MINISTRY OF HEALTH

HIV Self-Testing & Assisted Partner Notification Services

A guidance document for the delivery of HIV Self-Testing and Assisted Partner Notification Services in Kenya

National AIDS and STI Control Program

BE SELF SURE
THE HIV *SELF-TESTING*

Republic of Kenya

HIV SELF-TESTING & ASSISTED PARTNER NOTIFICATION SERVICES

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NATIONAL AIDS & STI CONTROL PROGRAM

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Foreword

HIV self-testing (HIVST) provides an opportunity to those currently unreached by existing HIV testing and counseling services to test themselves and know their HIV status. Knowledge of one's HIV status has wide-reaching benefits, including increasing awareness of HIV prevention methods and treatment availability; and support positive behavior change such as consistent condom-use. All of these will bolster the efforts of on-going activities aimed at reducing new HIV infections by 75% by 2020 and achieve Vision 2030 through universal access to comprehensive HIV prevention and treatment services.

Kenya is a recognized leader in the global community as one of the first countries to endorse HIVST as strategy to expand access to HIV testing. Over twenty studies were conducted in Kenya between 2010 and 2017, which contributed to the growing body of knowledge supporting the roll-out of HIVST. In 2017, NASCOP with key stakeholders including the private sector conducted a pharmacy-centered pilot dubbed "Be Self Sure" to generate demand and best practices to guide implementation of HIVST in the private sector.

Assisted partner notification services (aPNS) for index clients with HIV infection involves elicitation of information about sexual partners, needle sharing partners and contacting them to ensure that they test for HIV and are linked to care. NASCOP aims to implement aPNS to improve identification of people living with HIV in Kenya

The development of this operational manual was necessitated by the need to provide guidance on the innovative approaches, procedures and standards required in the implementation of HIV self-testing. Target beneficiaries of this manual are HTS providers in both private and public sectors, implementing partners, researchers and any other healthcare workers providing HIV services within the community and clinical setting. It is my hope that this operational manual provides guidance to the country in achieving the gaps in the first 90 as the country moves toward universal access to HIV services and in attaining Kenya's blueprint vision 2030 of ending the HIV epidemic.

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Dr. Kigen Bartilol
HEAD NASCOP

Executive Summary

HIV self-testing (HIVST) is a process whereby an individual conducts his or her own HIV test using a simple oral-fluid or blood-based test. HIVST has shown to be a potentially high impact, low cost intervention to reach population groups that are not testing, and to increase the number of people living with HIV identified and initiated on treatment. HIVST also provides an opportunity to provide linkage to HIV prevention services for those who test negative.

In 2016, WHO released the Guidelines on HIV self-testing and partner notification that recommended the use of HIV self-testing as an additional tool for use in the expansion of HIV Testing Services (HTS). This operational manual is based on the WHO guidance, research and implementation projects conducted in the country. It is guided by the principles of HIV testing services as outlined in the National HTS guidelines 2015 (re-print) and the Guidelines for Use of Antiretroviral Drugs for Treating and Preventing HIV Infections in Kenya (2018).

This operational manual permits the dispensing of HIV self-tests in both public and private sectors; through facility, community health workers, pharmacies and other innovative service delivery channels such as vending machines. It also details the delivery of HIVST through two distinct approaches: assisted by a health provider or independent of a health provider (unassisted).

In the public sector, HIV self-test kits will be distributed to sexual partners of all clients presenting at antenatal care, postnatal care, Tuberculosis/Sexually Transmitted Infection (TB/STI) and Family Planning (FP) clinics and comprehensive care clinic (CCC) among other entry points. HIVST is also recommended as a strategy to target men, key populations and young people (aged 15-24). However, special consideration should be given to adolescents (aged 15 to 17) who must conduct a self-test with the assistance of a qualified health provider. Within the private sector, self-tests will be availed through workplace programs and sold through retail pharmacies.

All health providers dispensing HIV self-tests are required to be familiar with the referral and linkage mechanisms available for a self-tester. The key messages on self-testing for demand generation have been included to guide the public promotion of self-testing.

Guidance on the quality standards, strategy to adopt and roll out aPNS and biosafety recommendations that all HIV self-tests that must adhere to is also provided.

Partner notification services is an approach commonly used in the control of infection diseases. For HIV, several studies conducted in SSA countries including Kenya, Cameroon, Mozambique and Malawi have demonstrated the effectiveness, safety from social harms and cost-effectiveness of HTS to the sexual partners of individuals diagnosed with HIV (6–11). According to a major study in Kenya, aPNS increased uptake of HTS and helped identify undiagnosed infection with yield ranging from 35% - 62% with no serious reports of IPV (Cherutich et al 2017).

In the Kenyan study, the proportion of new HIV diagnosis among sexual partners of HIV infected individuals was up to 35 percent and immediate assisted partner services showed 4 to 5-fold increase in HIV testing, HIV case-finding and linkage of HIV- positive partners to care among recipients of aPNS, with a 15-fold increase in first time HIV testers in the aPNS intervention arm (10). One would need to interview only four index clients in Kenya to identify one HIV-infected sexual partner making it one of the most effective HTS strategies. Barriers to aPNS at the community and facility level included lack of trust in the healthcare workers, legal barriers, security risks for the healthcare workers, cost and logistical implication, low uptake of aPNS by the health care workers and lack of understanding of aPNS as a strategy (12).

aPNS has also been piloted in HIV program settings by LVCT Health. HTS providers at two informal settlements of Mlolongo and Kawangware in Nairobi from December 2015 to May 2016 used contract referral- to change the term to mutual agreement 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 (program data, unpublished) as well as PrEP. Of 341 clients who tested HIV-positive, 205 participated in the program and 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. During the implementation of the pilot study 2013- 2015, no intimate partner violence (IPV) cases were attributed to the intervention.

Definition of Terms

Assisted Partner Notification Services: Assisted partner notification services (aPNS) refers to a voluntary process where consenting HIV positive clients are assisted by a trained provider to elicit their sexual and/or drug injecting partners and notify them of their potential exposure to HIV infection with an aim of offering them HTS

Data protection safeguards -Institutional safeguards put in place to ensure that any information, contacts and addresses provided by the index client are kept private and confidential. It is the duty of each health care provider to strictly ensure all databases adhere and comply with health system information safeguards against function creep. Health service providers should ensure that information on one's health status held is subject to strict rules of data protection and confidentiality, and must be protected from unauthorized collection, use or disclosure.

Directly assisted HIV self-testing: Refers to when individuals who are performing a self-test 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.

Distributor: An agent who supplies HIVST kits to stores and other businesses that sell to consumers e.g. wholesale.

Mutual 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).

Elicitation of partners: This refers to the listing of all sexual and/or drug injecting partner(s) of an index client.

Emancipated minor: A person who is not legally an adult (18 years and above) but who because he or she is married, is a mother/ father of a child or otherwise no longer dependent on the parents, may not require parental permission for medical or surgical care.

HIV self-testing: (HIVST): this is a process whereby an individual collects his or her specimen, performs a test and interprets the results, often in a private setting either alone or with someone he or she trusts. HIVST can either be directly assisted or non-assisted.

HIV Testing Services (HTS): indicate the full range of services that a client is offered together with HIV testing. This includes counseling (pre- and post-testing); linkage to appropriate HIV prevention, care and treatment services and other clinical support services. Coordination with laboratory services to support quality assurance and delivery of correct results is necessary.

Index client: An individual newly diagnosed as HIV-positive and/or an HIV-positive individual who may or may not be enrolled in HIV treatment services i**ncluding adolescents and young people.**

Index testing: voluntary process where Health care provider asks index clients to list all of their: (1) sexual (2) injecting drug partners within the past year, and/or (3) children and offer them HTS.

Informed Consent: As defined in section 2 of HIV/AIDs Prevention and Control Act.

Key Populations: Groups who, due to specific higher-risk behavior, are at an increased risk of contracting HIV, irrespective of the epidemic type or local context. Legal, cultural and social barriers related to their behavior or identity increase their vulnerability to HIV. In Kenya these populations include: men who have sex with men (MSM); people who inject drugs (PWID) and sex workers (SW).

Mutual Agreement Referral: HIV-positive clients enter into a mutual agreement with a trained provider and voluntarily offer 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.

Non-reactive results: It means that the test indicates that HIV antibodies were not found in the blood or oral fluid sample. Anyone whose result is nonreactive to a rapid HIV test (including a self-test) does not need further testing but should be supported to re-test if they have had a recent potential HIV exposure or are at on-going HIV risk.

Partner Notification: 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.

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

Provider Referral: With the informed consent of the HIV-positive client, a trained provider confidentially contacts the person's partner(s) directly and offers the partner(s) voluntary HTS. For purposes of these Guidelines, a provider refers to a health care worker including a medical doctor, pharmacist, pharmaceutical technologist, nurse, clinical officer, a laboratory technician or technologist or a counsellor who has completed the relevant training as approved by the Minister responsible for matters for Health and as defined by Section 2 of the HAPCA.

Reactive Results: It means that the test indicates that HIV antibodies are present in the blood or oral fluid sample. Anyone whose result is reactive to a rapid HIV test (including a self-test) need to undertake additional HIV testing services done by a trained provider following the national HIV testing algorithm.

Service Provider: In the context of HIVST is an organization, business or individual which offers service to others either for free or on payment of a fee.

Sexual Partners: Individuals who have any form of sex, whether vaginal, anal, oral sex with the index client. These include casual and steady sexual partners.

Unassisted HIV self-testing: Refers to an individual obtaining a kit for HIV self-testing and performing the HIV test following the instructions in the insert provided by the manufacturer.

Vendor: In the context of HIVST is an outlet which sells directly to the consumer e.g. chemists.

Abbreviations

aPNS	Assisted Partner Notification Services
ART	Antiretroviral therapy
CCC	Comprehensive Care Clinic
CHV	Community Health Volunteers
CIST	Client Initiated Self-Testing
DHIS	District Health Information System
DICE	Drop in center
HCMP	Health Commodity Management Platform
HCW	Health Care Worker
HCV	Health Care Volunteer
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HTS	HIV Testing Services
KAIS	Kenya AIDS Indicator Survey
KASF	Kenya AIDS Strategic Framework
KDHS	Kenya Demographic Health Survey
MOH	Ministry of Health
MSM	Men who have sex with men
NASCOP	National AIDS and STI Control Programme
NGO	Non –Governmental Organizations
PEP	Post Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Child Transmission
PITC	Provider Initiated Testing and Counselling
PWID	Persons who inject drugs
RDTs	Rapid Diagnostic Tests
SDP	Service Delivery Points
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infections
SW	Sex workers
TB	Tuberculosis
UNAIDS	The Joint United Nations Programme on HIV and AIDS
VCT	Voluntary Counselling Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

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Chapter One: Introduction

1.1 Background

Globally, 36.7 million people are estimated to be living with HIV in 2015 (UNAIDS, 2016). Kenya continues to scale up HIV prevention, care, treatment and support services, making good progress in reducing the number of new HIV infections and reducing AIDS related mortality over the years. Over 1.4 million adults and 98,000 children are estimated to be HIV infected in Kenya.

The Kenya AIDS Strategic Framework (KASF) 2014/15-2018/19 sets ambitious targets for HIV prevention, care and treatment to be achieved by 2019. KASF aims to reduce new infections by 75% and AIDS related mortality by 25% by 2019. Further, Kenya has adopted the ambitious United Nations 90-90-90 global targets with the expected results of ensuring that 90% of people living with HIV know their status, 90% of people diagnosed are put on antiretroviral drugs, and 90% of those on ARVs achieve viral suppression by 2020. HIV self-testing (HIVST) is an empowering and innovative way to help achieve the first of the United Nations 90–90–90 treatment targets) – for 90% of all people with HIV to know their status by 2020.

The Kenya Demographic Health Survey (KDHS, 2014) indicates that 83% of women and 71% of men aged 15-49 years have ever tested for HIV. However, only 53% of HIV infected individuals have correct knowledge of their HIV status (KAIS 2012). In order to meet these ambitious targets and increase individuals' knowledge of their HIV status, the Ministry of Health launched updated HIV Testing Services (HTS) Guidelines (NASCOP 2015).

These guidelines emphasize accelerated identification of HIV infected persons and outline testing strategies, specific populations and service delivery points for targeted HIV testing. One of the innovative strategies to promote knowledge of individuals' HIV status is self-testing (HIVST).

1.2 HIV Self Testing

HIVST has been reported to be less costly than provider-based screening in resource-limited settings (Linas, 2015) and can address gaps in achieving first 90. It is thus likely that HIVST will enhance health system efficiency by focusing health services and resources on people with a reactive self-test result who need further testing, support and referral. In addition, by reducing the number of facility visits for frequent non-reactive testers and eliminating the need for individuals to travel distances or wait in long queues to access HIV testing, HIVST may also be more convenient for users.

While available evidence suggests that there is no significant harm associated with HIVST, public health programmes should be sensitive to the risks associated with disclosure and coercion to forceful testing. 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. An emergency helpline has been put in place for testing support and referral to additional support systems (refer to Chapter 4: Referral and Linkages).

1.3 Rationale and objectives of the HIVST Operational Manual

The HIVST operational manual has been written in line with the National HTS guidelines 2015 (re-print) and the national Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya-2018 edition. Both provide the framework within which HIVST can be implemented safely, effectively and accurately. This document considers the basic rights of individuals and families; the legal and ethical considerations are informed by the following legislative documents shown in figure 1.

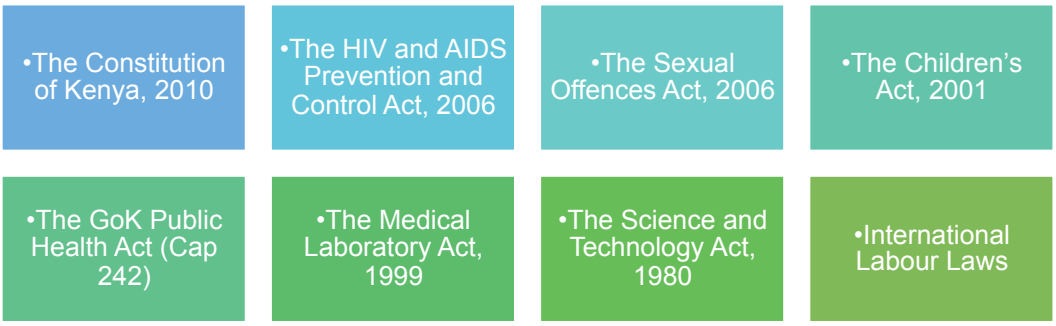

Figure 1: Documents considered for basic rights of individuals

The specific objectives of this guideline are to:

1. Outline programmatic approaches to HIVST
2. Describe the package of support services required for HIVST
3. Describe commodity management systems required for HIVST
4. Outline the coordination mechanisms for HIVST
5. Outline the referral and linkage mechanisms for HIVST
6. Outline quality assurance strategies for HIVST
7. Describe the monitoring and evaluation plans for HIVST

1.4 HIVST Providers

HIVST should only be dispensed by trained health care providers. These include;

- Health program managers and officers in health programmes
- Clinicians and nurses
- HTS trained personnel
- Trained Community Health Workers and Volunteers
- Trained Peer educators especially those supporting key populations
- Pharmacists

1.5 Target Population for HIVST

The target population for HIVST is guided by the country HIV prevalence and incidence rates to expand access to testing to those unreached by routine HTS (NASCOP program data 2017). This will complement already existing HTS strategies. The primary objective of HIVST is to expand access to HTS particularly for those that are currently unreached by the routine HTS program. Men, young people and key populations are among the population groups who may benefit most from HIVST. (Refer to Chapter 3 for further information on target populations).

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Chapter Two: Approaches for HIV Self Testing

This section outlines the various HIVST Service delivery approaches and channels. It highlights:

- Approaches for delivering HIVST services such as, directly assisted and unassisted methods and the level and type of support provided
- Various public and private sector channels through which HIV self-test kits can be distributed

2.1 HIVST Delivery Approaches

HIVST can be delivered through two distinct approaches to reach different target populations. The approaches vary in terms of the level and type of support provided. These are:

1. Directly assisted HIV self-testing
2. Unassisted HIV self-testing

Directly-assisted HIVST:

- Refers to trained providers, peer educators or community health workers giving an individual an in-person demonstration before or during HIVST on how to perform the test and interpret the test result. This approach can be used to support self-testers with disabilities, low literacy levels, and individuals who may require or request direct assistance in the form of in-person demonstrations and explanations before, during and/or after testing. This is especially recommended for self-testers aged 15 to 17 who will require additional support and counselling.

Unassisted HIVST

- refers to when an individual self-test for HIV and uses an HIVST kit with instructions for use provided by the manufacturer without the help of a trained provider or peer.

Figure 2: Approaches to HIVST

Both directly assisted and unassisted HIVST may include additional tools such as telephone helplines, mobile phone text messages, videos, social media and internet-based applications which provide technical support, counselling and referrals for further HIV testing, prevention, care treatment and support service.

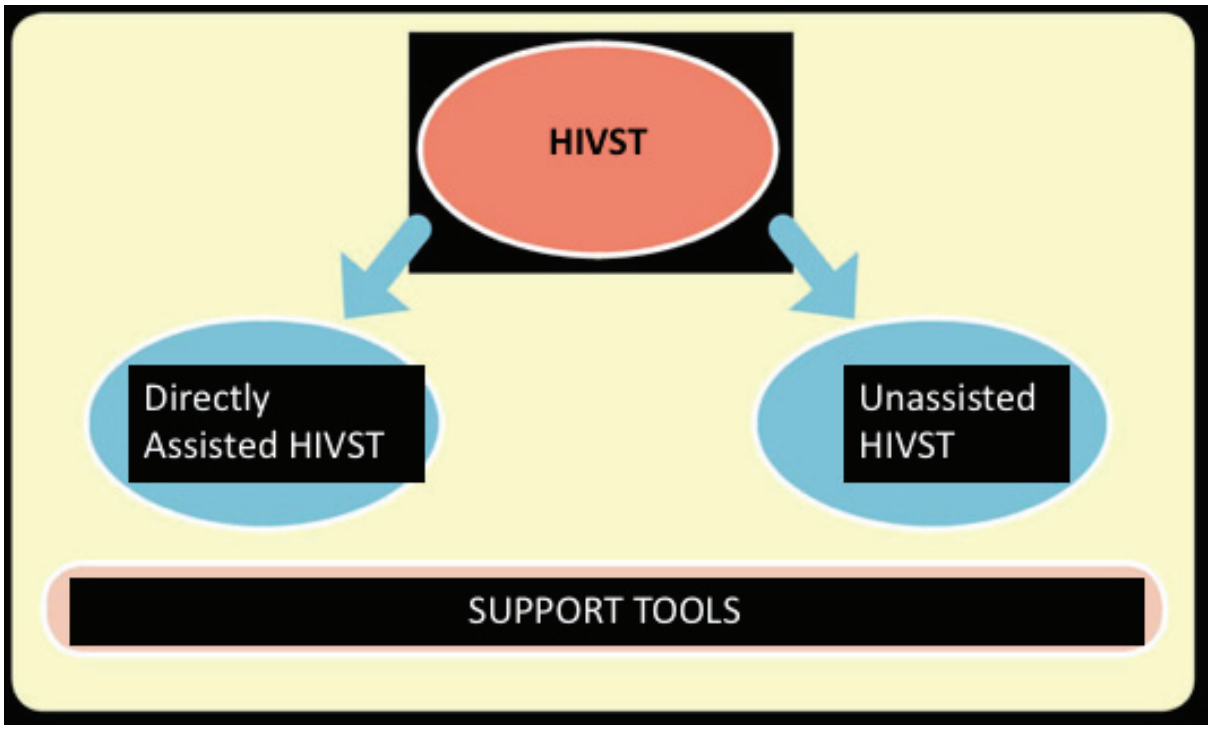

Figure 3: Approaches to HIVST

Table 1: HIVST Approaches and support tools

Support Tools	Assisted HIV	Unassisted HIV
Brief in-person one-on-one group demonstrations on how to correctly use the kit and how to interpret results	□	
Manufacturer's instructions for use: □ Pictorial/written □ Brochures or flyers that include information on local HIV services and contact details, for example, health clinic, 24hr hotline □ Online instructions	□	□
Internet-based, virtual or social media demonstrations on how to correctly use the kit and how to interpret the results	□	□
Remote support via telephone, social media, text message, QR code, Internet-based or mobile messaging applications	□	□

2.2 HIVST Service Delivery Channels

The selection of HIVST service delivery channels is dependent on the context, setting and target population. The channels used should complement other existing HIV testing strategies such as Provider Initiation Testing and Counselling (PITC), Voluntary Testing and

Counselling (VCT) and address any gaps in HIV testing coverage. The channels can be facility based, community based or through other conduits such as vending machines, the internet or other public and private sector channels. These are shown in Figure 2: HIVST service delivery channels.

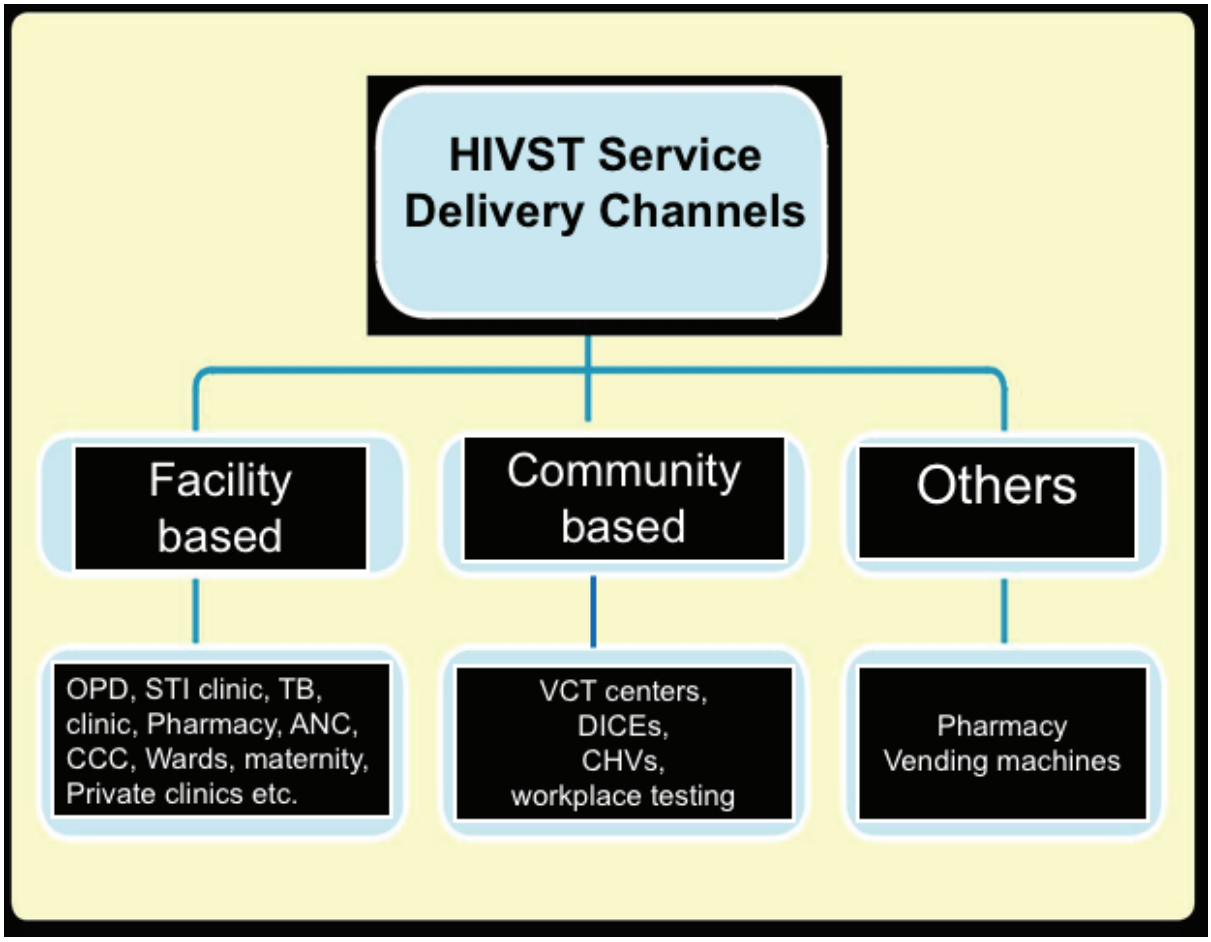

Figure 4: HIVST service delivery channels

Note: The vending machines should be placed in institutions that have the mechanisms to offer support to clients. Refer to 1.4

Facility based channels: Self-testing can be accessed at both public and private health facilities. All clients seeking health services can be offered an opportunity to self-test for HIV while waiting for other services or be provided with a self-test kit to take home for use on themselves or distribution to a sexual partner. Self-testing is complementary to the existing approaches for HIV testing.

Community based channels: HIVST can be offered to community members and targeted populations such as key populations, youth and adolescents through existing community-based structures such as VCT centres, Community Health Volunteers (CHVs), home based HTS, Drop-In Centres (DICEs) and during outreach services.

Other channels: Alternative HIVST service delivery approaches include provision of HIVST services through:

- Couples and Partners testing e.g. providing women in antenatal or postpartum care and sex workers at DICEs with HIVST kits to issue to their male sexual partner(s) and social networks.
- Outreach services through integration with other models across existing HIV, MNCH and public health programmes such as the VMMC programmes,
- programmes targeting TB, STI and viral Hepatitis patients and those providing contraceptive services.
- Public-private sector channels such as pharmacies or drug stores and voucher programmes
- Sale or distribution at institutions of higher learning, youth recreation centres and youth focused events, which is pursued by the national stakeholder in regards to implementation

HIVST kits will be availed for public health programmes as well as for general public consumption through the channels shown in figure 1. For programmatic utilization, HIV self-tests will be distributed through the existing HTS programme both at facility and community levels. At community level, self-test kits will be delivered through existing community programmes for health programmes and general public use. The general public will access self-tests through all other outlined channels.

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Chapter Three: HIV Self Testing Service Delivery Packages

This section covers the components of a HIVST service package and provides guidance on:

- The guiding principles of HIV testing
- The standard operating procedures for the dispensing of HIV self-test kits to the public
- The package of information to accompany HIV self-test kits
- Information on assisted partner notification services (aPNS)

3.1 Guiding Principles of HIV Self-Testing

All forms of HTS, including HIVST, regardless of approach, are guided by core principles (5 Cs) i.e. Consent, Confidentiality, Counselling, Correct results and Connection- linkage to care and other appropriate post-test services. All HTS, including HIVST, must always be voluntary, and informed consent for testing must be obtained before the test. The five core principles of HTS apply and should be underscored in HIVST with additional emphasis as highlighted below:

THE 5CS

i. Consent**-** Informed consent is important for persons who wish to undertake an HIV test. Clients for HIVST should be well informed and should voluntarily do the test without any form of coercion. For assisted HIVST, verbal consent is sufficient.

ii. Confidentiality**-** HIVST enables people to screen themselves for HIV in the privacy of their preferred space, hence there is no fear of breach of confidentiality. In instances of assisted HIVST, confidentiality should be maintained by the person assisting the

self-tester. Shared confidentiality with partner, relevant others and health care providers should be encouraged to clients with reactive test results for further assistance and support.

iii. Counseling- Everyone who wishes to carry out HIVST is entitled to adequate information before and after the test. Clients should utilize information provided in the test kit inserts. Information can be provided by HTS providers one on one, test kits dispensing points, phone helpline, and computer-based applications such as online two-way text, brochures and flyers, audio or video counseling services and YouTube videos.

iv. Correct results- Adequate and clear instructions with graphic illustrations on how to conduct self-testing should be provided with the test kits to ensure a person obtains the correct results. Self-testers should follow the manufacturer's instructions in the test kits insert to conduct a self-test. Specific quality assurance measures should be in place to ensure correct test result.

v. Connection- All clients seeking HIVST should be advised on available linkage and referrals for HIV post-test services based on outcome of the test and other needs. Those with HIV negative results but with recent exposure or with an ongoing risk should be encouraged to seek further advice from a health provider. It is recommended that individuals whose self-test results are reactive seek further HIV testing services from a qualified service provider using the national algorithm. All inserts should clearly display information on this requirement. A catalogues of health facilities can be accessed through the NASCOP website.

3.2 Standards and Procedure for HIV Self-Testing

All HIV self-tests distributed and dispensed to the public must have undergone validation and approval by the national regulatory body (see Chapter 6).

Individuals with non-reactive self-test results should be advised to re-test as per their risk to HIV infection as outlined in the national HTS guideline re-testing recommendations (see Appendix 1). If the HIVST result is reactive, the individual should be advised to seek further testing from a trained HTS provider, where the approved national HIV testing algorithm will be utilized to conduct the HIV test, as shown in figure 5.

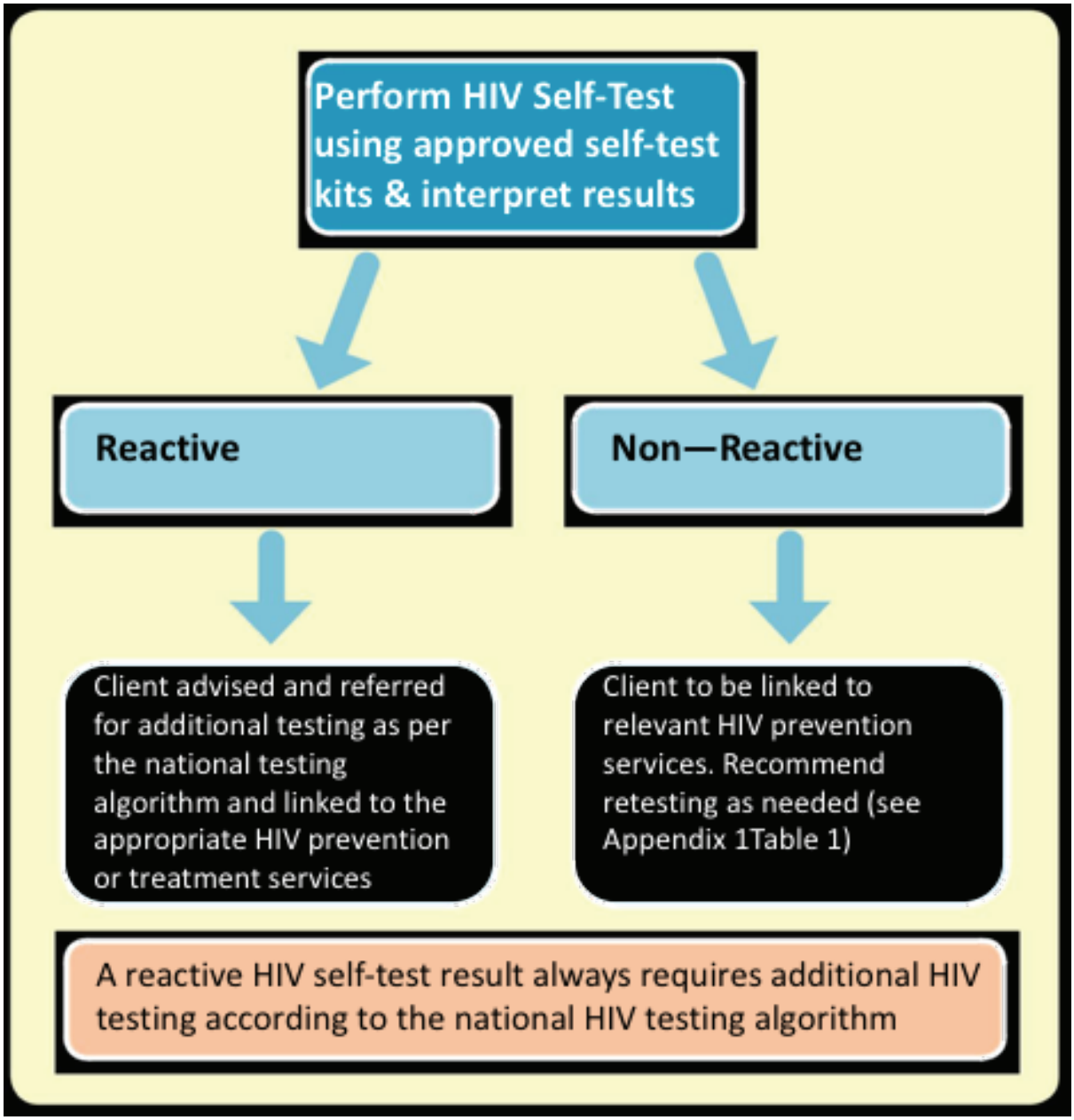

Figure 5: HIVST Flow chart

HIV self-tests will be dispensed through three main service delivery channels. (Refer to Chapter 2). Table 2 below shows the recommended dispensing procedure according to population, entry point and service delivery channel.

Table 2: Recommended Distribution Criteria for HIVST

Channel	Population and/ Or Entry Point	Recommended Dispensary Criteria
Facility	Sexual Partners of ANC/PNC/L&D clients	Provide a self-test kit to all women (who should themselves undergo routine testing, or will have been previously tested through routine health-provider based testing**) and where their: • sexual partner status is unknown • risk of IPV has been assessed and is low. **Refer to PMTCT, ART and HTS guidelines for further information
	Sexual/drug injecting Partners of Key Populations (MSM, FSW, PWIDs)	Provide a self-test kit to all KPs. Dispensing should be through DICES including use of the existing peer educator model
	Sexual Partner of Index Client found at all entry points	Issue HIVST kits to all clients testing HIV positive to give to their sexual partners, if risk of IPV has been assessed and is low
	Adolescents (aged 15-17), for those 18+ see above	Assisted self-testing (see additional guidance below)
Community	Men	Distribution through outreaches to all men who request for a self-testing and to all women for their sexual partners
	General population (e.g. workplace testing)	Provide a self-test to all persons who wish to test for themselves and for distribution to their sexual partners
Other: Pharmacies	General population except adolescents (age 15-17)	For sale to all those who require a test

Table 3 shows the recommended dispensing procedure for clients wishing to conduct an HIV self-test for either directly assisted or unassisted HIVST.

Table 3: Dispensing Procedure for HIVST

	Approach	
	Directly Assisted HIV ST	Unassisted HIV ST
Indications	• Can be carried out in all settings (facility based, community based and other e.g. pharmacies) • Suitable for all population groups	• Suitable for community based and other non-traditional testing channels e.g. pharmacies, vending machines • Suitable for all other population groups except adolescents aged 15-17 (see additional guidance on adolescent HIVST)
Procedure	Step 1) Provide client information package and pre-test counselling	Step 1) Provide client information package (FAQs, website and helpline details)
	Step 2) Provide a demonstration of the kit and/or explain instructions for use as provided in the test kit packet	Step 2) Dispense the kit
	Step 3) Allow the client to collect his/her own sample and conduct the test with guidance from the health provider	
	Step 4) Interpret the result of the test together with the client after the specified time	
	Step 5) Provide post-test counselling and information on where additional services can be sought (see Chapter 4: Linkage and referral)	

3.3 Additional Guidance o-n Adolescent HIVST

An adolescent is an individual aged between 10- 19 years. In Kenya, as relates to HTS, adolescents aged 15 years and above can undergo a HIV test without consent from a parent or guardian, as indicated in the revised national ART guidelines (2018). Any adolescent (aged 15-17) who wishes to self-test can do so; however, the test must be conducted with the support of a qualified HTS provider. Pharmacists must ask for a national identification document if in any doubt of the age of the customer. In addition, parents and guardians of adolescents and children should be made aware that HIVST is for those aged 15 years and above and only the specified trained personnel can supervise a self-test on an adolescent. In the event that an adolescent below 18 years inadvertently conducts the HIVST, or a third party conducts the self-test on the minor, the adolescent should immediately be referred to a health facility for additional services.

Strategies to promote HIV testing among adolescents and young people

The transition between childhood and adulthood is a critical and sensitive period for an individual. Sexual exploration is common in this age group and as a result, many in this age group are vulnerable to risky behavior and are ill-equipped with correct information regarding HIV. A large proportion of those currently unreached through conventional testing strategies are adolescents and young people (15-24).

Targeting this age group with HIVST requires an innovative approach that is cognizant of the changing cultural norms and behaviors of individuals in this age group. Majority of people in this age group will be found in schools, institutions of higher learning and vocational centers. A smaller proportion may be married, or orphaned and/or assuming care of younger siblings. Others may be employed, self-employed or not engaged in any vocation or activities.

It is recommended that a variety of social media platforms and radio messages are used to sensitize and educate adolescents on HIVST. For those adolescents not able to access social media, ‘talking walls’ (spaces where messages written anonymously and posted in public) in the community, schools and other places where adolescents frequent can be used to pass the message. The messages can also be printed out in brochures that can be distributed to parents/guardians and to young people.

Assisted self-testing may be offered through outreaches, VCT centres, in outpatient and family planning clinics. Facilities and public health programs can create adolescent and youth days where assisted HIV self-testing can be offered in addition to other services. Additionally, as social networks are influential in this age group, peer-to-peer referrals can also provide an effective channel with which to reach them.

The Home, Education, Eating Activities, Drugs and Alcohol, Suicide and Depression, Sexuality and Safety (HEEADSS) assessment looks at different parameters of an adolescent to ensure optimal wellness. The tool is used to understand adolescent behavior and assess risk-taking behavior to provide appropriate interventions. It is recommended that public health programs focusing on HIV testing (including HIVST) among adolescents and young people adopt the tool to understand and support the mental and emotional health this age group.

See Appendix 2 for the HEEADSS assessment tool.

3.4 The HIVST Information Package

To ensure an individual is prepared to competently and correctly conduct a HIV self-test, various client education materials may be used to provide counselling, information on testing and linkage to other health services. Table 4 below outline the available materials for those conducting a self-test

Table 4: Client Education Materials

Client Education Material	Purpose	Where it can be found
Instructions for use (IFUs)	Provides information on the test and a step-by-step list of instructions on how to conduct and interpret the test	Included in the kit packaging
Frequently Asked Questions (FAQ) brochure	Provides responses to a list of commonly asked questions	• Pharmacy counters and clinic receptions • Attached to the kits being distributed (public sector) • HIVST Mobile App ('Be Self Sure' on Google Playstore)
Instructional videos	A visual step-by-step demonstration of how a self-test is conducted and interpreted	• Online (www.besure.co.ke) • Video sharing websites e.g. YouTube • Manufacturer websites • HIVST Mobile App ('Be Sure' on Google Playstore)
Posters, banners, leaflets/handouts	Provides a summary of self-testing and where more information can be found	• Pharmacies • Health Facilities

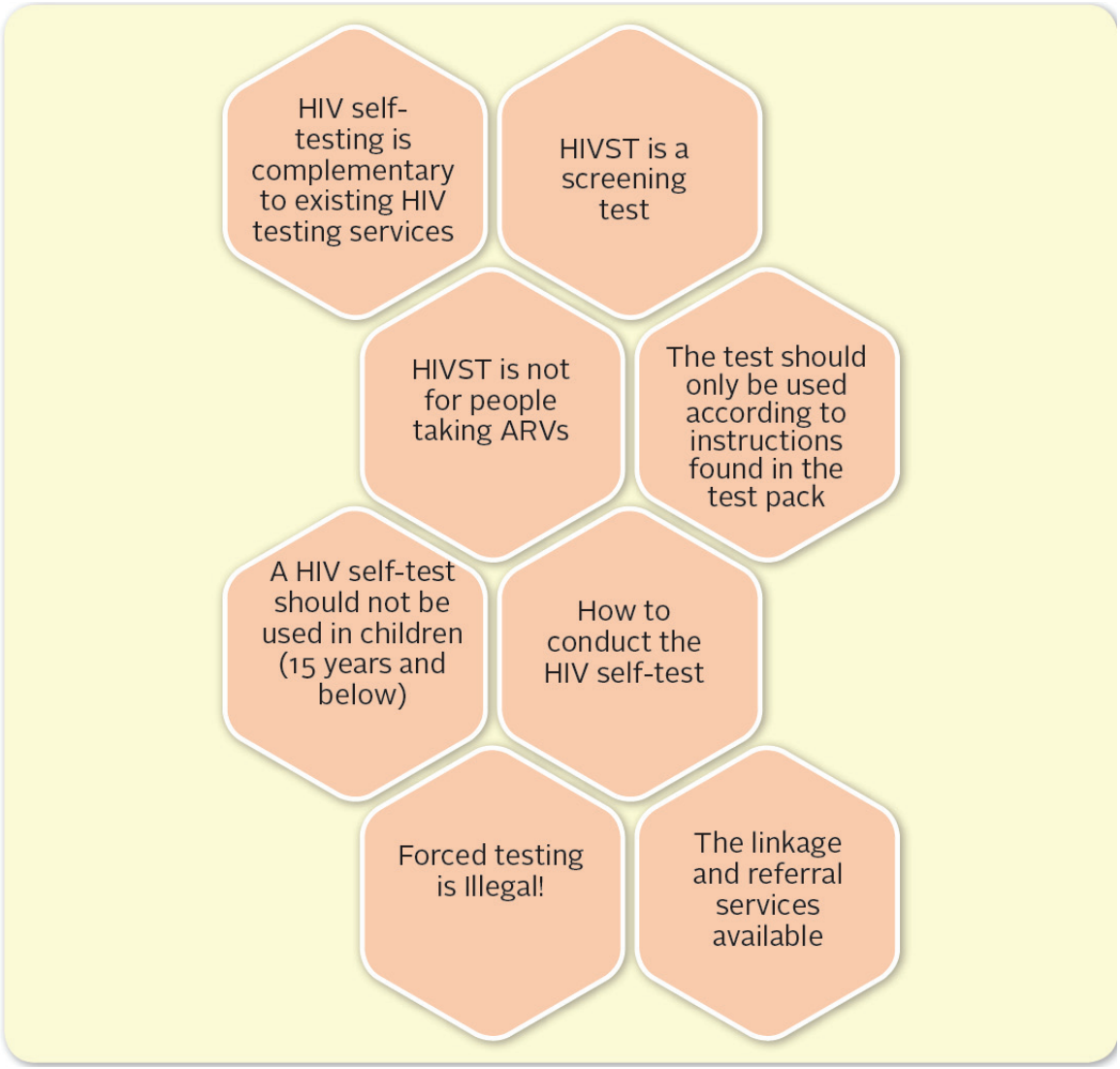

Figure 6: Client IEC Material

To ensure correct and accurate information on HIV self-testing is disseminated, key messages can be relayed to clients through public messaging and relayed through the health provider at the point of dispensing the kits.

Key Messages

1. HIVST is complementary to existing HIV testing services
2. HIVST is a screening test. Should the test be reactive, they should go for further testing in a health facility. If the test is non-reactive and they were exposed to HIV less than 3 months ago, they will need to test again after 4 weeks and annually or as per need thereafter, and continue using other prevention methods such as condoms.
3. The client should receive general instructions on:
   a. How to use the test kit (refer to the instructions for use in the test pack)

b. How to handle and store the test kits
c. How to interpret the test results
d. Safe disposal of the used test-kits

4. Linkage and support – the client should be informed on where to seek further testing if positive and for additional services (refer to Chapter 4: referral and linkage)
5. Ethical and legal obligations – the client should be informed that:
   a. HIVST should not be used on another person without obtaining their consent
   b. HIVST kits should not be dispensed to children under 15yrs
6. The following people should use a HIVST under supervision of an HCW
   a. Adolescents 15 – 17 years
   b. People with disabilities (mental disability, blind etc.)
   c. People who are unable to read
7. HIVST is not recommended for people who are already on HIV treatment
8. HIVST should only be used according to the manufacturer instructions

3.5 HIV Self-Testing Promotion and Communication

To create awareness and increase utilization of HIVST, advocacy and communication strategies should aim to emphasize on correct usage and interpretation of self-test results. Table 5 outlines the various communication strategies that may be used to create awareness and generate demand for HIV testing, prevention and treatment services.

Table 5: Communication Objectives and Strategies for HIVST

Target Group	Objective and Communication Strategy
Healthcare Providers	Objectives: • To sensitize healthcare providers on HIVST as an additional tool of increasing access to HTS. • To promote integration of HIVST into existing HIV prevention and treatment programmes e.g. PMTCT, PrEP/PEP, VMMC, KP programmes and other routine health services e.g. FP clinics, TB/STI clinics
	Communication strategy: • Guideline dissemination • Continuous Medical Education sessions (CMEs) • On the Job Training (OJTs) • Dissemination of Information Education Communication (IEC) materials, etc.
General Population	Objectives: • To increase awareness of HIVST as a testing option • To promote the need to know one's HIV status • To increase awareness of the various HIV prevention options and treatment availability
	Communication strategy: • Health talks in facilities and community spaces • Mass media campaigns • Billboards, posters, brochures and flyers • Digital and social media platforms internet adverts, WhatsApp, Facebook, Twitter, YouTube • Use of self-testing champions drawn from CHVs, peer educators, social network influencers and expert patients • Leverage on existing workplace wellness programmes to promote HIVST • Include messaging on HIVST through insurance providers

3.6 Partner Notification and Disclosure

Clients should be informed about the potential health benefits of disclosing their HIV status to their partners prior to receiving their self-testing kits. Clients with a reactive HIVST results should be encouraged to visit an HTS service point with their partners for further testing as per the national HTS testing algorithm and receive support for assisted partner notification services (aPNS). Clients whose test result is non-reactive (negative) should also be encouraged to disclose their status to their sexual partners and encourage their partners to know their HIV status through use of HIVST kits or a visit to an HTS delivery point.

Health providers should assess for the potential of social harm and/or violence following disclosure, such as intimate partner violence (IPV) (see Appendix 3 for the IPV tool) and provide guidance and referral as appropriate.

More information and guidance on aPNS are provided from chapter 9.

4

Chapter Four: Referral and Linkage

This chapter describes the different approaches for linkage to services prior to, during and after conducting an HIVST.

4.1 Linkage Approaches for HIVST

In line with the national HTS guidelines, appropriate, comprehensive and effective referral linkages to HIV treatment and prevention programs/ interventions should accompany HIVST.

All individuals intending to conduct an HIV self-test should be encouraged to share their test results with a trained health care provider, whether reactive or non-reactive, to facilitate referrals to appropriate post-test services.

Individuals whose self-test results are reactive must be advised and facilitated to access further HIV testing services with a qualified HTS service provider to determine their HIV status. A trained HTS provider should offer individuals who test HIV negative following a self-test an opportunity to undergo counseling. This is especially for purposes of assessing their HIV risk and linkage to prevention services. During risk reduction counselling, the individual should be assisted to assess their own risk of HIV infection and the need for additional health services.

Situations of risk may include recent, actual or potential exposure and ongoing exposure to HIV including:

- Unprotected sex with a person of known HIV positive status
- Unprotected sex with a person of unknown HIV status

- Rape
- High risk sex such as sex work, anal sex
- Drug users sharing needles

All individuals undertaking HIVST should also be referred for any other health services they may need, including psychosocial support, Sexual and Reproductive Health (SRH) services, VMMC, TB services and screening for non-communicable diseases among other services.

Information on referral services should be made available to all the individuals who undertake HIVST whenever needed through either physical or online systems. Table 6 below provides a list of potential linkage tools and how they may be used to facilitate and promote linkage to HIV services.

Table 6: Linkage Tools

Target Group	Objective and Communication Strategy
Referral Directory for HIV services	Available through the NASCOP website for those seeking accredited HIV prevention and treatment centres
Physical Escort	A healthcare worker, peer educator or community health volunteers can conduct escorts to the facility or testing center.
Community-based Follow Up	This is especially applicable where HIVST is offered at community level and follow up is conducted through telephone or SMS by trained community health care workers, peer and outreach workers.
Telephone helpline	Where trained counsellors offering counselling services can offer linkage to HTS and other services
Through public gathering (barazas)	Can be conducted by local administration and in market places where information on the availability of local HIV services can be provided
Mass media messages, posters, fliers etc.	Where information on the need to seek HIV prevention and treatment services are provided
Vouchers, coupons or rebates	Sold together with a self-test, these may be redeemable for additional health services and commodities e.g. condoms, family planning. Insurance schemes may also provide these to access discounted self-tests in pharmacies
Online Audio or Video Counselling Services	Can provide step-by-step instructions on what to do following a reactive self-test
Bulk mobile phone text message services	Can be used to provide information on HIV, reminders to test and messages promoting HIV prevention and treatment services
Opinion leaders and civil society groups	Can be used to engage their networks to create demand for HIVST, offer HIVST support and encourage linkage for re-testing, prevention and treatment services

For further assistance the following tools can be used:
- Helplines - 1190, 1195 (GBV), 0800 72 48 48
- Be Self Sure Mobile Application on Google Playstore
- Website - http://www.besure.co.ke
- National referral directory for HIV services

5

Chapter Five: Commodity Management

This section covers: commodity management, kit selection, quantification and procurement, test kit allocation and inventory management.

5.1 Commodity Management

This represents the set of practices that must be coordinated to ensure that appropriate, high quality supplies are available whenever and wherever they are needed. It entails proper coordination and management of commodities in order to ensure the six rights in supply chain, i.e. the right commodities in the right quantities, in the right condition delivered to the right place at the right time and for the right cost.

5.2 Kit Selection

The selection of the kits to be procured nationally will be guided by the HIVST selection criteria. (See Chapter 6). Only kits that have undergone in-country validations by Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) will be considered for public roll-out. The private sector must ensure that all kits distributed and retailed through pharmacies are the nationally approved HIV self-test kits.

5.3 Quantification and Procurement

In the public sector, quantification will be done through the annual national forecasting and quantification process. Procurement for the public sector will be done by the Kenya Medical Supplies Authority (KEMSA). Quantification within the private sector will be determined

according to the established need. As indicated above, private sector providers commercially procuring HIV self-test kits must procure only KMLTTB approved HIV self-test kits.

5.4 Allocation and Test Kits Distribution

The allocation and supply of HIV self-test kits for the public sector will be done according to the current commodity management system for the public sector (refer to The Public Procurement and Disposal Act, 2005) Kits will be allocated initially based on estimates and subsequently on consumption reports. Data on the number of test kits issued will be generated through the county reporting and allocation system. The allocation and distribution plan in the private sector will be based on the demand and will follow the established channels.

5.5 Inventory Management

The management of kits should be aligned to the existing inventory management system. This will include receipt of kits; storage according to the manufacturer's instructions and in adherence to the recommended storage guidelines; and distribution to service delivery points (SDPs). Standard Operating Procedures (SOPs) in inventory management and proper record keeping shall be ensured by use of the existing tools e.g. stock cards and reporting systems.

Expiry of commodities should be tracked to ensure First Expiry First Out (FEFO) or First in First Out (FIFO) is adhered to, to prevent commodity wastage and stock outs. Cost efficiency is achieved when commodity expiry is minimized. Expired test kits should be disposed in accordance to the Public Procurement and Disposal Act, 2005 while adhering to the Material Safety Data Sheet of the HIV self-test kit.

6

Chapter Six: Quality Assurance

This section aims to provide guidance on how to ensure the quality of kits and the testing procedure. This section also advises on the public health and environmental safety standards as applicable to HIVST.

6.1 Benefits of Quality Assurance in HIVST

Quality Assurance is a systematic planned approach for monitoring assessing and improving quality of goods and services on a continuous basis. Quality assurance is an integral part of all HIV testing services and should be implemented through simple and practical approaches at all levels. The primary objective of quality assurance in HIVST is to produce quality results that are legally defensible and of maximal benefit to the client.

The benefits of quality assurance in HIV self-testing are as follows:

- Ensures that the client gets accurate, reliable and prompt test results
- Assures the needs and expectations of clients and communities are met in terms of HIV testing.
- Illustrates how the HIVST process and supporting service delivery mechanisms will be improved.
- Ensures standardization that will facilitate access to quality services
- Assures the adequacy and competency of the health care worker/individual handling the test kit
- Ensures cost effectiveness in the service delivery
- Allows for the identification and correction of gaps in the HIVST process

6.2 Components of Quality Assurance for HIVST

WHO Prequalification

All test kits for national procurement MUST attain WHO pre-qualification

In-country laboratory validation

All test kits must undergo in-country laboratory validation by KMLLTB to ensure that they meet the minimum inclusion criteria.

Registration and listing by regulatory bodies

All HIVST kits must be listed by the Pharmacy and Poisons Board (PPB) and validated, certified and registered by KMLTTB as per legal notice 113 of 2011 before being dispatched into the market.

Lot to Lot validation

All procuring entities must ensure that any new lots of HIVST kits coming into the country are evaluated by KMLTTB to ensure that products delivered meet criteria for quality and performance.

Post-market surveillance

Post-market surveillance will be conducted periodically by KMLTTB to assess the quality and performance of the test kits in use, in compliance with the set standards.

6.3 Quality Assurance of the HIV Self-Testing Procedure

Capacity building and sensitization on HIVST

All HIVST service providers shall be sensitized according to the national sensitization package (can be accessed through NASCOP HTS Program). This includes capacity building and knowledge on how to conduct the self-tests. (Refer to Chapter 3).

Infection, prevention and control

While the risk of HIV transmission through HIV self-tests has been demonstrated to be minimal, clients shall be made aware of correct practices to avoid public health and environmental contamination risks (see Appendix 3)

Referral and linkages

Information on referral and linkage to appropriate HIV and other services shall be made available to all clients. In the event of a reactive HIV self-test result, clients must be made aware of where additional testing can be conducted. (Refer to Chapter 4)

Table 7: Factors to Consider When Selecting HIV Self-Testing Kits

Target Group	Objective and Communication Strategy
Qualifications	WHO pre-qualified PPB listed KMLTTB validated, approved and certified
Accuracy	High sensitivity >99% High specificity >99% High reproducibility >98%
Ease of Use	▪ Should not require additional equipment to perform ▪ Should not require technical training to perform the test ▪ Stable end-reading points ▪ Results should not need interpretation with additional equipment
Rapidity of the test (time to results)	Should avail a result within 20 minutes
Storage Conditions	Storage at room temperature for several weeks (provided there are no significant temperature fluctuations)
Shelf Life	Above 12 months
Packaging	▪ Single packing of complete set with retractable lancets (blood kits) and securely sealed and suitable for individual use only ▪ Shall have lot number, dates of manufacture and expiry ▪ Kit insert with all relevant details including MSDS shall be availed
Disposal	Used kits/waste should be disposable in accordance with public health and environmental laws of Kenya.

7

Chapter Seven: Coordination

This section outlines the various players and their roles in the coordination of HIVST.

7.1 Coordination

The coordination of HIV self-testing services will be done in line with the coordination mechanism as described in the Kenya HIV Testing Guidelines (Chapter 10). The coordination of HIVST is a multi-sectoral and multi-level activity that spans the national, county and lower level structures. At each level, various bodies are responsible for various functions as indicated in Table 8 below.

Table 8: Coordinating Bodies of HIVST- National Level

Institution	Roles and Responsibilities
NATIONAL	
National AIDS and STI Control Programme (NASCOP)	NASCOP is responsible for the development and dissemination of HIVST policy, strategic documents, guidelines and implementation support tools, provision of technical assistance on the implementation and capacity building of the County Health Management Teams (CHMTs). It also coordinates the implementing partners who provide HIVST services at all levels. Development of HIVST M & E tools and indicators as well as quality assurance is part of NASCOP s roles and responsibilities through the leadership of the national HTS technical working group NASCOP will also be responsible for coordination of quarterly HTS TWG meeting to provide an opportunity to different players and stakeholders to share updates on HIVST.
National AIDS Control Council (NACC)	At the national level, NACC provides strategic guidance on the HIV response and coordinates all stakeholders to promote utilization of HIVST services. It will also be responsible for the coordination of the Civil Society (CSOs) and Community-based Organizations (CBOs).
National HIV Reference Laboratory (NHRL)	NHRL will be responsible for: ▪ Overall quality assurance in HIVST services ▪ Verification of new lots ▪ Conduct post market surveillance HIV self-test kits
Kenya Medical Supplies Agency (KEMSA) or local Distributors (private sector only)	Kenya Medical Supplies Agency (KEMSA) or local distributors (private sector only) will be responsible for distribution of HIV self-kits to public facilities and participating pharmacies in the country
Regulatory Authorities	These include Kenya Pharmacy and Poisons Board (PPB), Kenya Medical Laboratory Technologist Board (KMLTB), Nursing Council of Kenya (NCK), Clinical Council of Kenya and Kenya Medical Practitioners & Dentist Board among others. NASCOP shall work with these bodies in ensuring adherence to HIVST protocols. KMLTTB will be responsible for validation of HIVST test and will routinely provide a list of approved test kits to MOH, NASCOP. PPB will be responsible to routinely provide an updated list of approved pharmacy outlets to MOH, NASCOP. This will help inform where HIVST test kits can be placed for clients to access.
Professional Associations	These includes but is not limited to, Pharmaceutical Society of Kenya (PSK), Kenya Pharmaceutical Association, Kenya Medical Association (KMA), and Kenya Private Hospitals Association. NASCOP shall work with these bodies in the coordination of HIVST services within the private sector. This will include distribution of the HIVST kits and dissemination of guidance. These groups will also support NASCOP in ensuring adherence to HIVST guidelines.
Manufacturers and Suppliers of Test kits	▪ Ensure HIVST kits brought into the country conform to the national guidelines ▪ Submit IVDs including HIVST and technical dossier to KMLTTB for validation purposes ▪ Apply to KPPB for registration of IVDs ▪ Provision of patient education information in the inserts ▪ Provision of training to their distributors
Donors and Technical Partners	Provide financial and technical assistance to the Ministry of Health for roll-out of HIVST and capacity building of Health workers and support HIVST quality assurance
Implementing Partners	Complement the work of the ministry in rolling out of HIVST and capacity building of health workers

Table 9: Coordinating Bodies of HIVST- County Level

Institution	Roles and Responsibilities
County Level	
County Health Management Teams (CHMT)	▪ Management of HIVST service delivery including human resource management and training ▪ Ware housing and distribution of HIVST commodities ▪ Printing and distributions of M&E tools and the nationally recommended IEC materials ▪ Development of infrastructure for HIVST services ▪ Provision of supervision of HIVST services ▪ Conduct monitoring and evaluation activities ▪ Ensure the provision of quality HIVST services ▪ Distribution and utilization of data collection and reporting tools ▪ Coordination of data reporting at service delivery points
Service Delivery Points (Public and Private)	▪ Provision of quality HIV Self testing services ▪ Performance monitoring and reporting ▪ Commodity management and reporting ▪ Human resource management ▪ Provision of follow up confirmatory HIV testing
Community level Organizations (FBOs, CBOs) and Mission Hospitals	▪ Community mobilization and advocacy ▪ Provision of quality HIV services ▪ Provision of or referral for follow up confirmatory HIV testing ▪ Data collection and reporting
Donors and Technical Partners	Provide financial and technical assistance to County Health Management Teams for implementation of HIVST services, capacity building of Health workers and support HIVST quality assurance
Implementing Partners	Complement the work of the County Health Management Teams in rolling out of HIVST and capacity building of health workers

7.2 Private sector involvement in HIVST

The private sector will play a key role in scale up of HIVST in Kenya and assist in expanding access to HTS to those who have been previously unreached using traditional HTS approaches.

Table 9 outlines the potential areas of involvement for private sector players in the scale up of HIVST. Table 10 identifies private sector stakeholders who may be involved in the implementation of HIVST and highlights examples of strategies for engagement and distribution of HIV self-tests.

Table 10: Areas of Involvement for Private Sector Players in HIVST

Thematic areas	Key areas of involvement
Coordination	▪ Disseminate the national HIVST guidelines and distribution protocols ▪ Disseminate HIVST communication materials to drive demand e.g. distribution of branding materials, leaflets and fliers at pharmacy counters ▪ Pooled procurement agreements to access competitive pricing for self-tests e.g. negotiated access price for companies distributing self-tests ▪ Create opportunities for multi-stakeholder partnerships to expand access to HIVST e.g. incorporating HIV self-testing in corporate wellness programs and through corporate sponsored community testing days
Standardization	▪ Ensure product standardization e.g. only the nationally approved kits are availed in the private sector ▪ Provide feedback for post-market surveillance e.g. documentation of issues that arise from customer complaints for action by the regulatory authority ▪ Adhere to national guidelines for testing, care and prevention e.g. referral of reactive HIV self-tests to authorized HTS centres for confirmatory testing according to the national algorithm
Technical Assistance	▪ Scale-up access to points providing HIV self-tests e.g. provide vending machines and dispensers in restrooms, shopping malls etc. ▪ Establish referral mechanisms for additional health services e.g. linking of pharmacies with HTS sites for confirmatory testing ▪ Provide visibility over HIVST uptake e.g. share distribution information and profile of clientele purchasing self-test kits with the national HTS program
Policy and Dialogue	Should avail a result within 20 minutes
Storage Conditions	▪ Incorporate HIVST into industry policy on HIV e.g. update workplace testing policies to encourage HIV self-testing ▪ Provide insights into private sector HIVST implementation e.g. generate reports, participate in national TWGs discussing HIVST and HIV prevention, disseminate research findings, etc.
Financing	Increase value of purchasing self- tests e.g. bundling of HIV self-tests with condoms, provide vouchers or rebates through insurance schemes to subsidize the cost of HIV self-tests

Table 11: Private Sector Stakeholders for HIVST in Kenya

Channel	Groups	Examples of areas for HIVST engagement and distribution
Retail Pharmacies	▪ Members of Pharmaceutical ▪ Society of Kenya (PSK) ▪ Members of Kenya Pharmaceutical Society (KPA) ▪ Independent ▪ Hospital owned	o Availing of HIV self-tests in pharmacies o Display posters and videos of self-testing in pharmacies o Avail leaflets and FAQs on HIV self-testing at pharmacy counters o Provide information on support tools (website, helpline and mobile phone application) for self-testers o Provide information on referral sites for HIV prevention and treatment services o Disseminate training videos, guidelines and protocols during member meetings/fora o Partner with community organizations to distribute self-tests during outreaches o Provide representation at national TWGs to share information on HIVST implementation through community pharmacies o Conduct pooled procurement to access negotiated prices for self-tests o Collaborate with the national HTS program by providing insights on HIVST uptake
Hospitals/Clinics	▪ Faith-based ▪ NGO- based ▪ Clinician owned ▪ Corporate owned ▪ • Private enterprise	o Provide HIV self-tests for secondary distribution to partners o Provide confirmatory testing services for self-testers o Provide HIV care and treatment services and o HIV prevention services in accordance with national guidance o Collaborate with the national HTS program by providing insight on HIVST uptake
Companies	▪ Corporates ▪ Small and Medium sized Enterprises (SMEs) ▪ Micro-enterprises	o Install and manage vending machines or dispensers at the workplace o Provide workplace testing with HIV self-testing as a provided option for employees o Provide rebates or vouchers for employees to purchase self-tests at subsidized costs o Collaborate with the national HTS program by providing insight on HIVST uptake
Insurance Schemes	▪ Local ▪ International	o Provide access to free or discounted self-testing to members of insurance schemes to encourage testing and knowledge of status o Collaborate with the national HTS program by providing insight on HIVST uptake

8

Chapter Eight: Monitoring and Evaluation

This section aims to inform policy makers and health managers on the monitoring and evaluation tools and activities that will inform achievement of the national goals through HIVST.

8.1 Monitoring and Evaluation Framework for HIVST

Monitoring and evaluation for HIVST will focus to inform mainly the program goal and objectives performance rather that inputs and processes. Table 12 below shows the indicators of focus and the method and frequency of data collection. Information will be gathered through a triangulated approach with emphasis on entire sector rather than through the public sector. The different approaches will include;

- Routine Health Management Information system (HMIS) that will include integrated supportive supervision and periodic reviews. In addition,
    - Data from sentinel sites could be used where necessary and possible
    - Commodity data from the public sector will be collected through existing logistics tools
    - Data on commodities distributed from the private sector will also be collected
- Rapid assessments and surveys/evaluations
    - These surveys will not be conducted as ‘stand-alone’ activities but will be incorporated into existing routinized surveys that are conducted every 5 years.

Table 12: Monitoring and Evaluation Framework for HIVST

Outcome	Purpose	Source (RHIS, Survey/ Research, Rapid Assessments)	Frequency of Collection
1. **Achievement of the 'first 90' identification target**	To show benefits of HIVST as HTS strategy	Survey	Yearly
2. **Number of kits distributed by entry point**	To show availability of HIVST products for the targeted population	▪ RHIS ▪ Rapid assessment ▪ Distribution data	Monthly Quarterly
3. **Utilization of HIVST services**	Planning, Forecasting & Quantification	Survey	Every 5 years
4. **Uptake of HIVST**	Show level of acceptability of HIVST	RHIS – HTS register Survey	Monthly Every 5 years
5. **Usability of the blood and oral self-test kits**	To show which method is user friendly and guide procurement	Rapid assessment Survey	Baseline –one year after implementation
6. **IPV among HIVST users**	Show existence & level of IPV due to HIVST	Survey	Every 5 years

9

Chapter Nine: Introduction to aPNS

1.1 Rationale for aPNS

The Protocol to the African Charter on human and people's rights on the rights of women in Africa (Maputo Protocol) as well as the General Comments on Article 14 (1) (d) and (e) of the Protocol recognizes that information about the health status of one's partner may be obtained through notification by a third party (usually a healthcare worker) or disclosure by the person themselves.

While disclosure should be encouraged, there should be no requirement to reveal one's HIV status or other information related to one's health status.

In the context of HIV, healthcare workers may be authorized, without being obliged to, decide, depending on the nature of the case and according to ethical considerations to seek additional information on an index client's sexual partners and or drug injecting partner. Such a decision should be made in line with constitutional safeguards on privacy, confidentiality, and informed consent. Additionally, any exercise of assisted partner notification must be informed by international set standards, premised on the African Commission's General Comment no. 1, World Health Organization HIVST and Partner Services Guidelines (2016), and in accordance with the following principles:

i. The Index Client in question, aged 18 years and above, has been thoroughly counselled on the benefits of aPNS, according to the HTS guidelines (2015);
ii. A real risk of HIV transmission to the partner(s) exists, as determined by history of the relationship;
iii. The Index Client has given **written informed consent** for sexual partners to be contacted;

iv. The Health care provider at all times is guided by the tenets of privacy and confidentiality as set out in the Constitution of Kenya and the ethics of health care practice;
v. The identity of the Index Client is not revealed to the sexual partner (s);
vi. Follow-up, including linkage to care is provided to ensure support to those involved, as necessary;
vii. The person providing HIV treatment, care, or counselling services has ensured that the person living with HIV is not at risk of any form of violence resulting from the notification through screening of partner violence;
viii. Safeguards against any forms of violence as set out in the provisions of the Protection Against Domestic Violence Act, 2015;
ix. Any contacts shared by Index Client are safeguarded against function creep using due diligence exercised by the Institution and health care provider

Assisting people who are HIV-positive in notifying their sexual and/or drug injecting partner(s) with the intention of offering HIV testing services (HTS), is a way of facilitating partner testing and overcoming the current challenge of reaching people who could benefit from the full range of HIV testing services. In summary, aPNS aims to increase uptake of HTS among sexual partners of HIV-positive individuals, with a view to increasing identification of persons testing HIV positive and linkage to care.

The HIV epidemic in Kenya exhibits extreme population, geographical, age and gender disparities. Although current evidence is on heterosexual adult populations, similar benefits could be extended to children of the index clients and their sexual partners, adolescents and their sexual partners, female and male sex workers, Transgender, MSM and partners of people who inject drugs. Further to this, aPNS could also enhance couples counseling and offer opportunity for prevention including VMMC and PrEP for high risk clients.
Key populations, who include MSMs, female and male sex workers, transgender and PWIDs, contribute a disproportionately high number of new HIV infections annually despite their relatively small population. According to the Kenya HIV Prevention Responses and Modes of Transmission Analysis 2009 (13), these populations represent less than 2% of the general population, but they contribute a third of all new HIV infections. aPNS offers an opportunity for HIV testing among index clients or sexual partners who might be within this population group.

1.2 Objective of aPNS

The objective of partner notification is to break the chain of HIV transmission by offering HTS to persons who have been exposed to HIV and linking them to HIV treatment, or HIV prevention services (e.g. VMMC, PrEP, condoms), if negative. The specific objectives are

1. To reduce new HIV infections
2. To scale up HTS for unreached populations
3. To refer and link to care newly diagnosed persons

1.3 Objective of aPNS

These guidelines are anchored on international and national legal and policy frameworks including the following:

a) ***The Constitution of Kenya*** (14)***:*** The Constitution of Kenya 2010 under Articles 28 (human dignity), 29 (c) (right against any form of violence), 31 (privacy) 35 (Right to information) and 43(1)(a) (right to health). A reading of these provisions thus ensures the highest standards of meaningful life and health for every individual in all spheres of life.

b) ***Health Act 2017*** (15)***:*** The Health Act 2017 provides guidance on i**nformed consent for HIV disclosure** in sections 8 & 9 and on confidentiality in section 11.

c) ***HIV Prevention and Control Act 2006*** **(17)*:*** Section 18 (get exact quote from the section), provides that the results of a HIV test be confidential and only be released to the individual with written consent, further, the section outlines situations where another person may give consent to disclosure on behalf of the client. Section 22 Disclosure of information (1) No person shall disclose any information concerning the result of an HIV test or any related assessments to any other person except— (a) with the written consent of that person;

d) ***Pursuant to Article 2 (6) of the Constitution,*** the following treaties, conventions, international guidelines and General Comments shall also guide aPNS

e) ***East Africa Community HIV Prevention and Management Act, 2012,*** which advances the principles of HIV and AIDS education and information, informed consent, privacy and confidentiality section 23 (3) of the EAC HIV prevention and control ACT allows a person providing treatment, care and counselling services to a person living with HIV to notify the party of their status.

f) ***African Commission on Human and People's Rights General Comment No. 1*** which recognizes that in the context of HIV, healthcare workers should be authorized, without being obliged to, decide, depending on the nature of the case and according to ethical considerations, whether to inform a patient's sexual partners

of his or her HIV positive status. The African Commission stresses that the duty of States Parties includes ensuring that citizens are in the position to claim and exercise their right to self-protection in a nondiscriminatory framework as articulated in Article 2 of the Maputo Protocol. States Parties thus should enact laws and policies to address HIV- and other sexually transmitted infections.

g) ***World Health Organization (WHO) HIVST and Partner Services Guidelines*** (18)***:*** In 2016, the WHO released partner notification guidelines in which a strong recommendation for voluntary assisted partner notification services to be offered as part of a comprehensive HIV package of testing and care. This guidance provides the normative framework for initiating and scaling up partner notification at country level. The Kenya national guidance for partner notification largely borrow from these.

h) ***HTS guidelines*** (2)***:*** The HTS 2016 guidelines propose disclosure to sexual partners as standard of care especially with regard to reasonable opportunity to disclose. However, the aPNS guidance is progressive and implies active support to sexual partners as they receive HIV testing and linkage to HIV care. It is instrumental to distinguish between disclosure which is a mechanism for HIV infected persons to inform family and significant others of their status for the purposes of emotional support.

> ***In all these scenarios, partner services shall be voluntary, confidential and client-centered***

1.4 Target Audience for aPNS guidance

aPNS guidance targets all health care providers particularly those providing HTS at all entry points of testing including but not limited to (PMTCT, PITC, VCT, VMCC, PrEP, TB, STI, Family Planning and Drop in Centres) services at the facility and community levels. Also targeted are HIV prevention implementing partners, facility in charges and county health management teams.

10

Chapter Ten: aPNS Implementation Considerations

Assisted partner notification services (aPNS) refers to a voluntary process where consenting HIV positive clients are assisted by a trained provider to elicit their sexual and/or drug injecting partners and notify them of their potential exposure to HIV infection with an aim of offering them HTS. Clients are empowered/assisted to disclose their HIV status to their partners. Specific Objectives of aPNS:

1. To reduce new HIV infections
2. To scale up HTS for unreached populations
3. To refer and to link to care newly diagnosed persons

Assisted PNS is a highly skilled intervention that requires detailed skills and guiding principles. This chapter outlines principles, approaches, benefits and special considerations, implementation considerations and target populations for aPNS.

2.1 aPNS 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, freedom from violence, 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. 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.
All partner notification services must be guided by the HTS core principles of 5Cs above mentioned.

In addition to the 5 C's, the following principles guide HIV partner notification services and should be considered and adhered at all times.

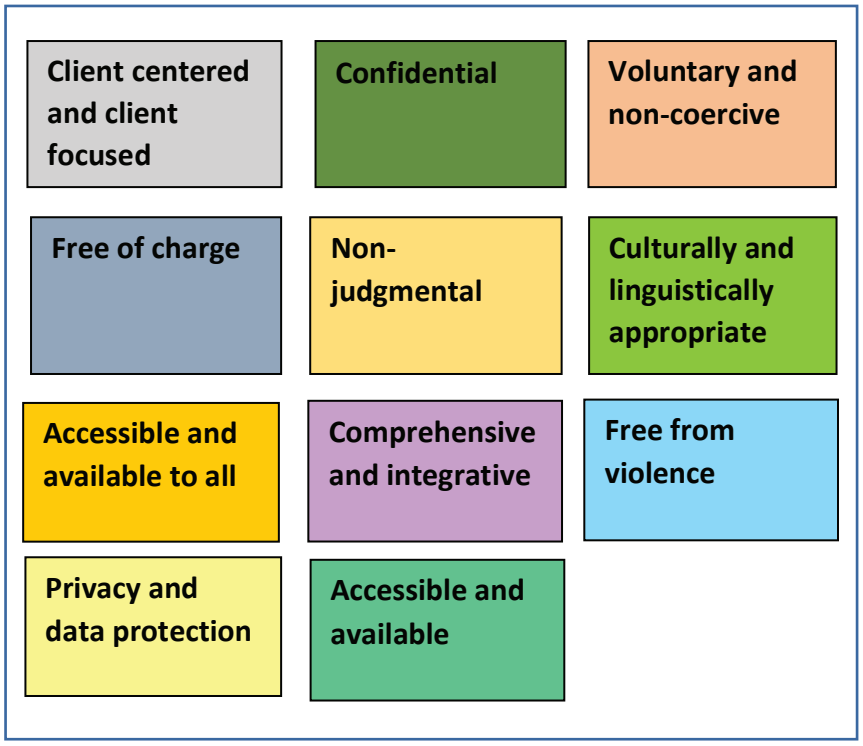

Figure 1: Principle guide for HIV notification

The following principles guide HIV partner notification services and should be considered and adhered to always.

1. **Client centered and client focused:** Partner notification services should be focused on the needs and safety of the index client and his or her partner(s) and children). The client chooses the most appropriate method and level of disclosure (i.e. full to none) for informing each partner based on his/her circumstances
2. **Confidential:** The confidentiality of the index client and all named partners and children should be maintained at all times. The identity of the index client should not be revealed

and no information about partners should be conveyed back to the index client (unless explicit consent from all parties is obtained).

3. **Voluntary and non-coercive:** index partner testing services should always be voluntary; mandatory or coercive approaches are never justified
4. **Free from Violence:** The right to self-protection and the right to be protected are also intrinsically linked to other rights including freedom from all forms of violence. Caution should be exercised in relation to the conditions and environments under which the right to be informed on the health status of one's partner may be exercised, in particular, where the revealing of a partner's health status may result in negative consequences such as harassment, abandonment and violence.
5. All health care providers are guided by the principles of beneficence (to do good), non - maleficence (do no harm) and justice.
6. **Privacy and data protection**: Information on one's health status held by health providers or institutions is subject to strict rules of data protection and confidentiality, and must be protected from unauthorized collection, use or disclosure.
7. **Free of charges:** Partner services should be free of charge for infected persons and their partners and social contacts.
8. **Non-judgmental:** Partner services should be delivered in a non-judgmental manner, free from stigma or discrimination
9. **Culturally and linguistically appropriate:** Partner service providers strive to provide partner services in a nonjudgmental way. Providers need to be informed about what is appropriate for the culture and ensure that services are available in the languages spoken by their clients.
10. **Accessible and available to all:** Partner testing should be available to all index clients regardless of where they are diagnosed (e.g. in a health facility or community setting).
11. **Comprehensive and integrative:** Partner testing services should include strong referral and linkages to HIV treatment and prevention services.

2.2 Approaches of aPNS

aPNS is provided using passive or assisted approaches. Assisted partner notification services (such as provider, mutual agreement 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. Voluntary assisted partner notification services should be part of a comprehensive package of testing and care offered to people with HIV. Table 13 below highlights the features of passive HIV partner notification and assisted HIV partner notification services.

Table 13: Passive and Assisted HIV Partner Notification Services

Passive HIV Partner Notification Services	Assisted HIV Partner Notification Services
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.	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 comprehensive HTS to sexual partners of index clients. If the sexual partner is tested at home, provide testing and referral services to the household of the HIV-positive individual.

2.3 Benefits and Special Considerations of aPNS

The aPNS approach enables an index client to recommend sexual partners for testing and take charge of their HIV care. The identification of sexual contacts and their linkage to HTS offers immediate access to HIV prevention, care and treatment services as appropriate. Assisted PNS contributes to the goal of reducing new HIV transmission, treatment adherence and increasing retention in treatment and facilitates earlier diagnosis. As a result, the client is in a better position of preventing HIV transmission to their sexual contacts. Table 14 highlights these benefits.

Table 14: Benefits of aPNS

	Individual (index or sex partner)	Family	Population/Public Health
Benefits	▪ Timely access to ART therefore increasing quality of life and reduces HIV-associated morbidity and mortality. ▪ Improves adherence and retention to treatment ▪ Increased access to prevention options including counseling, condoms, VMMC, PEP and PrEP ▪ Enhanced self-worth; **client empowerment)** ▪ Enhanced support for those not ready to notify sex partners	▪ Mutual knowledge of HIV status increases trust ▪ Mutual support to access HIV prevention, treatment and care services ▪ Improves support for the prevention of mother-to-child transmission ▪ Prioritization of effective HIV prevention for sero-discordant couples (condoms, antiretroviral therapy, pre-exposure prophylaxis) for HIV-negative partners	▪ Reduced HIV transmission ▪ Increased number of persons on ART ▪ Earlier initiation in ART resulting in a reduction in advanced HIV disease cases requiring more resources, including a reduction in tuberculosis

2.3.1 Some key considerations in aPNS include;

- Potential for Intimate Partner Violence (IPV)– aPNS provider should screen for possibility of IPV
- Risk of stigma with unintentional disclosure of HIV status
- Laws or policies that stigmatize, criminalize or discriminate against key populations or people living with HIV
- Difficulty in identification of partners - some people and groups such as key populations may be reluctant to name partners and/or may not know their partners. This depends on relationship dynamics and the aPNS provider should explore innovative approaches and provide further counselling to the index client.
- Locating and notifying partners - locating partners may be difficult, particularly for non-primary/casual partners and for mobile, vulnerable or key populations. Assisted PNS providers can seek escort of CHWs, peer counselors, mentor mothers to help locate homesteads or preferred test areas in the community. Consider telephone referrals for distance partners-

- Safety of the Health care provider- In accordance with section 12 (1) (b) of the Health Act, Health care providers have a right a safe working environment that minimizes the risk of disease transmission and injury or damage to the health care personnel.
- Costs and logistical implications of aPNs as per 9.4.8 below

2.4 Implementation Considerations

This section will cover what to consider when implementing aPNS including training of aPNS providers, prevention and management of social harms, support for health care providers, supportive laws and policies for aPNS, human rights, civil society and PLHIV, ethical issues in aPNS and cost of implementation.

2.4.1 Training of aPNS Providers

Before HTS providers are allowed to provide aPNS, they should be taken through training using the NASCOP approved aPNS training guide for health-care providers in order to acquire skills to deliver aPNS. Only qualified health care and HTS providers can be trained on aPNS in accordance with section 2 of the HIV Prevention and Control Act.

All aPNS providers must have undergone HTS training using the NASCOP approved curriculum for HTS. To deliver aPNS, health providers will require training and support on how to effectively initiate aPNS, locate and identify partners and offer HTS. It should be made clear that aPNS (whichever approach is used) must always be voluntary. All aPNS providers should be trained on attitude change for them to appreciate their values and aPNS.

Participants will be taken through aPNS training for three days using an approved Ministry of Health guide for health-care providers. They will be provided a chance to do role plays and group work. They will be taken through tools to be used in aPNS and how to complete them correctly. Approaches with written standard operating procedures, policies and protocols for delivering HIV partner notification services should be used at all times.

It is important to start with a training on how to sensitively and non-judgmentally engage in a discussion about sexual partner(s), facilitate mutual disclosure for sero-discordant couples and partners, and recognize and minimize risks of Intimate Partner Violence. Additionally, training will be needed in 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.

Providers should be adequately trained on 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.

Providers should be 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 capable to effectively deliver aPNS.

2.4.2 Social Harm Following Partner Notification

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, particularly for key populations and other vulnerable groups. aPNS implementers should be sensitive to the potential for harm arising from disclosure of HIV status.

Recognizing that different forms of violence can occur (as defined in the Protection Against Domestic Violence Act, 2015) between couples and partners worldwide, aPNS providers should discuss potential risks with HIV-positive clients and, if the safety of the client is not compromised, offer voluntary partner notification services 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 of the approaches to use.
Assisted PNS is offered on a confidential and voluntary basis which should be emphasized throughout the process. Partner notification should only occur with the expressed consent of the HIV-positive client and be made to their partner(s) alone, and to nobody else. An IPV screening tool is provided in Appendix 5 for use by aPNS providers

2.4.3 Prevention and Management of Social Harms

HIV testing, and especially partner notification, may take place in a social environment. This social environment, while initially targeting intimate partners, may often expand and include family members and other contacts in society.
While HIV testing is important, possible social harms must be mitigated against. These include intimate partner violence (IPV), relationship dissolution and family disintegration. Measures must be taken, as in all HTS services, to screen for possible resultant harm, screen for possible testing and screen for suitability of receiving results.

While reports of social harm and other adverse events following HIV partner notification, using passive or assisted approaches, have been rare. Studies on aPNS services have shown little IPV, if any beyond that expected by an individual based on their own history, incidents of adverse violent or relational outcomes. In other words, where there is previous history of IPV, the risk of further IPV, supposedly as a result of the test is much higher and providers need to be very clear on this and screen appropriately.

Concerns exist about the possible harm that could result from disclosure of HIV-positive status, particularly for key populations and other vulnerable groups. Fears about social harm are of concern in situations where certain behaviors 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.

Although these concerns have been raised where hypothetical questions on the social impact of disclosure or partner notification have been assessed, when adverse events have actually been measured, few have occurred.
(https://www.ncbi.nlm.nih.gov/books/NBK401676).

The health-care worker provider needs to have the ability to establish safety prior to the provision of the services. This can be achieved through the acquisition of skills that can be incorporated into the HTS training or can be acquired through updates for those providers already trained in the provision of services.

Further to this, where aPNS is being implemented there is need to have developed, or established, a referral network of providers for those that may experience adverse outcomes of the service. These providers will include those that provide care for discordant couples,

youth, survivors of partner violence and psychosocial support for those whose relationships may undergo difficulties because of having gone through the aPNS.

Survivor continuity of care- in the setting where violence occurs includes;

1. Health care provision for physical trauma
2. Psychological support for mental trauma
3. Security - safe spaces through the county government
4. Linkages for access to justice in accordance to the Domestic Violence Act, 2015.
5. Help line

It may well be that those who go through the service may also use this as an avenue to care and support for the relationship and as such there will be a need for providers to be sufficiently discerning and be able to refer clients for psychosocial support services as necessary.

2.4.4 Support for Health Care Providers

Support to healthcare workers will be strengthened through continuous training of healthcare providers as well as through subsequent counsellor supervision and mentorship as the service develops. Continuous mentorship and supervision of healthcare workers, with regular debriefing sessions will be vital in strengthening their capacity to deliver optimal services envisioned in these guidelines.

2.4.5 Supportive Laws and Policies for aPNS

The Constitution of Kenya 2010, in Article 43 (1) (a) sets out the right of every citizen to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. Constitution of Kenya 2010 - Article 31 (c) further provides that every person has the right to privacy, which includes the right not to have information relating to their family or private affairs unnecessarily required or revealed. Assisted Partner Notification services will ensure that all citizens at risk of HIV are notified and given access to HIV testing services and consequently treated if required, and in accordance with the principles of informed consent, privacy, and confidentiality.

Other laws and policy documents that support aPNS are:

1. Health Act 2017- Section 15. (1) that states that the national government ministry responsible for health shall develop health policies, laws and administrative procedures and programs in consultation with county governments and health sector

stakeholders and the public for the progressive realization of the highest attainable standards of health including reproductive health-care and the right to emergency treatment; (i) put in place policy intervention measures to reduce the burden of communicable and non - communicable diseases, emerging and reemerging diseases and neglected diseases.

2. Health Act 2017- Section 8(1)(b) which states that every health-care provider shall inform a user of the range of promotive, preventive and diagnostic procedures and treatment options generally available to the user.

3. Health Act 2017- Section 9. (1)(f) states that no specified health service may be provided to a patient without the patient's informed consent unless any delay in the provision of the health service to the patient might result in his or her death or irreversible damage to his or her health and the patient has not expressly, or by implication or by conduct refused that service.

4. HIV Prevention and Control Act 2006-Section 19(2) states that the Government shall, to the maximum of its available resources, take the steps necessary to ensure the access to essential healthcare services, including the access to essential medicines at affordable prices by persons with HIV or AIDS and those exposed to the risk of HIV infection.

   Other provisions at the international and regional fora include: The EAC HIV prevention and management Act, the Protocol to the African Charter on human and people's rights on the rights of women in Africa (Maputo Protocol) as well as the General Comments on Article 14 (1) (d) and (e) of the Protocol

5. WHO guidelines on Partner Notification Page 36- Disclosure encouraged when safe and beneficial
6. Kenya HTS guidelines- Page 28 – reasonable opportunity to disclose
7. Sustainable Development Goals, particularly SDG 3.3 that by 2030 end the epidemic of HIV/AIDS.

2.4.6 Human Rights, Civil Society, PLHIV

Assisted partner services will be provided within the context of human rights generally, the participation of civil society in the development and implementation of any intervention and the meaningful involvement of People Living with HIV.

Human rights play an increasingly important role in the provision of health care in Kenya today. Indeed the 'rights based' approach in the provision of health-care is the desired modality of service delivery and aPNS will be delivered in full accordance with the rights-based approach that has, enshrined within its core, human rights

Public participation as recognized in the Kenyan constitution of 2010. (Article 118 (a) is a requirement in the development of programs affecting or involving Kenyans today.

Interventions, plans, activities and budgets call for public participation and, in this context, the participation of civil society in the development of the guidelines around aPNS lends itself to the strengthening and incorporation of the public in this key health intervention.

Public support for the intervention is required for the overall success of aPNS that will involve notification of partners who have been exposed to HIV, support for those needing to go and access testing services and support for anyone that may need necessary resultant HIV care. It is the broader health environment that will support the framework within which aPNS services can thrive.

The meaningful involvement of People Living with HIV has been a clarion call in HIV care for the past two decades. The assisted partner notification services will be premised on persons who have HIV and as such, their involvement in the development of the guidelines especially regarding implementation considerations will be key.

2.4.7 Ethical Issues in aPNS

Assisted PNS is a voluntary and anonymous public intervention to increase knowledge of HIV status by individuals who may have been exposed through sexual contact, needle sharing or any other high-risk activity. The index case should not be forced to disclose his or her partner's identity and is in control of the information he or she chooses to disclose to healthcare workers. Index client's information is also not revealed to the contacts[31].

Further to this, where aPNS is being implemented there is need to have developed, or established, a referral network of providers for those that may experience adverse outcomes of the service. These providers will include those that provide care for discordant couples, youth, survivors of partner violence and psychosocial support for those whose relationships may undergo difficulties because of having gone through the aPNS.

It may well be that those that go through the service may also use this as an avenue to care and support for the relationship and as such there will be a need for providers to be sufficiently discerning and be able to refer clients for psychosocial support services as necessary.

2.4.8 Cost Implication of aPNS

Cost considerations for assisted Partner Notification

Introduction

Assisted partner notification services are cost-effective and affordable in the Kenya setting (Cherutich et al). Given that aPNS is an enhancement of HIV testing services, programme managers and implementers should ensure that they invest in a robust HIV testing system that will enable identification of index patients. When implemented with fidelity and high coverage, aPNS may avert hospitalizations and HIV infections due to increased uptake of ART.

Cost elements for aPNS

The major drivers of the aPNS unit costs are human resource costs, especially the health advisors, which is a new cadre in Kenya that is equivalent to a nurse. Personnel related costs represented between 54-70% of all costs depending on the task-shifting approach, with supplies (including HIV test kits and office stationery), taking up close to a fifth of all costs (17%). To enable appropriate budgeting and planning the costs should including hiring, training and retraining. Additionally, costs are be affected by added costs of community follow-up including transport and field allowance. In order to save costs, programme managers are recommended to apply cost-effective mechanisms such as bicycles and motorcycles that enable access even to remote location. Depending on circumstances, there may be need to plan for costs for escorting HIV-infected index clients and their sex partners for enrollment in HIV care.

Evidence from Kenya and other low-income settings support task-shifting as a potential strategy for reducing costs for HIV testing and aPNS in Africa. Community health workers reduce HIV testing costs by between 30-55% and overall aPNS costs by an average of 30%. Additionally, lower cadre workers improve health systems by reducing waiting times, reducing workload and enhancing quality of care. Community health workers, when appropriately trained and deployed may offer high quality aPNS.

Overall, over 90% of budget impact is attributed to aPNS and ART. Sustained efforts to reduce delivery costs of ART should be encouraged to include task-shifting of ART initiation and monitoring, point of care viral load measurements and lower drug prices. This would have significant impact on the scale up of Apns.

Budgeting process

Given that aPNS is delivered on HTS platforms, it is recommended that aPNS should be budgeted under HTS programs. In essence, this will leverage on the infrastructure available and minimize costs of providing aPNS. Further savings would be made by training staff that already provide HTS services. This would ensure that only specific competencies of aPNS such as community engagement, tracing and locating sex partners are added to the already acquired competencies. Program managers should take advantage of the country operations plan, the global fund and ministry of health resources to include aPNS as an essential service.

2.5 Priority Populations for aPNS

aPNS targets all age groups and sub-populations. This service is an index client targeted intervention whereby focus is placed on clients testing HIV positive. For PLHIV, HCW should make efforts to follow up and offer HTS to their sexual partners and needle sharing partners. These clients should be willing to provide consent and sexual partner information.

HIV partner services should be prioritized for HIV+ Clients who meet at least one of the following criteria:

Men: Globally HTS uptake coverage for men continues to be lower than women. Reports suggest that HIV testing has been successfully integrated into reproductive health services including antenatal care but not consistently into other relevant clinical settings. Also, male partner testing is not widely implemented, and where offered, not taken up. Traditionally HTS is offered in health facility settings yet men are poor health seekers. Barriers hindering male access to and uptake of HTS are often due to their perceptions that health services particularly antenatal care setting are not friendly to men.

Key populations (PWID, FSW, MSM): This include men who have sex with men (MSM); people who inject drugs (PWID) and sex workers (SW). Despite their small number, these populations suffer from an estimated 30% of new infections annually. It is therefore important to engage their sexual partners for aPNS because of their increased risk.

Adolescents and Youth: 21% of new HIV infections occur among young women aged 15-24 annually. KAIS 2012 reported that up to 7% of children had sex by the age of 10 years, It is therefore important to put interventions in place for those below the age of 17 years to curb the new infections as the adolescents become actively engaged in sex. It is therefore a priority to follow their sexual partners since condom use is low in this age group and the practice of unsafe sex is high. This puts partners at increased risk.

Newly identified positives, viral load unsuppressed clients in CCC and those with recurrent OIs or STIs at the CCC*:* Newly infected individuals, clients with an unsuppressed viral load and those in care but who have recurrent opportunistic infections and sexually transmitted infections have a higher risk of sexually transmitting HIV. They should be approached for aPNS as a way of reducing risk of HIV transmission to their partners.

11

Chapter Eleven: aPNS Process

3.1 Introduction

This chapter provides a guide on aPNS protocol to help aPNS providers understand how to administer aPNS to clients attending routine HTS and those enrolled at the Comprehensive Care Clinic (CCC) for care and treatment services. The aPNS process should be part of the comprehensive HTS and discussion about aPNS and its benefits should feature in all components of HTS.

3.2 aPNS Entry Points

Effective assisted partner notification services (aPNS) will be delivered within the existing HIV testing services (HTS) protocol in line with the national HTS guidelines, 2016. aPNS is guided by the 5 C's in HTS, that is, confidentiality, counseling, consent, correct results and connection to care and other relevant services. aPNS is aimed at the elicitation, reaching out and testing of sexual contacts and injecting drug partners of HIV infected clients. Children of HIV infected mothers should also be followed up for testing. This service may be offered during HIV Testing and Counseling Services and Care and Treatment.

The process also involves assessment for other health related conditions, such as TB and STI, as well as risk to IPV. Further, appropriate messaging on risk for cervical cancer should be conducted. Referral and linkage to these other services is anticipated.
aPNS can be offered through a passive or an active approach and clients can access services through the following entry points:

- Routine HTS/PMTCT services - aPNS is incorporated in the HTS protocol. All clients seeking HTS should be introduced to aPNS and its benefits in all stages of HTS (Pretest, Testing, Post-test, Assessment of other health conditions and referral and linkage).
- Comprehensive Care Clinic (CCC) - At the CCC, HCWs should initiate aPNS to clients enrolled in CCC particularly those that did not receive counseling on aPNS during routine HTS. For those that were offered aPNS, it is recommended that they are queried regularly for change of partners as they progress with care and treatment services.

3.3 HTS aPNS Protocol

As part of comprehensive HTS, aPNS should be discussed with clients as they go through all stages of HTS (pretest counseling, testing and post-test counseling). Detailed information about aPNS within HTS protocol is shown in Figure 8.

3.3.1 Pretest Counseling Session

Follow HTS protocol on pretest counseling and also be sure to introduce aPNS, describe its benefits and conduct a risk assessment with focus on sexual partners in the past 12 months.

3.3.2 HIV Testing Session

During the HIV testing process, explore with the client the benefits of disclosure to sex partners and empower them to carry out disclosure or obtain written consent of partner(s) to share private information.

3.3.3 Post-Test Counseling Session

Follow the post-test protocol/steps in HTS guideline. Review and update the list of contacts provided at pre-test and obtain contact information of contacts such as name(s), physical location, phone number and HIV status-if known. Explore with the client the preferred approach of aPNS (client referral, mutual agreement referral and dual referral) and agree on the method that works effectively. Take into consideration the risks for IPV when determining the best approach. Document outcomes of notification and testing in aPNS register and if mutual agreement referral method is chosen by the client, review progress within 2 weeks or as agreed. (NOTE: always consider if right to privacy has been safeguarded). Record test result and notification peculiarities in aPNS register.

3.4 Comprehensive Care Clinic (CCC) aPNS Protocol

Delivery of aPNS to CCC clients will ride on existing structures and systems. At the CCC the provider establishes whether the client for follow up visits is sexually active and should review if the client has been offered aPNS before. If aPNS has already been offered, the provider should determine whether all line-listed partners have already been tested or if there are any additional contacts. Figure 8 summarizes the steps of aPNS in HTS and CCC protocols.

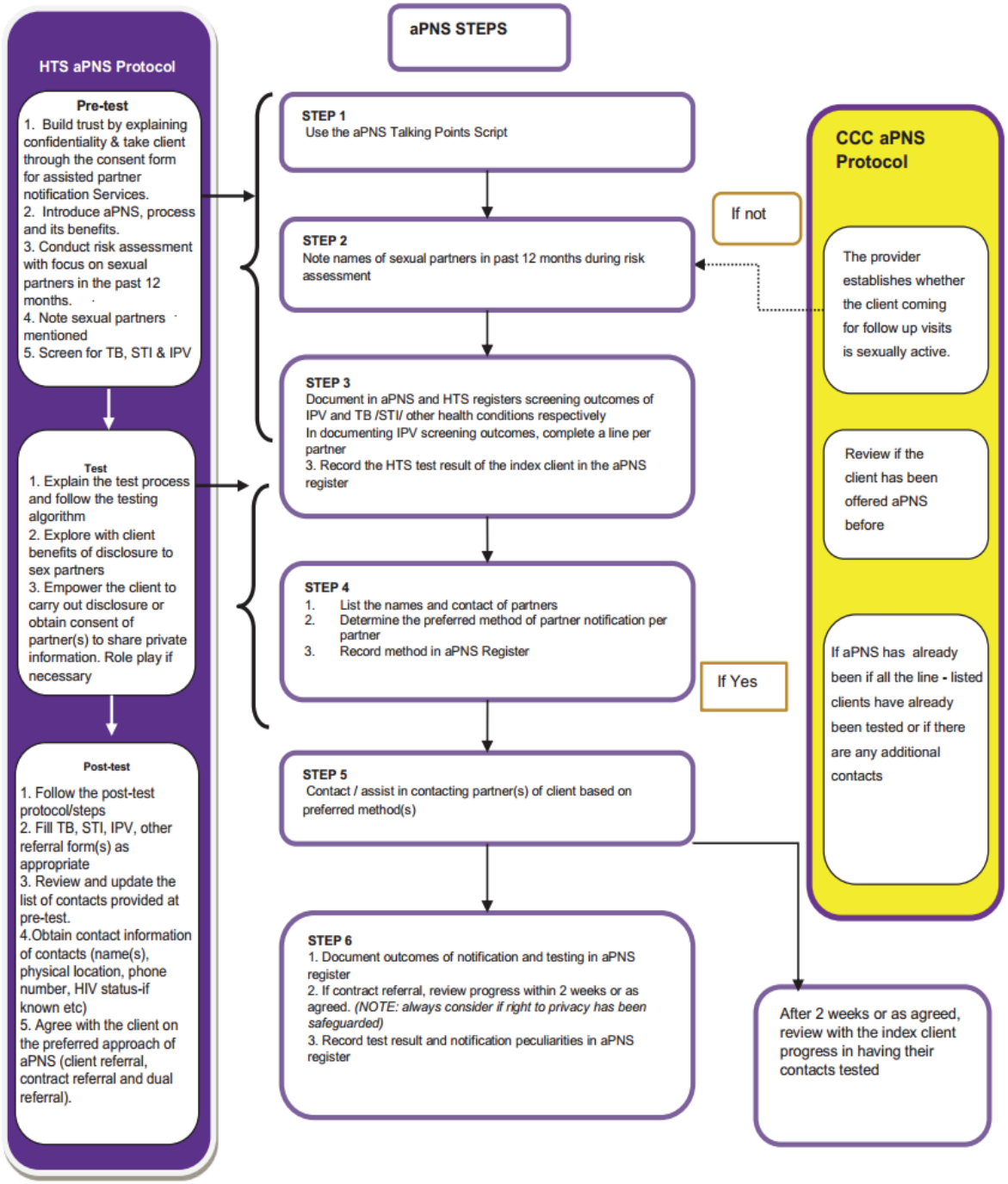

Figure 2: Steps of aPNS in HTS and CCC protocols

3.5 Referral and Linkage

This section provides a guide on referral and linkage for the HIV positive and negative contacts of aPNS index clients. The referral and linkage of the contacts of the aPNS index clients should be in line with the national HTS guidelines as well as the guidelines on use of antiretroviral drugs for treating and preventing HIV infection.

3.5.1 Referral and Linkages of Contacts of aPNS Index Clients

All HIV positive individuals should receive comprehensive referral and linkage to post-test services. Those who test HIV negative should be linked to effective prevention interventions, such as PrEP, PEP, VMMC, FP, Condoms and GBV/IPV care and services. Clients in need of other post-test services such as SRH or TB services should be linked appropriately. Effort should be made to ensure follow up of the clients to determine if they accessed the services referred for. Client linkage should be documented in the aPNS and HTS referral and linkage register.

12

Chapter Twelve: aPNS Monitoring and Evaluation

4.1 Introduction

The National HIV/AIDS M&E Framework provides information on the key indicators that are required for national level HTS monitoring and evaluation**.** This guideline provides additional indicators to monitor and evaluate assisted Partner Notification Services.

4.2 Indicators

The following Indicators will be used to monitor the implementation of aPNS at different levels

Table 16: Indicators of aPNS

#	Indicator	Numerator	Denominator	Data source
1*	Percent of index clients offered aPNS services	Number of index clients offered aPNS services	Number of index clients newly identified including high viral load clients	aPNS register (Num High VL register (Den) MOH 731(Den)
2	Percent of index clients who accept aPNS services	Number of index clients who accept aPNS services	Number of index clients offered aPNS services	aPNS register
3*	Number of partners/children listed by index clients	Number of partners/children listed by index clients		
4	Percent of partners/children successfully contacted – Client referral method	Number of partners/children successfully contacted – client referral method	Number of partners/children who preferred the client referral method	aPNS register
5	Percent of partners/children successfully contacted – Mutual agreement referral method	Number of partners/children successfully contacted – Mutual agreement referral method	Number of partners/children who preferred the mutual agreement referral method	aPNS register
6	Percent of partners/children successfully contacted – Provider referral method Percentage of Index clients reporting IPV Percentage of Index Clients referred to safe spaces or offered other survivor continuum of care	Number of partners/children successfully contacted – Provider referral method	Number of partners/children who preferred the provider referral method	aPNS register

Table 17: Indicators of aPNS continued

#	Indicator	Numerator	Denominator	Data source
7	Percent of partners/children successfully contacted - Dual)	Number of partners/children successfully contacted – Dual method	Number of partners/children who preferred dual referral method	aPNS register
8	Percent of partners/children known HIV-positive at the time of contact/line listing	Number of partners/children known HIV-positive at the time of contact/line listing	Number of partners/children listed by index clients	aPNS register
9	Percent of partners/children eligible for HIV testing	Number of partners/children eligible for HIV testing (exclude known positives)	Number of partners/children listed by index clients	aPNS register
10*	Percent of eligible partners/children receiving an HIV test after contact	Number of eligible partners/children receiving an HIV test after contact	Number of partners/children eligible for HIV testing	aPNS register
11*	Percent of eligible partners/children testing HIV positive	Number of partners/children testing HIV positive	Number of eligible partners/children receiving an HIV test after contact	aPNS register
12*	Percent of HIV-positive partners/children linked to HIV treatment	Number of HIV-positive partners/children linked to HIV treatment	Number of partners/children tested HIV positive	aPNS register
13*	Percent of HIV-negative partners linked to prevention services e.g. condoms, PrEP, VMMC	Number of HIV-negative partners linked to prevention services e.g. condoms, PrEP, VMMC	Number of partners/children tested HIV negative	aPNS register

**Core indicators for reporting in the DHIS2*

4.3 Data Capture and Reporting

Data will be captured by the service provider using the at the point of service delivery. Sites with EMRs will capture individual data electronically in the customized aPNS module; a mirror of the aPNS log. Summary of the data in EMR will be automatically summarized and linked to DHIS.

Data quality audit for aPNS should be integrated into the existing DQA processes.
Rapid assessments and surveys will be conducted periodically for selected indicators on need basis to inform major program decisions.

4.4 Confidentiality of Medical Records

Information from HTS service delivery points should be treated with the same level of confidentiality that all medical records are given. Only authorized officers should be permitted to handle client-level data. Results of all HIV tests should be systematically recorded as well as the details of all the test kits used. Records must be kept confidential and in lockable storage location that is only accessible to authorized persons.

4.5 Data Demand and Use

Program monitoring and evaluation will done be through cascades like the one shown below. This can be applied to monitor aPNS service delivery e.g. uptake and coverage of the different subpopulations to inform decision making at any level.

Appendices

Appendix 1: Retesting Recommendations

Republic of Kenya

Ministry of Health

National AIDS and STI Control Program (NASCOP)

HIV Testing Services Protocol with Incorporated aPNS and HST interventions

1. Pre- Test Counselling/Information

- Introduction (Provider & Client) and provider role in HTS
- Contracting with the client
- Time the session likely to take
- Assure client confidentiality/shared confidentiality
  - Talk about the records and information to be gathered by the provider
- Benefit of HIV testing (to individuals, sexual partners and families)
- Informed Consenting for the HIV services
- HIV package provided
  - HIV Combination Prevention- Pep, PrEP, Condoms,ARVS
  - Partner Notification Services (aPNS) and HIV Self-Testing (HIVST)
  - Referral to HIV care and treatment and other integrated services

2. Pre-Test Counseling

- HIV information
  - Risk assessment and reduction -. Explore the person's risk of HIV and his or her prevention strategies.
- Need for disclosure and importance to reach out to partners for HTS
- Benefit of **assisted partner notification services (aPNS) and self-testing (HIVST)**
- **Discuss aPNS and HIVST** how it is related to HIV prevention, care and treatment services
- Client preparation, testing process & interpretation of test results
- Interpretation of test results using charts

3. Perform test

- **During the 15 minutes as you wait for the test results**
  - Discuss Combination Prevention e.g PrEP, Risk Reduction, STI treatment, Condom information & demonstration, Voluntary Medical Male Circumcision (VMMC), Elimination of Mother To Child Transmission of HIV (eMTCT)
  - Screen for and provide information and referrals for; Intimate Partner Violence (IPV), STI and cancer screening Tuberculosis (TB), Family planning/contraceptive needs etc
  - **Establishing number of sexual contacts and children**
  - Document in the MOH 362

Discus further on aPNS and HIVST as the confirmatory test is running for the clients who test positive with the screening test

4. POST TEST COUNSELLING

- Check if client is ready for results and help them to interpret

Table 18: Retesting Recommendations

Scenario/ Population	Recommendation for Re-Testing
General Population	Re-test annually (for children, re-testing is only required if there is a new exposure)
Key Population	Re-test every 3 months in case of frequent instances of high-risk exposure
Negative partner in discordant union	Re-test at the initiation of ART for the HIV positive partner, and every 3 months until HIV positive partner achieves viral suppression. Once viral suppression is confirmed re-testing can be performed every 6 months. Other prevention services should still be recommended, including consistent and correct use of condoms. Assess for eligibility and willingness for PrEP.
Pregnant Women	Test in first trimester or first contact; re-test in the third trimester. All women who were not tested during the third trimester should be tested during labour and delivery
Breastfeeding Mothers	Re-test after delivery at 6 weeks, at 6 months then follow testing recommendations as per their risk category
Persons with a recent (e.g. less than a month) specific exposure incident	Test at initial presentation and re-test at 4 weeks, after which annual re- testing applies
Symptomatic STI patients	Test at initial presentation and re-test at 4 weeks, after which annual retesting applies
PWID	Re-test every 3 months
Individuals on PrEP	Re-test every 3 months
All Persons newly diagnosed as HIV positive	retest with a second specimen using the same testing algorithm at CCC, before enrollment into care initiation of ART (particularly pregnant or lactating women, children under 5, TB patients, KPs), to rule out potential misdiagnosis

Appendix 2: HEEADDS Assessment Tool

HEEADSS is the mnemonic for Home, Education and Employment, (Eating and exercise), Activities and peers, Drugs, Sexuality, Suicide and depression, Safety, Spirituality.

The HEADSS framework for Psychosocial Health Assessment (adapted from Goldenring & Cohen) Example questions:

Home

1. Where do you live?
2. Who lives there with you?
3. How do you get along with each member? Who makes the rules at your place?
4. Who could you go to if you needed help with a problem? Have there been any recent changes?

Education and employment

1. What do you like about school/work? What are you good/not good at?
2. How do you get along with teachers/your employer and other students/workmates?
3. Is there an adult at school that you can talk to about important things? Have your grades changed recently?
4. Many young people experience bullying at school/work, have you ever had to put up with this? Do you have some plans for your future?

Eating exercise

1. Who cooks at home? Do you eat meals with your family?
2. Is anyone worried about your weight? Are you happy with your weight? Do you worry about your weight?
3. How do you get to school or work? Do you play a sport?

Table 13: HEEADDS

Who should be assessed?	All Young people (from age 10-24)
When to assess	Routinely as part of a comprehensive hospital consultation and should be reviewed during subsequent patient encounters according to issues identified.
What to assess	The focus of HEADSS is the assessment of psychosocial health and wellbeing
Strategies to address psychosocial issues identified	If psychosocial issues are identified, management options will depend on the level of concern, the skill of the physician and local resources available. Physicians may choose to educate the young person about health risks, provide guidance in order to reduce risks and promote their strengths and their health. In addition, they may choose to refer the young person to an adolescent physician, drug and alcohol service or a mental health practitioner or service. A working knowledge of local networks is critical.

Appendix 3: Biosafety Recommendations

Standard Precautions

The following steps should be taken to ensure personal and environmental safety.

- *Hand hygiene*- Testers should wash their hands with soap and clean running water before and after the HIV self-test procedure
- *Good housekeeping*- Testers should ensure the testing area has been left clean after testing has been completed.
- *Safe waste disposal*- The contents of the test kits should be disposed of as per the manufacturer's instructions. In case of assisted HIVST, the provider should follow the standard operation procedures for infection control.

Appendix 4: Sample Consent Form

Sample Consent Form

I…… …. of Telephone Number…….

Do hereby willingly consent as follows:

1. That I have been counselled to the best of my satisfaction on the benefits of Assisted Partner Notification services;
2. That the provider has also stated to me the other options available to encourage my partner (s) to get tested;
3. That from my assessment, based on the information shared by the Provider, no possible or eminent risk is likely to occur from the shared contacts;
4. That the decision to share my partner(s) contacts is made freely, willingly and voluntarily;
5. That the provider undertakes that they will maintain privacy and confidentiality and my identity will at no time be revealed to my partner(s);
6. That the provider undertakes that all contacts shared will only be used for the sole purpose of contacting my partner(s) for HIV testing and due diligence will be exercised to protect this data;
7. I affirm that I was given an opportunity by the undersigned medical provider to ask all questions and they were answered satisfactorily and I therefore agree without coercion to share the contacts.

…… ……

Patient's Signature and date Service provider

Appendix 5: IPV Tool

Screening for Intimate Partner Violence- considers the following psychometric issues:

- Does your partner physically hurt you?
- Does your partner insult you or talk down to you?
- Does your partner threaten to harm you?
- Does your partner scream or curse you?
- Describe your relationship- no tension, some tension or a lot of tension
- Do you work through your arguments with a lot of difficulty, some difficulty or no difficulty?
    - Do arguments ever result in you feeling down or bad about yourself?
    - Does your arguments result ever result in hitting, kicking or pushing?
    - Do you feel threatened by what your partner says?
    - Do you feel safe in your current relationship?
    - Has your partner ever abused you physically?
    - Has your partner ever abused you verbally or emotionally?
    - Has your partner ever threatened you?
    - Has your partner ever deliberately withdrawn any form of support, including financial support?
    - Has your partner ever abused you sexually?

Note: For any 'yes' to the above questions, the health care worker should refer for GBV interventions.

Appendix 6: MoH 362 Register for aPNS

PARTNER NOTIFICATION SERVICES LINE LIST																						
Index client information						Sexual/Needle sharing Partner/Children Information								Contact Tracing and Outcome				Contacts HIV Testing		Linkage to Care		
Serial No. (a)	HTS Number (MOH 362) (b)	Date: (dd/mm/yyyy) (c)	Index client Name (Three names) (d)	Age [Years] (e) Sex (M/F) (f)	PNS accepted? (Y/N) (r) If No, please indicate why? (s)	Name(s) (t) *Indicate the nick name in bracket where applicable*	Age (Years) (u) Sex (M/F) (v)	Relationship to index client (SP/ PWID/C)(w)	Occupation N/A-Children (x)	Screened for IPV (Y/N/NA) (y) IPV Screening Outcome 1-Physical 2-Emotional 3-Sexual 4-No IPV 5-N/A-CHILD (z)	Cell phone No. Primary/Alternate (aa) Currently living with index client [Y/N/D](ab)	Knowledge of HIV status [KP/Neg/Unknown] (ac) If Pos and enrolled in Care, indicate CCC Number (ad)	Preferred PNS Approach (Con/D/Pr/Cr) (ae)	By Phone/Physical (dd/mm/yyyy) Outcome (C/NC)	By Phone/Physical (dd/mm/yyyy) Outcome (C/NC)	By Phone/Physical (dd/mm/yyyy) Outcome (C/NC)	Consented Testing Y/N (ai)	Date booked for testing [dd/mm/yyyy] (aj) Date HIV testing done (dd/mm/yyyy) (ak)	Tested [Y/N/D] (al) HIV Test Outcome [Pos/Neg/I/N/A] (am)	Linked [Y/N] (an) Date linked to Care (dd/mm/yyyy) (ao)	Facility linked to Care (ap) CCC No. (aq)	Comments (ar)

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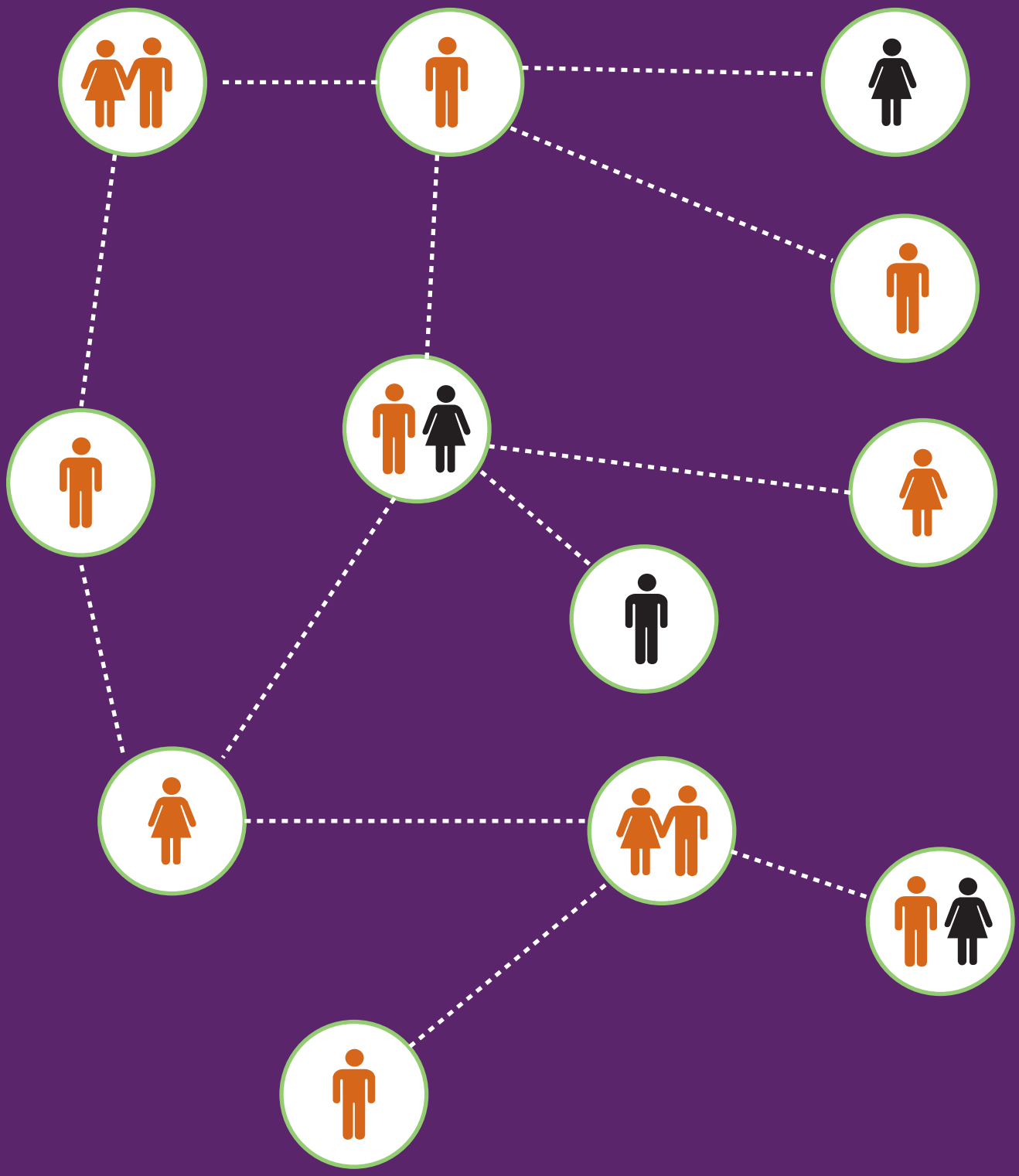

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