs per new HIV-positive case identified according to notification approach were, provider: US$ 36; contract: US$ 18; and passive: US$ 8. The costs per partner tested were, provider: US$ 19; contract: US$ 9; and passive: US$ 4 *(20)*. The results of these studies highlight the potential cost-effectiveness of partner notification services in reaching high-risk individuals.

Assisted partner notification costs vary considerably due to differences in the unit costs of healthcare resources, the service delivery approach, and in particular the type of personnel utilized in service implementation. Epidemiologic differences, most notably in HIV prevalence and the proportion of partners newly diagnosed as HIV-positive, also result in cost differences across countries and regions. It is important to note that in high prevalence settings programme costs may be higher than those in low prevalence settings because more tracing and notification services will be needed. However, because

these services are likely to identify high numbers of HIV-positive individuals in need of ART, they have the potential to be cost-effective. Therefore, it is important that programmes make a context-specific assessment of the appropriate approach and quantity of resources needed in order to balance total programme costs and the cost-effectiveness potential of different assisted partner notification services *(113–115)*.

3.2.4 Recommendation

Having reviewed the evidence presented in the above-mentioned randomized controlled trials, observational studies, and studies on values and preferences, feasibility and cost-effectiveness, and having conducted a review of national policies, the GDG came to a consensus and decided to make a recommendation on HIV partner notification.

Using the GRADE method for rating the quality of the evidence provided by the randomized controlled trials, the GDG determined this evidence to be of moderate quality. After also taking into consideration the potential public health benefits and risks, the GDG deemed that the benefits of HIV partner notification strongly outweigh the potential risks. Therefore, the GDG came to a consensus and advised that WHO make a strong recommendation to support the offer of assisted HIV partner notification for all HIV-positive persons as part of HTS.

NEW

Recommendation

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

3.3 Implementation considerations for success

When implementing partner notification services, it is important to consider all the components that are necessary for a successful programme, including: training of providers; context-appropriate service delivery models; methods to facilitate linkage to prevention, treatment, care and support; and the surrounding legal and policy environment.

To maximize the benefits of assisted HIV partner notification services, multiple service delivery points should be available throughout an individual's interaction with the health system from the moment HIV infection is detected. A person may not be ready to disclose their status or the identity of their partner(s) when first testing HIV-positive. Therefore, when an individual enrols in care, the clinic should reassess whether the person has disclosed his/her status to all his/her partners, and if not, partner notification services should be offered. These assessments should be repeated at semi-annual, or annual, follow-up visits with individuals, given that a person's readiness to disclose or to consent to partner notification services may change over time as trust in the health providers increases.

3.3.1 Supportive laws and policies

Supportive policies are essential for successful and effective programme implementation. Therefore, prior to implementing an HIV partner notification programme, it is important to assess the policy environment. In some settings, medical secrecy laws may prohibit HIV partner notification; in other contexts, restrictive laws and policies may put clients and their partners at risk of stigmatization, discrimination, criminalization and punitive actions.

Countries should review their laws and policies to consider how these could be revised to be more supportive of people with HIV and the programmes that serve them. This includes prohibiting mandatory or coercive partner notification practices and revising laws and policies that stigmatize, criminalize and discriminate against people from key population groups and people with HIV (see Box 3.5).

Box 3.5. Structural barriers to HIV partner notification services

- Laws and policies that include any form of mandatory HIV testing
- Laws and policies that include any form of mandatory HIV partner notification
- Laws and policies that criminalize HIV transmission
- Laws and policies that criminalize behaviours of key populations, such as people who inject drugs, sex workers, men who have sex with men and transgender people
- Lack of confidentiality of medical information
- Lack of anonymity in partner notification

3.3.2 Training and mitigating risks for the delivery of HIV partner notification services

All persons newly diagnosed with HIV should be offered voluntary HIV partner notification services by a trained provider at the time of diagnosis and periodically throughout their interaction with treatment and care services, as an individual's circumstances and willingness to discuss partner notification may change. It should be noted that some people will decline this intervention based on anxieties about potential repercussions for themselves and/or their partner(s). Concerns about whom to contact (such as primary and/or other partners) should be discussed with the HIV-positive client, and partner notification options undertaken only after the benefits and risks have been explored together.

Programme managers should identify and develop approaches with written standard operating procedures, policies and protocols for delivering HIV partner notification services. Regardless of the approach utilized, it is critical that all HIV-positive clients are made aware that partner notification services are always voluntary and that clients will still have access to other services if they decline notification services (see Box 3.6). Mandatory or coercive partner notification is never warranted *(116)*.

Box 3.6. Important information for HIV-positive clients consenting to voluntary partner notification services

Programmes should ensure that HIV-positive clients who consent to voluntary partner notification services are informed of and understand the following:

- The purpose of partner notification services
- What partner notification services entail
- That partner notification services are voluntary and clients still have access to other health services if they decline
- The different approaches available for notifying partners (provider, contract, dual or passive referral)
- Potential risks and benefits, and how to minimize risks
- How and to what extent privacy and confidentiality can be protected
- Where support services are available, and how to contact and access those services if needed, particularly if harm is experienced

Source: CDC, 2008 *(117)*.

Training providers in assisted HIV partner notification

In order to deliver assisted HIV partner notification services, health providers will require training and support in how to effectively trace and locate partners. It should be made clear that partner notification (whichever approach is used) must always be voluntary. Of critical importance is training on how to sensitively and non-judgementally engage in a discussion about sexual partner(s), facilitate mutual disclosure for serodiscordant couples and partners, and recognize and minimize risks of IPV. Specific training aimed at sensitizing providers to the needs of young people (see Box 3.4) and key populations may also be required.

Additionally, training will be needed in counselling and interviewing, as well as documentation and reporting using standardized forms to link HIV-positive client records on partner notification attempts and outcomes, as well as HIV test uptake, test result and linkage to care. It is important that providers are adequately trained in how to support clients to make informed and safe choices concerning whom to (or not to) contact, and how to ensure and protect the confidentiality of HIV-positive clients and their partners. Providers should clearly understand that they are not permitted to disclose personal or health-related information about their client, or the client's partner(s), without their consent. Criminal justice, law enforcement or other non-health-related service providers should not be involved in partner notification, especially in instances where the behaviour of key population groups is criminalized.

It is also important that providers are trained to avoid harm that may be directed at them personally, especially when referrals are carried out in homes or other non-facility

settings. Context-appropriate strategies could include avoiding dangerous areas and being accompanied by community health workers when making visits to private homes.

On completion of training, a range of health worker cadres, as well as trained lay providers, should be well positioned to effectively deliver assisted partner notification services.

Mitigating risks and protecting against potential harm

Trained providers must be able to offer support and counselling to HIV-positive clients and the partners they notify. The focus should be on supporting and encouraging disclosure of HIV status, when safe and beneficial, and the importance of linking to HIV prevention, treatment and other relevant services *(12)*. Providers who identify serodiscordant couples and partners should encourage mutual disclosure in a process that is facilitated by providers trained in couples/partner counselling *(12)*. It is essential that clear information be supplied to HIV-positive partners on the benefits of adhering to treatment, and that prevention options (such as PrEP, condoms, and voluntary medical male circumcision (VMMC)) be discussed with HIV-negative partners, in order to prevent onward HIV transmission *(12)*. Providers should be particularly careful to protect client confidentiality, in the event that partners have not yet disclosed their HIV status to each other *(12)*.

Providers will need to determine which clients may be at risk of social harm or physical violence. Various screening tools for IPV are available *(118)*. In addition, referrals for in-depth counselling and access to helplines and safe locations may be necessary. In consultation with the client, the risk of harm should be assessed by the provider to determine which partner notification service approach is most appropriate, including more supportive options such as dual referral or couples HTS, or whether not to proceed with partner notification at all.

3.3.3 Methods for contacting partners

Providing options for partner notification

All people diagnosed as HIV-positive should promptly be offered voluntary partner notification services. There are many notification models that can be utilized, depending on the context, setting and preferences of the client (see Box. 3.2 for definitions of passive and assisted partner notification, as well as Table 3.2 below).

HIV-positive clients should be informed about all the available options and be made aware that they may use different notification models for different partners. For example, HIV-positive individuals may want to use a passive approach to contact some partners, whom they feel comfortable notifying on their own, but prefer the provider to assist them in contacting others. If HIV self-testing is approved nationally, it can be offered to partners through either passive or assisted methods.

Depending on the context, some partner notification approaches may be more feasible or appealing to certain populations. For instance, young people may prefer using new technologies, text messaging and other Internet-based communication systems, whereas older populations may prefer in-person meetings, telephone calls or e-mail. Depending on the setting, key populations who experience stigma, discrimination and criminalization for their behaviour may prefer anonymous methods such as provider

referral. Given these different preferences across settings, it is important that HIV-positive clients have options presented to them so that they can choose an approach that is safe, effective and acceptable to them.

Table 3.1. HIV partner notification service delivery approaches

Assisted HIV partner notification services (provider, contract or dual referral)	Passive HIV partner notifications services
• Provider delivers counselling and offers HIV-positive clients assistance with disclosure and notifying their partner(s) through one of the 3 referral methods. • Provider contacts partner(s) either by phone, Internet, e-mail or an in-person home visit to inform them of their potential exposure to HIV infection and offers them HIV testing services (HTS). • Provider offers home-based HTS to the household (including partners and family members) of the HIV-positive individual.	• Provider delivers counselling and encourages HIV-positive clients to disclose their HIV status to their partner(s) and notify them of their possible HIV exposure, either in-person or by telephone call, text message, e-mail, etc. • Provider gives HIV-positive clients a letter or card inviting their partner(s) to attend the health facility. When the partners present themselves at the health facility, they are offered HTS. • HIV-positive clients may use anonymous messaging services such as a phone call, e-mail or Internet to notify their partner(s) on their own.

Facilitating linkage to prevention, treatment and care

Partners of HIV-positive clients who are also diagnosed HIV-positive should be linked to early treatment and care to improve their own health and to prevent further HIV transmission. Newly diagnosed partners should, in turn, be offered partner notification services for all of their sexual and drug injecting partners. HIV-negative partners can be informed about and linked to relevant and effective prevention services, such as condoms, VMMC, PrEP, harm reduction and opioid substitution therapy services for people who inject drugs, in order to reduce the risk of future HIV infection.

Notification services also provide an opportunity to offer partners of HIV-positive individuals additional screening and testing services for TB, hepatitis B and C, and other STIs, as well as access to contraceptive services. This approach has been found to be particularly effective when tracing the household contacts of HIV-positive clients to offer combined HIV testing and TB screening (see Box 3.7). For example, in South Africa out of 59 457 household members of HIV-positive clients who received HIV testing and TB screening, 15.5% were found to be HIV-positive. Nearly all HIV-positive people identified (97%) also received TB symptom screening, and 21.3% were TB symptom positive *(119)*.

A list of existing interventions and approaches to further facilitate linkage to care for HIV-positive individuals and their partners is available in the WHO *Consolidated guidelines on HIV testing services (13)*.

Case example: A community-based partner notification programme in Kenya

LVCT Health is a non-governmental organization in Kenya that delivers HIV testing services (HTS), prevention interventions, and care and treatment to the general population, key populations, and adolescents in community and facility settings. The programme is funded by the Presidents Emergency Plan for AIDS Relief through the U.S. Centers for Disease Control and Prevention through a cooperative agreement. A pilot partner notification programme was conducted in two informal settlements of Mlolongo and Kawangware in Nairobi from December 2015 to May 2016. Lay counsellors offering HTS in community settings (HTS sites, outreach, and door-to-door) used contract referral to identify the sexual partners and family members of HIV-positive clients, as well as social contacts among key populations who could benefit from HTS.

Lay counsellors received training on partner notification, screening for intimate partner violence (IPV) and creating a confidential and safe environment for HIV-positive clients to identify the sexual partners whom they wished to notify. The counsellors used a register to record phone numbers and the physical location of identified partners. Counsellors notified partners face-to-face and encouraged them to test for HIV. Counsellors made appointments for clinic or home visits for partner testing, including with their family members if requested. Results of partners identified, notified, and tested were reviewed on a weekly basis with monthly supervision of counsellors.

Of 341 clients who tested HIV-positive, 205 participated in the programme. The 205 HIV-positive clients identified 580 partners/contacts, of whom 331 (57%) returned for HIV testing; 116 (35%) were found to be HIV positive. Among the HIV-positive partners/contacts, 104 (90%) were adults, while 12 (10%) were children. A total of 91% of the HIV-positive contacts were enrolled in HIV care. No social harm was reported.

Partner notification results

	Male	Female	Children	Total
HIV-positive clients	74	131	0	205
Partners/family identified	194	150	236	580
Partners/family tested for HIV	113	92	126	331
Partners/family HIV-positive	48 (42%)	56 (61%)	12 (10%)	116 (35%)

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.

Source: Annex 21.

Box 3.7. Existing recommendations for TB contact investigation

In settings of high HIV prevalence it is recommended that all household and close contacts [of TB patients] be counselled and tested for HIV (*strong recommendation, very low quality evidence*).

It is recommended that all household contacts of an index [TB] case who is a person living with HIV should be counselled and tested for HIV (*strong recommendation, very low quality evidence*).

It is recommended that all household and close contacts of people with TB who have symptoms compatible with active TB should receive counselling and testing for HIV as part of their clinical evaluation (*strong recommendation, very low quality evidence*).

Source: WHO, 2012 *(120)*.

3.3.4 Documentation, monitoring and reporting systems

All documentation, monitoring and reporting systems must ensure the security and confidentiality of HTS client data as well as the personal and medical information of partners. Data collected to monitor partner notification services should include information on:

- Number and percentage of HIV-positive persons who are offered assisted partner notification services
- Number and percentage of HIV-positive persons who accept assisted partner notification services
- Number of partners identified per HIV-positive client
- Number and percentage of identified partners who were notified
- Number and percentage of partners who accept HTS
- Number and percentage of partners who test HIV-positive
- Number and percentage of HIV-positive partners enrolled in care and treatment
- Number and type of adverse events occurring to HIV-positive clients following partner notification

Approaches to implementing partner notification should be routinely monitored and periodically evaluated to determine their impact. These assessments should be used to inform programmatic decisions about whether to continue certain approaches, which specific approaches are being used for different population groups, and the appropriate level of resources needed to balance total programme costs and cost-effectiveness.

Further reading

- Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2015 (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/).
- Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/guidelines/keypopulations/en/).
- Responding to intimate partner violence and sexual violence against women. Geneva: World Health Organization; 2013 (http://www.who.int/reproductivehealth/publications/violence/9789241548595/en/).
- Guidance on couples HIV testing and counselling – including antiretroviral therapy for treatment and prevention in serodiscordant couples: recommendations for a public health approach. Geneva: World Health Organization; 2012 (http://www.who.int/hiv/pub/guidelines/9789241501972/en/).
- Recommendations for investigating contacts of persons with infectious tuberculosis in low- and middle-income countries. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/77741/1/9789241504492_eng.pdf).
- HIV and adolescents: guidance for HIV testing and counselling and care for adolescents living with HIV. Geneva: World Health Organization; 2013 (http://www.who.int/hiv/pub/guidelines/adolescents/en/).

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Chapter 3

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