



Society for Family Health
Better Choices. Healthier Lives.

SELF-TESTING AFRICA (STAR)PROJECT

STANDARD OPERATING PPROCEDURE

V.1.0

SOCIETY FOR FAMILY HEALTH

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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CBDs	Community Based Distributors
CITC	Client Initiated Testing and Counselling
DHS	Demographic and Health Survey
DMO	District Medical Office
GBV	Gender-Based Violence
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
HIV	Human Immunodeficiency Virus
HIVOFT	HIV Oral Fluid Tests
HIVST	Human Immune Virus Self-Testing
HTC	HIV Testing and Counselling
HTS	HIV Testing Services
ID	Identification
IEC	Information, Education and Communication
M&E	Monitoring and Evaluation
MIS	Management Information System
MoH	Ministry of Health Zambia
PICT	Provider-Initiated Counselling and Testing
PLHIV	People Living with HIV
PRISM	Partnership for Integrated Social Marketing Project
PSI	Population Services International
SFH	Society for Family Health
STAR	Self-Testing Africa
USAID	United States Assistance for International Development
VCT	Voluntary Counselling and Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organisation
ZAMBART	Zambia AIDS Related Tuberculosis (Project)
ZDHS	Zambia Demographic and Health Survey

1.0 INTRODUCTION

Society for Family Health (SFH) recognizes the importance of supporting HIV testing and counselling services. As such, SFH has made significant contributions to ensure as many people as possible in Zambia know their HIV status. In a five year USAID funded project, the Partnership for Integrated Social Marketing Project (PRISM), SFH provided HIV testing and counseling (HTC) services to 1,021,629 clients through 10 static New Start outlets which also conducted outreach services between 2009 and 2014. In addition, PRISM also enrolled HIV+ clients to receive post-test support through the Horizon Program developed specifically for the project. In February and June 2010, PRISM aired the 'Get Tested Together, Get Tested Today' mass media campaign for couples testing. The mass media spots were accompanied by IPC mobilization efforts with traditional leaders (chiefs and headmen), religious leaders and others. The proportion of people coming for HTC as couples rose from average 5% during fiscal year 2009 to 14% during fiscal year 2010. The proportion of people coming for HTC as couples rose again during Year 2 from an average of 14% to over 20%; where it remained for the life of the project.

Despite, these successes scored, SFH recognizes that the traditional channels of HIV testing face a number of challenges. At national level only 37% of men and 46% of women received HTC in the last 12 months according to the 2013 Zambia Demographic and Health Survey (ZDHS). In this regard, SFH has taken the bold stance to introduce novel means of increasing the numbers of people accessing HIV Testing Services (HTS). Working within a partnership framework funded by UNITAID through Population Services International (PSI), SFH is one of the three countries piloting HIV self-testing using oral fluids (HIVOFT) tests at scale. This project, HIV-self testing Africa (STAR) will contribute to the overall goal, or anticipated impact of catalyzing the HIVST market in resource-limited settings through effective use of HIVOFT for self-testing. The direct outcome of this project will be increased effective use of HIVOFT for self-testing among target populations in the three target countries of Malawi, Zambia, and Zimbabwe. In the first two years, commencing August 2015, 742,922 HIVOFT will be distributed across the three countries and in the second Phase, (two years from 2017) an additional 1,920,578 HIVOFTs will be distributed) to the targeted rural, urban, and peri-urban populations, providing sufficient evidence to estimate the market size, while still ensuring availability of ART for all individuals diagnosed through project activities. The project will simultaneously develop an evidence base for public health policy makers in order to inform the development of the World Health Organization's normative guidance on HIVST and appropriate country-level policies and demonstrate a viable market for HIVST, using HIVOFT.

In Zambia, the project will be implemented in four districts in phase I, namely Ndola, Kapiri-Mposhi, Lusaka and Choma with the aim of distributing 200,447 test kits. SFH will implement 3 models of distribution of the kits, specifically a health facility model and two community-based models using VMMC health promoters and dedicated HIV self-test (HIVST) distributors. SFH's research partner ZAMBART will undertake an impact evaluation of the project and also a clinical performance study to ascertain accuracy of the materials used to provide guidance to potential testers.

This document outlines the standard operating procedures (SOPs) related to the STAR Zambia project in Zambia. It provides details of the modus operandi of the project and also explanations of all the tools that will be employed.

2.0 APPROACHES

SFH will pilot three models for distribution of HIV self-test kits as follows:

- i. Health facility distribution

- ii. Community based distribution using VMMC demand creation agents (health promoters)
- iii. Community based distribution using dedicated HIVST distributors

All the distribution channels will utilize community distributors who will be trained to distribute kits and provide post-test support to testers. The three models are described in detail below:

2.1 FACILITY LEVEL

All the facilities participating in the project will have a facility distribution model. There will be an HIVST distributor based at the facility who will act as a link between the community based distributors (CBDs) and the facility. As such, the first role of the facility based distributor will be to distribute the HIV Self-test kits to the CBDs and account for and maintain stock levels using project specific stock control cards and registers which are described in detail later. The facility based distributor will also distribute kits to people who will prefer to access them from the facility as opposed from the community. Thirdly, the facility based distributor will also act as a link for individuals who have self-tested at the facility or within the community to post-test services such as confirmatory testing and voluntary medical male circumcision (VMMC). Testers will present a “self-referral card” to the facility distributor on which the post-test service required will be recorded by the distributor who will direct the tester to the facility area providing the service.

Demand creation for facility distribution will be two-fold from the community by the CBDs and from within the facility while assuring additionality for HIV testing so that clients who would normally be accessing regular voluntary counselling and testing (VCT) and provider initiated testing and counselling (PITC) at the facility continue to do so. The target audience for the facility distribution are the general population and potential clients will be offered the HIVST option as part of the VMMC package and HIV care support and treatment package. Facility distribution will be done from the out-patient department (OPD) or any location within the facility as deemed appropriate through facility assessment which will be done by SFH in liaison with facility staff. Acceptors will collect HIV test kits on-site, together with information brochures, envelopes for putting used test kits and self-referral cards. Each potential tester will be provided with verbal information by the distributor on how to do conduct a self-test, interpret results and important post-test steps. Testers will have the option of being assisted by the distributor to do the test or will take the kit to conduct the test at their convenience.

This channel is expected to increase VMMC uptake by embracing potential clients and will also capture clients who may not opt to test using standard HTC and is expected to increase HIV testing uptake. Routine VCT or PITC at the facility will continue to be available as provided by the health facility for those clients opting for it.

HIVST kits will not be given to the third parties to avoid distortion of information once they are issued out. The health facility model will be implemented in all 16 health facilities participating in the project in Ndola, Lusaka, Kapiri-Mposhi and Choma districts.

Facility staff will be oriented to their role in the project as detailed in the facility engagement section of this standing operating procedure.

2.2 COMMUNITY LEVEL (VMMC)

A select number of existing VMMC health promoters currently creating demand for VMMC services in SFH supported sites will be trained to distribute HIVST kits in addition to VMMC demand creation. As in the facility model, all potential testers will obtain HIVST kits as well as information brochures, envelopes for putting used test kits and self-referral cards from the distributor. The target audience are potential VMMC clients within the communities surrounding the project facilities. Each potential tester will be provided with verbal information by the VMMC distributor on how to do conduct a self-test, interpret results and important post-test steps, particularly linkage to VMMC for negative males. Testers will have the option of being assisted by the distributor to do the test or will take the kit to conduct the test at their convenience.

This activity will be carried out during regular VMMC demand creation visits in the communities within designated zones of the health facility catchment areas using currently used interpersonal (IPC) approaches that include one-on-one discussion with potential clients in homes and "hot spots" (areas where potential VMMC clients are found such as market places) and large group discussions. In addition to demand creation through interpersonal communication, drama and road shows will be employed. This testing channel is expected to increase VMMC intake by reaching out to potential clients who may have not accessed VMMC through the facility based HIV testing.

HIVST kits will not be given to the third parties to avoid distortion of information once they are issued out. The VMMC model will be implemented in select SFH-supported health facilities currently providing VMMC services in Lusaka, Kapiri-Mposhi and Choma districts.

2.3 COMMUNITY LEVEL (DEDICATED HIVST DISTRIBUTION)

A select number of community volunteers in all sixteen project facilities will be trained to distribute HIVST kits. As in the facility model, all potential testers will obtain HIVST kits as well as information brochures, envelopes for putting used test kits and self-referral cards from the distributor. The target audience general population within the communities surrounding the project facilities. Each potential tester will be provided with verbal information by the Community Distributor on how to do conduct a self-test, interpret results and important post-test steps, including linkage to confirmatory test and HIV care for positives, and VMMC for negative males. Testers will have the option of being assisted by the distributor to do the test or will take the kit to conduct the test at their convenience.

This activity will be carried out during routine distributor visits in the communities within designated zones in HF catchment area using currently used IPC approaches that include one-on-one discussion with potential clients in homes and "hot spots" such as market places and large group discussion. In addition to demand creation through IPC, drama and road shows will be employed.

This distribution channel is expected to increase HIV testing uptake by serving potential testers who may have opted out of existing HTC settings at the health facility or due to other HTC accessibility barriers. Through increased access to testing, it is envisioned that the number of people taking up post-test HIV care support and treatment (for positive testers) will also increase.

HIST kits will not be given to the third parties to avoid distortion of information once they are issued out. The model will be implemented in all 16 health facilities participating in the project in Ndola, Lusaka, Kapiri-Mposhi and Choma districts.

2.4 LINKAGE TO CARE

All testers will be encouraged to return their used test kits to designated collection boxes within the community or at the health facility. At the facility, a lockable collection box similar to a tender box will be placed at a designated place within the facility, likely in the outpatient department.¹ A similar box will be placed within the community in a place that the community decides upon.² Clients will be encouraged to return the used kits be in sealed envelopes with a barcode on the inside as an identifier to any of these available collection boxes. This information will be given to the potential tester when being given an HIVST kit. The collection box keys will be kept by the STAR Programme Officer based at the SFH Regional Office. The program officer will collect the delivered kits from each collection box once a week and transport the sealed envelopes to the regional office for reading of results. None of the HIVST distributors will have access to the delivered used test kits for purposes of confidentiality; reading of results will be done by the programme officer and verified by the M&E officer and recorded in the database. At the time of collecting the sealed envelopes, the program officer will also collect the self-referral cards that will be handed in by the testers to obtain number of people who returned for post-test results.

The client's results and access to post-test services will be linked using the barcodes on the sealed envelopes and on the referral cards to the matching number captured in the database. The database, which will be managed by the M&E Officer at the SFH Regional Office will have client level information from the client intake forms filled in by the distributors using electronic tablets; this information will later be completed in the database with test results and access to post-test services from the returned used test kits and referral cards using the barcode to match data. Regional level data from the database will be accessed by the Research, Monitoring and Evaluation and program staff at SFH Headquarters who will aggregate and analyse the data for the project. As needed relevant results will be shared with ZAMBART.

Post-test follow-up in the community visits at tester's homes will be conducted by the distributor if the tester had consented to such a visit upon obtaining the test kit agreed.

2.5 BARCODES

SFH has devised a barcode system to use as a unique identifier for each client who obtains a HIVST kit and to also assist track client results and access to post-test services. The barcode will use human readable numbers as follows: each code will include the district code (two digits) followed by the facility code (two digits) and lastly the client codes (five digits) to develop a unique identifier with nine digits on the barcode. Table I below shows the codes for the districts and respective facilities.

¹ Each facility is unique in its set up. The STAR project team will engage the facilities on the most suitable place for the collection boxes

² This discussion will be part of the community engagement session.

Table I: District and Facility Codes

District	District Code	Health Facility	Health Facility Code	Examples of Client codes (ranging from 00001 -10000)	Example of Barcode
Ndola	01	Twapia *	11	00001 00002 00003	01/11/00001 01/11/00002 01/11/00003
		New Masala	12		01/12/00001
		Nkwazi	13		
		Kawama	14		
Kapiri	02	Kapiri Urban	21		
		Chilumba	22		
		/Nkole*	23		
		/Mpunde*	24		
Choma	04	Mbabala*	41		
		/Batoka*	42		
		Masuku Mission	43		
		Railyway Surgery	44		
Lusaka	03	Ngombe/*	31		
		George	32		
		Chilenje	33		
		Kaunda Square	34		

*Facilities with asterisks are STAR Zambart study sites for randomization..

The barcodes will be produced in quadruplet copies; the first barcode will be stuck on the distributor register, the second one inside envelope to be used by the client to deliver used test kits, and the third one will be stuck on the self-referral card. The fourth barcode will be placed on the return test kit card. The distributor will issue the envelope, return test kit card and self-referral card to the client together with the HIVST kit.

2.6 HEALTH FACILITY ENGAGEMENT AND SENSITIZATION

After approval to conduct the STAR project has been obtained from the Ministry of Health (MOH) headquarters, the SFH STAR team will proceed to introduce the project to the provincial and district medical offices through a series of meetings at that level. Once the project has been introduced to the district and provincial medical offices, the participating facilities will be engaged through series of meetings that firstly presents the proposed project approaches and expected outcomes and secondly maps out available facility resources such as space and community volunteers that the project will work with. The meetings will also address any questions or concerns facility staff may have concerning the impact of the project on the facility operations and their individual work and will also highlight expected roles and responsibilities of the health facility staff. The project will endeavour to ensure that facility staff are not encumbered with undue additional work as most of the work be done paid community volunteers recruited for the project.

However the facility staff have a crucial role to play in the success of this project. The expected roles and responsibilities as well as areas of collaboration with SFH include the following:

- 2.6.1 The HIVST kits that will be used by the distributors will be stored at the health facility in the area where the facility stores their regular HIV test kits and other medical consumables

- 2.6.2 The distributors will be selected from within the facility catchment area using criteria developed by SFH in consultation with the facility staff; all distributors will be recruited in liaison with the facility staff;
- 2.6.3 For the health facility model, SFH will work with facility staff to find a suitable location for the facility distributor to operate from;
- 2.6.4 Community engagement will be done in consultation with the facility staff;
- 2.6.5 The self-referral cards will be completed by the facility distributor however in the event that the facility distributor is not available, relevant facility staff at the VCT and VMMC departments will be oriented on how to fill in the cards. Furthermore, we expect that the facility staff in these areas will indicate the term “OFT” in the VCT and VMMC registers to show that client had undertaken HIVST prior to seeking the particular service at the health facilities;
- 2.6.6 Staff at the VCT department will be oriented to the fact that HIVOFT are screening tests and that confirmatory testing is required for those testing positive using HIVOFT; those testing negative do not require confirmatory testing;
- 2.6.7 Staff at the VMMC department will be oriented to the need for the department to accept verbal reports of a positive or negative test of the tester using OFT without repeating the tests and proceed to assess eligibility of the client for VMMC using the set VMMC criteria; clients providing a verbal positive results will require confirmatory testing as per facility procedure. In line with this, the MOH VMMC Coordinator will be engaged to facilitate this process as well as the national VMMC technical working group and;
- 2.6.8 SFH will hold monthly meetings with the facilities to update on progress of implementation and chart the way forward.

2.7 COMMUNITY ENGAGEMENT AND SENSITIZATION

The community engagement and sensitization will be done in full consultation with the health facility. The first part of the facility engagement will involve having a series of meetings with select community gatekeepers and opinion leaders such as members of the Neighbourhood Health Committees, Community Advisory Boards and leaders of the local community churches two – four weeks before HIVST kit distribution begins. These meetings will serve to introduce the project to the community so that when HIVST kit distribution begins, communities are fully aware of the project. Following these meetings, one week before kit distribution begins, wider community sensitization will be undertaken in the form of public address (PA) announcements in the facility catchment area and drama shows in select areas such as market places and the health facility.

3.0 TOOLS

A number of data collection tools will be used to collect project specific data depending by the project staff and distributors. The tools are listed below:

- i. Client Intake Form
- ii. HIV Self-Testing Register
- iii. HIV Self-Testing Referral Card
- iv. Returned Used Test Kit Card

- v. Social Harms Reporting tool
- vi. Stock Control Cards
- vii. Report and Requisition for Facility HIVST

3.1 CLIENT INTAKE FORM

The Client Intake Form (CIF) will be used to record client's demographics, history, linkage as well as testing data.

The CIF comprises of five (5) sections for which it is a requirement that all fields are accurately filled in for it to be considered complete. Each sub-section is briefly described below, and the data entry expectations are clearly defined. The Community, Facility and VMMC HIV Self-Testing Distributors will complete the introductory section as well as sections A to C of the form using an electronic tablet as they enrol clients. In cases where the tablet battery is low and for any another reason that the electronic tablets cannot be used to capture the data, the distributors will use the hard copy version of the CIF to collect that data and transfer the client details to the tablet once the tablet is ready for use. The filled in hard copy versions of the CIF will be collected from the distributor at the end of each month for record and safe keeping. The distributors will click the send button upon verifying that all the client details and sections are complete, thus enabling the CIF to be uploaded on the main database at the regional office as well as the Society for Family Health (SFH) HQ server. The electronic versions of the CIF will have drop-down menus and skip options to make it as simple as possible for the distributor to use. Section D of the CIF constitutes the linkage portion and will be filled in by the Management Information Systems Assistants (MIS) at regional office using data points from the Self-Referral card and results from the Returned used Test kit Cards. This section will not appear on the distributor's electronic version of the CIF but will appear in the main database to allow inputting of data by the MIS.

3.1.1 Introduction

3.1.1.1 Barcode:

The distributor will paste the barcode right in the box on the client Intake form. The barcode will help identify clients and link all data captured to the right.

In an event that the distributor is using the tablet, the barcode will have to be typed in or scanned for the particular client to minimise errors.

3.1. 1.2 Date Test Kit given

This is the date when the client was issued with the HIVST kit. It should be filled out in the format of DD/MM/YYYY

3.1.1.3 Distribution Model

This refers to the model of implementation for distributing the HIVST kits. This field requires to record whether the test kit is being distributed at the facility, VMMC or Community model.

3.1.1.4 District

This is the official district name as assigned by the government for the Republic of Zambia to the region where the health facility is located.

3.1. 1.5 Province

This is the official province name as assigned by the Government of the Republic of Zambia to the region where the district is located. The field should be completed together with the district name.

3.1.1.6 Clients phone number

This is a required field and must be filled with either 1) a complete phone number, or 2) an indication that the client was asked for this information but either “refused” or had “no number”, which should be entered using 000000000. The number to be captured is the client’s own number and not another person’s. The phone number will be nine (9) digits.

3.1.1.7 Health Facility Linked to

This is the facility that the client is linked to for delivery of the Self-Referral form by the distributor at the time the HIVST kit is issued and described as the facility associated within the catchment area from which the distributor is working.

3.1.1.8 Home Address

This is a REQUIRED field and must be filled as the actual physical address for the client. If for some reason the client does not know the physical address, the nearest landmark to their home and or name of village/ community must be recorded.

3.1.1.9 Age

This is age of the client at the date of receiving the HIVST kit which should be captured in numeral. If the client does not remember their exact age, the distributor will fill in the number “00”.

3.1.1.10 Sex

This is the gender of the client and should have either the male or female option ticked. It is a required field and must be entered.

3.1.1.11 Marital Status

This is the marital status of the client and it should have one of the following options ticked: Single, Married, Separated, Divorced or Widowed.

3.1.1.12 Education

This is the client’s highest level of education. Each client should be asked this in order to ascertain social demographics of HIVST. Only one option should be selected: None, Primary, Secondary or Tertiary.

3.1.1.13 Occupation

This is the client’s profession and one of the following options must be ticked. i.e. self – employed, employed or unemployed.

3.1.1.14 Distributor ID Number/name

This number will comprise the District code, facility code, serial number of distributor and initials e.g. 04-44-01-PQ. Each distributor will be required to key in their assigned ID.

3.1.2 Section A: Assessment

The assessment section consists of nine (9) fields which should give an indication of the clients known language, and additional background information.

- 3.1.2.1 Which of the following languages are you most fluent in? The distributor should ONE language that the client is most fluent in. i.e. Tonga, Nyanja, Bemba or English.
- 3.1.2.2 Client receiving test kit with partner? The distributor should tick yes or no if they are receiving the kit with the partner present.
- 3.1.2.3 Has your partner tested for HIV in the last 12 months? The distributor should indicate one of the responses as provided by the client: i.e. yes, no, don't know or not applicable if one does not have a partner.
- 3.1.2.4 Have you tested for HIV before? The distributor should tick yes or no based on the client's response.
- 3.1.2.5 If yes, how long ago was the test done? If the client tested for HIV in the past, one of the following responses should be ticked: Less than 3 months, 4 to 6 months, 7-12 months or more than 12 months.
- 3.1.2.6 If tested, what was your result? One of the following responses must be captured: positive, negative, don't know or decline.
- 3.1.2.7 Are you on Anti-Retroviral Therapy (ART)? The distributor must capture one of the following responses as provided by the client: yes, no or decline.
- 3.1.2.8 In the last 12 months, how many sexual partners have you had sex with, without a condom? The distributor should indicate the response in number as provided by the client. If the client says "none", the response should be "0". If the client declines to respond, the response should be "9999".
- 3.1.2.9 Are you circumcised? This question is for MEN ONLY and one of the following responses must be captured: yes, no or decline.

3.1.3 Section B: Testing

- 3.1.3.1 How long will it take you to test? The distributor should tick only one option given by the client: within one (1) day; within one (1) week; within two (2) weeks or more than two (2) weeks. This is to ascertain how long the client feels it will take him/her to test.
- 3.1.3.2 Would you need any assistance from the volunteer to perform HIV Self- Test? The distributor should indicate yes or no as provided by the client.
- 3.1.3.3. If yes, what kind of assistance? The distributor should tick one of the following responses as provided by the client: Distributor present observing only, Distributor assisting with testing only, Distributor assisting with testing and reading results or Distributor assisting with reading of results only.

3.1.4 Section C: Linkage

- 3.1.4.1. What will be your preferred location for return of your used kit? The distributor should indicate one of the following options as provided by the client: Clinic, Community or Distributor.
- 3.1.4.2 Which facility do you prefer to go to for HIV care/ support services? The distributor should indicate yes or no based on the responses provided by the client.

- 3.1.4.3 Are you willing to be contacted by the distributor for further support/care after the self-test? The distributor should indicate yes or no based on the response given by the client.
- 3.1.4.4 If yes, how do you want to be contacted? One of the following responses should be ticked: by mobile phone or at home/other setting.
- 3.1.4.5 When do you want to be followed up? One of the following options should be selected as provided by the client: within one (1) week, within two (2) weeks, within one (1) month or over one (1) month.

3.1.5 Section D: For Official Use

NOT TO BE FILLED BY THE DISTRIBUTOR. The MIS will capture the information on the questions below based on the information provided on the HIV Self- Testing Referral Card and Returned Used Test Kit Card by the client.

- 3.1.5.1 Did client receive post-test services? The MIS capture yes or no based on the client's responses on the Referral card.
- 3.1.5.2 If yes, what service was it? The MIS will capture confirmatory HIV test, VMMC or other post-test services as indicated on the client's Referral card.
- 3.1.5.3 Date for post-test services: This is the date that the post-test services were offered to the client as indicated on the HIV Self- Testing Referral Card.
- 3.1.5.4 What was the HIV self-test result? This is the result as read from the Returned Used test kit by the STAR Programme Officer and Management Information System (MIS) Assistant .i.e. Positive, negative, indeterminate or unknown.

3.2 HIV SELF TESTING REFERRAL CARD

The HIV Self-Testing Referral card will be issued to the client together with the HIVST kit. The card will have a barcode pasted right at in the box at the back by the distributor to help facilities identify individuals who self-tested in the community and have come to access post-test results as well as link the access of post-test services by client with the client level data in the database.

- 3.2.1 Date: The date should be filled in by the Distributor on the day that the client is given the referral slip and HIVST kit.
- 3.2.2 ATTENTION: STAFF ON DUTY this is the addressee
- 3.2.3 Health Facility: This is the name of the Health facility where the client will be linking for care
- 3.2.4 District: This is the official district name where the health facility is located as assigned by the government for the Republic of Zambia.
- 3.2.5 I hereby send: The distributor will write the name of the client
- 3.2.6 Sex: This is the gender of the client and should have either the male or female option ticked. It is a required field and should be entered by the distributor.

- 3.2.7 Age: This is age of the client at the date of receiving the HIVST kit which should be captured in numeral. If client does not remember their exact age, the distributor will indicate "00".
- 3.2.8 Referred by: This is the name of the distributor that refers the client to the named facility following the issuance of HIVST kit.
- 3.2.9 Signature: This is the signature of the distributor
- 3.2.10 Contact number: This is the distributors contact number

Sections 3.2.1 to 3.2.10 will be filled in by the distributor who gives the self-referral card and HIVST kits to the client.

- 3.2.11 Department receiving client: This is to be filled ONLY by clinic staff /Distributor at the facility. The clinic staff/ distributor at the facility will tick one of the boxes to indicate the post-test service that the client has been referred for being Confirmatory Test or VMMC. The clinic staff/distributor at the facility will complete all information in this section as per post-test service the client has received, include the date and ART number if client is enrolled in ART. The Referral Card is to be filed in the designated area by the facility/ health staff.

The Referral Slips will later be collected by the STAR Programme Officer / Medical Detailer and be handed to the MIS Staff at Region Office for entering all the data in the data-base.

3.3 RETURN USED TEST KIT CARD

The card is to be given to the client by the distributor upon being issued with the HIV Self-Test Kit and the Referral Slip. The distributor will paste the barcode in the required box and emphasize the need for completion of all fields by the client after taking the HIV self-test and before returning the used test kit card to the facility.

- 3.3.1 Age: This is age of the client at the time of performing the HIV self-test which should be captured in numeral. If the client does not remember their exact age, they will fill in the number "00".
- 3.3.2 Have you ever tested for HIV before? The client will select either yes or no
- 3.3.3 What was your previous HIV test result? The client will select either negative, positive or I don't know.
- 3.3.4 Are you currently taking ARVs? The Client will select yes or no.
- 3.3.5 When did you perform the HIV self-test? This is the date that the client undertook the HIV self-test which must be indicated as DD/MM/YYYY.
- 3.3.6 What result did you read on the self-test kit? This is the result as read by the client after performing the HIV-self test and must be indicated as negative, positive or invalid.
- 3.3.7 How easy or difficult did you find the process of self- testing? This is the clients description on the experience whilst undertaking the HIV self-test which would be categorized as being very easy, easy, difficult or very difficult.

****NOTE: The distributor will NOT fill in any part of this form except when the client requests for assistance.**

3.4 SOCIAL HARM TOOL

- 3.4.1 This tool will record all undesired harmful effects resulting from a social event or any other intervention such as an HIV test result, social harm or adverse effects that the clients may experience following the HIVST.
- 3.4.2 The distributor will follow up with the clients following the HIVST and note adverse effects including but not limited to: suicide, self-harm, gender based violence, stigma or discrimination from family or community, problems with personal relationships, and other events not listed here.
- 3.4.4 **Recording and reporting of incidents/ social harms:** The distributor will indicate the name of the community, person reporting the incident to them, month, and date report was generated as well as date received by supervisor. In addition, the type of incident will be noted, date of occurrence, who reported and whether it is serious or not:
- 3.4.5 In addition, the distributor will also fill in the form for the **serious incident**, indicating their **name, date of reporting, site/location, Date that the event occurred**, including the approximate time of occurrence and description of the event. The section on action taken is to be completed by the supervisor who will also give an indication if any referrals were provided to other organizations or agencies as needed to help address the problem.

****NOTE: DEFINITIONS** - *Serious incident refers to suicide, gender based violence, or self-harm. The distributor will indicate the nature of incident whether serious or not serious.*

3.5 HIV SELF-TESTING REGISTER

- 3.5.1 The distributor will complete the register by filling their name, district and health facility as well as tick one option for the distribution model: VMMC, Health Facility or Community.
- 3.5.2 Client's details: The distributor will complete the serial number, indicate the consent given by a tick, client's name, home address, age, sex as well as the date that the client is issued with the HIVST kit, attach the barcode slip in this box to assist link/identification of the client with other tools with the same barcode.
- 3.5.3 Stock balance: Stock received is the number of HIVST kits that the Distributor received at the start or at the point of restocking, Number (#) issued is the quantity of HIVST kits issued to client say one (1) and the balance is the number of HIVST kits after issuing

the client with one. For example, the distributor received 20 HIVST kits at the start, and issued the client with one (1) test kit, the balance would be 39. This will help the distributor track stock.

- 3.5.4 The table at the bottom of the page: Date: the distributor should indicate the date as well as the number of people reached with HIVST messages per day.

NOTE: The distributor may ONLY issue a second HIVST kit if the client reports that the results were invalid or HIVST kit was lost or destroyed. This should be noted by the distributor on the remarks column on the register. For invalid results, the distributor should fill in a new CIF and barcode and issue the client with the new return test kit card and referral card. For lost HIVST kit, the distributor will only issue a new HIVST kit as the client will not have used the Return Test Kit Card, envelope and referral card. The MIS will use a copy of the register to confirm the repeat test or re-issued HIVST kit as well as check all the other details for the client to be the same except the barcode in the case of invalid results.

3.6 STOCK CONTROL: REGIONAL AND HEALTH FACILITY HIVST STOCK CONTROL CARDS

The regional card stock control card will be completed by regional staff and the facility card by the health facility distributor to keep track of the quantities of the HIVST kits received and distributed to a health facility by the regional office and distributors by the facility distributor respectively. At regional level the Finance and Admin officers will have oversight of the stock controls working with the STAR program officer while at the facility level the Program officer will provide oversight to the work of the facility distributor. The supply chain section of this SOP provides more details.

- 3.6.1 Batch No: This is the number that appears on the box for the HIVST kits issued to the distributor or facility.
- 3.6.2 Maximum level: This refers to the highest number of kits to be issued whilst the minimum level refers to the least number of HIVST kits that the facility or distributor is expected to have at any given time to facilitate re-ordering and avoid stock outs.
- 3.6.3 Facility: this is the name of the facility receiving the kits.
- 3.6.4 District: Refers to the district that the facility is located.
- 3.6.5 Date: This is the date at which the facility staff receives HIVST kits from the Region or issues the HIVST kits to distributors.
- 3.6.6 Issued to or received from: This is the name of the distributor by model who issues or is issued with the HIVST kits or the health facility to which the kits are issued to.
- 3.6.7 Quantity received (+): This refers to the number of HIVST kits received by the regional office or health facility

- 3.6.8 Quantity issued (-): This refers to the number of HIVST kits issued to by the regional office to a health facility or facility distributor to other distributors
- 3.6.9 Loss adjustments: This refers to the loss adjustments made on the HIVST kits which ideally should be zero.
- 3.6.10 Expiry date: This refers to the expiry date of the HIVST kits.
- 3.6.11 Balance: This refers to the number of HIVST kits remaining with the region or facility distributor after issuing kits to the facility or distributors respectively.
- 3.6.12 Name/Signature: The name of the Facility Distributor for the Facility Stock card and Regional Staff for the Regional Stock card. The two will have to sign the stock cards once all the lines are completed on a sheet.
- 3.6.13 Remarks: These are notes or observations as made by the Facility distributor.

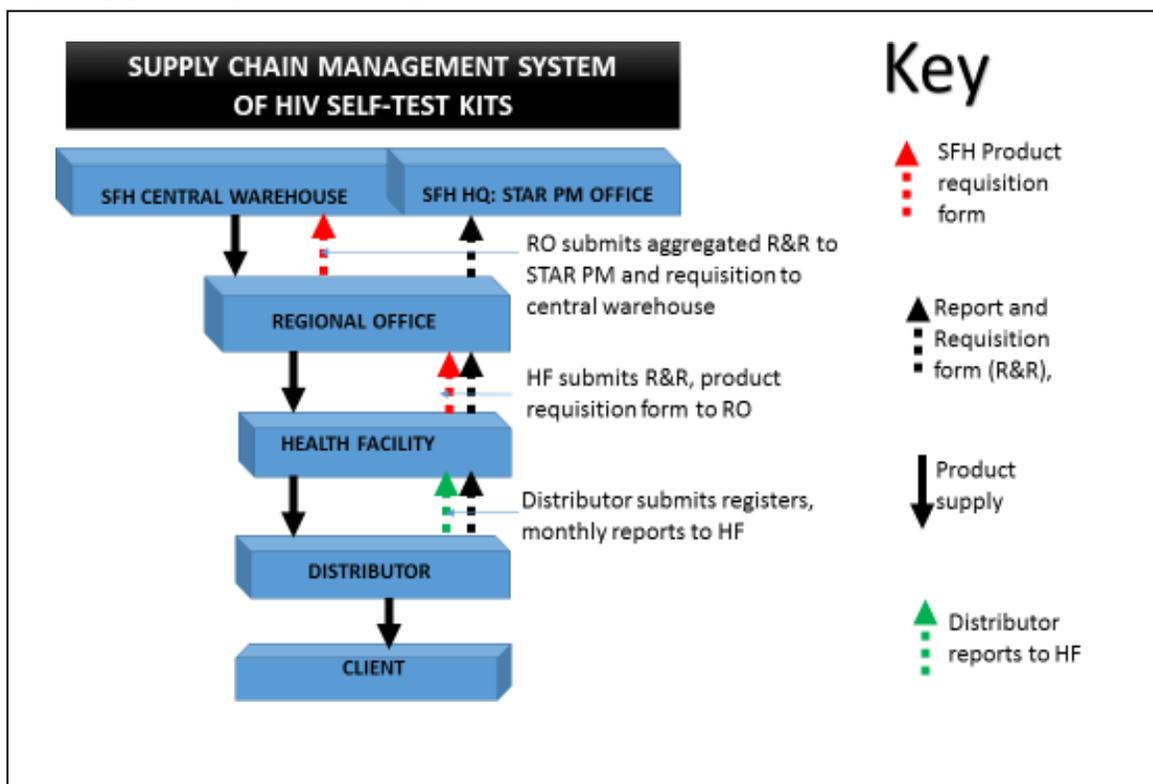
3.7 REPORT AND REQUISITION FORM FOR HIV SELF TEST KITS

REGIONAL AND FACILITY REPORT AND REQUISITION FORMS FOR HIV SELF TEST KITS

- 3.7.1 Reporting period from/to: This refers to the reporting period indicating the start and end date.
- 3.7.2 Maximum stock level: The highest number of HIVST kits applicable to the region or health facility
- 3.7.3 Re-order level: The lowest number of kits applicable to that level to allow re-ordering of new stock
- 3.7.4 Region: The name of the region reporting
- 3.7.5 District: The name of the district for which the report is completed
- 3.7.6 Unit: This refers to the entity
- 3.7.8 Beginning Balance of facility + CBD stock/last issue: Refers to number of HIVST kits at the start of the month plus CBD stock which were last issued.
- 3.7.9 Total Quantity Received during the month: Refers to the total number of HIVST kits received during the reporting month
- 3.7.10 Total Quantity dispensed for the month: Refers to the total number of HIVST kits distributed during the reporting month
- 3.7.11 Losses and Adjustments: Refers to any losses incurred and adjustments made during the reporting month
- 3.7.12 Physical Count of facility and CBD stock at the end of the month: Refers to the actual number of HIVST kits as counted by the region and facility including the stocks at the end of the reporting month.
- 3.7.13 Average Monthly Consumption (AMC) = (current + previous 2 months consumption) / 3: Refers to average monthly consumption which to be calculated by adding the current and two previous month's consumption divided by three.
- 3.7.14 Maximum Quantity (G x 3): Refers to the maximum number of HIVST kits for the facility or the region
- 3.7.15 Order Quantity (H - F): Refers to the number of HIVST kits ordered by the facility or the region

- 3.7.16 Explanation for Losses/Adjustments: Refers to explanations for the losses or adjustments incurred during the reporting and requisitioning month
- 3.7.17 Remarks: Refers to the notes and or observations made by personnel completing the form
- 3.7.18 Completed by, signature and date: Refers to the name, signature and date for regional staff or Facility based distributor completing the report.
- 3.7.19 Authorized by, signature and date: Refers to the name, position, signature of staff authorizing the reporting and requisition for HIVSTK for the month. It is a requirement that the date be completed too.
- 3.7.20 Ordered by, signature and date: Refers to the name/position and signature of person making the order for the month.

4.0 SUPPLY CHAIN MANAGEMENT



4.1 Community Based Distributor Level:

- 4.1.1 Community distributor will draw kits from the health facility through the facility community
- 4.1.2 Maximum stock levels of HIV self-test kits – 40 (representative of one week’s work when distributing 7-8 kits a day for 5 days)

- 4.1.3 Minimum stock levels for community based distributor – 10; training will be provided to community distributor to ensure that when they have 10 kits remaining, they need to re-order from the facility to re-stock kits to the maximum level.
- 4.1.4 Community based distributors re-stock from facility as and when their stock levels run low.
- 4.1.5 The CBD register will help the CBD to track number of kits s/he has at any given moment and will also be used to re-stock kits at the health facility.
- 4.1.6 The SFH Medical Detailer will work closely with the community based distributor to ensure good management of stocks by the CBD.

4.2 Health Facility Level

- 4.2.1 Kits will be stored at the health facility pharmacy
- 4.2.2 Facility community distributor will work with SFH STAR medical detailer, program officer and the facility pharmacy in-charge to re-stock the community based distributors with kits.
- 4.2.3 The facility community distributor records issues in the facility stock control as and when issues are made.
- 4.2.4 The SFH program officer is responsible for compiling the report and requisition (R&R) form that consolidates each facility's supply chain issues.
- 4.2.5 Facility community distributors will be provided with guidance on segregation of duties to ensure efficiency for all their expected duties³.
- 4.2.6 R&R form will be used to obtain stocks from the SFH regional office on a monthly basis and is submitted on the 5th day of the month; emergency orders will be done if facility reaches minimum levels of stocks before month end report (using same R&R form).
- 4.2.7 Maximum stock levels for the facility is 2500 kits (represents 6 weeks supplies of kits assuming 10 distributors per facility distributing 160 – 170 kits per month) and minimum is 800 (approximately two weeks supply)⁴.

4.3 Regional Level

- 4.3.1 Regional level will get stock from SFH central warehouse.
- 4.3.2 SFH Finance and Administration Officer will compile the R&R obtained from all facilities and forward a consolidated R&R to SFH central warehouse (with a report to STAR Program manager).

³ Robust training required for facility distributor. Close supervision is required to ensure this efficiency. The program officer is responsible for this aspect

⁴ Once implementation begins, this will be reviewed closely facility by facility to ensure we are not overstocking or understocking and individual facility level minimums and maximums will be adjusted accordingly

- 4.3.3 Maximum stock levels for the region is 10,000 kits (represents one six weeks supply of kits for 4 health facilities with the assumption of distribution of 160 – 170 kits per CBD/month for 10 CBDS at each health facility).
- 4.3.4 Minimum stock levels for the regional level is 3500 kits (two weeks supply for 4 health facilities).
- 4.3.5 Regional levels will submit R&R forms to SFH central warehouse for re-stocking once a month on the 10th day; emergency re-stocking using the same R&R form can be done if the region reaches minimum stock levels before the month end.

4.4 SFH Central Warehouse:

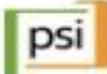
- 4.4.1 The SFH keeps all the organizations bulk stores of HIV test kits.
- 4.4.2 The Warehouse Manager receives the R&R forms from the regions and prepares number of kits to be distributed to each region.
- 4.4.3 Central warehouse sends each regions requirements by the 15th of each month.
- 4.4.4 The STAR program manager works with the Warehouse manager to monitor central level stock levels and provides guidance on need to re-stock with PSI.

APPENDICES

ANNEX I - CLIENT INTAKE FORM

HIV SELF TESTING CLIENT INTAKE FORM			
BARCODE: _____	Date Test kit given _____ / _____ / _____		
Distribution Model (Facility/VMMC/CBD) _____	District _____	Clients' phone number _____	
Province _____	Home address _____		
Health Facility linked to: _____	Number of living children _____		
Age _____ Sex <input type="radio"/> M <input type="radio"/> F	Marital Status <input type="radio"/> Single <input type="radio"/> Married <input type="radio"/> Separated <input type="radio"/> Divorced <input type="radio"/> Widowed		
Education <input type="radio"/> None <input type="radio"/> Primary <input type="radio"/> Secondary <input type="radio"/> Tertiary	Occupation <input type="radio"/> Self-employed <input type="radio"/> Employed <input type="radio"/> Unemployed		
Distributor ID Number/ Name: _____			
A. ASSESSMENT 1. Which of the following languages are you most fluent in? <input type="radio"/> English <input type="radio"/> Nyanja <input type="radio"/> Bemba <input type="radio"/> Tonga 2. Client receiving kit with partner? <input type="radio"/> Yes <input type="radio"/> No 3. Has your partner tested for HIV in the last 12 months? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know <input type="radio"/> Not Applicable 4. Have you tested for HIV before? <input type="radio"/> Yes <input type="radio"/> No 5. If yes, how long ago was the test done? <input type="radio"/> 0 to 3 months <input type="radio"/> 4 to 6 months <input type="radio"/> 7 to 12 months <input type="radio"/> More than 12 months 6. If tested, what was your result? <input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Don't Know <input type="radio"/> Decline	7. Are you on Anti-Retroviral Therapy (ART)? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Decline 8. In the last 12 months, how many sexual partners have you had sex with, without a condom? _____ 9. Are you circumcised? (For men only)? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Decline B. TESTING 1. How long will it take you to test? <input type="radio"/> Within 1 day <input type="radio"/> Within 1 week <input type="radio"/> Within 2 weeks <input type="radio"/> More than 2 weeks 2. Would you need any assistance from the volunteer to perform HIV Self-test? <input type="radio"/> Yes <input type="radio"/> No	3. If yes, what kind of assistance? <input type="radio"/> Distributor present observing only <input type="radio"/> Distributor assisting with testing only <input type="radio"/> Distributor assisting with testing and reading of results <input type="radio"/> Distributor assisting with reading of results only C. LINKAGE 1. What will be your preferred location for return of your used kit? <input type="radio"/> Clinic <input type="radio"/> Community <input type="radio"/> Distributor 2. Which facility do you prefer to go to for HIV care/support services? <input type="radio"/> Outside Catchment area <input type="radio"/> Within Catchment area 3. Are you willing to be contacted by the distributor for further support/care after the self-test? <input type="radio"/> Yes <input type="radio"/> No 4. If yes, how do you want to be contacted? <input type="radio"/> By mobile phone <input type="radio"/> At home or other setting	5. When do you want to be followed up? <input type="radio"/> Within 1 week <input type="radio"/> Within 2 weeks <input type="radio"/> Within 1 month <input type="radio"/> Over 1 month D. FOR OFFICIAL USE <i>NOT to be filled in by the Distributor.</i> 1. Did client receive post-test services? <input type="radio"/> Yes <input type="radio"/> No 2. If yes, what service was it? <input type="radio"/> Confirmatory HIV Test <input type="radio"/> VMMC <input type="radio"/> Other post-test services 3. Date for post-test services: _____ DD / MM / YYYY 4. What was the HIV self-test result? <input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Indeterminate <input type="radio"/> Unknown

ANNEX II: HIV SELF TESTING - REFERRAL SLIP

<div style="border: 1px solid black; width: 200px; height: 40px; margin: 20px auto; text-align: center; font-size: 8px;">Attach Barcode Here!</div> <div style="text-align: center; margin-top: 100px;">  <p>UNITED PSI HIV SELF-TESTING AFRICA</p> </div>	<div style="text-align: center; margin-bottom: 20px;">  <p>Ministry of Health</p> </div> <div style="text-align: center; margin-bottom: 20px;"> <p>HIV SELF TESTING REFERRAL CARD</p> </div> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>UNITED PSI HIV SELF-TESTING AFRICA</p> </div> <div style="text-align: center;">  <p>psi</p> </div> <div style="text-align: center;">  <p>SFH Strengthening Family Health</p> </div> </div>
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<p>Date: ___/___/20___</p> <p>ATTENTION: THE STAFF ON DUTY</p> <p>Health Facility _____</p> <p>District: _____</p> <p>I hereby send _____ Sex: _____ aged _____ years to you for further investigations and care after she/he performed an HIV self-test using oral fluid (OrasQuick).</p> <p>Referred by: _____</p> <p>Signature: _____</p> <p>Contact Number _____</p> <p><u>Department receiving client</u> (To be filled in by clinic staff)</p> <p>Confirmatory Test <input type="checkbox"/></p> <p>VMHC <input type="checkbox"/></p> <p>Other specify: _____</p>	<p>Was confirmatory HIV testing done?</p> <p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Result of Confirmatory HIV testing (Tick one):</p> <p>Non- Reactive <input type="checkbox"/></p> <p>Reactive <input type="checkbox"/></p> <p>Indeterminate <input type="checkbox"/></p> <p>Unknown <input type="checkbox"/></p> <p>Enrolled into ART? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Date enrolled on ART: ___/___/20___</p> <p>If enrolled in ART, provide the ART Number:</p>
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ANNEX: III SOCIAL HARMS TOOL
SOCIAL HARMS/ INCIDENTS IDENTIFICATION AND REPORTING TOOL

DEFINITION OF INCIDENTS/ SOCIAL HARMS

An adverse effect of Social harm is an undesired harmful effect resulting from a social event or any other intervention such as an HIV test result.

IDENTIFICATION OF INCIDENTS/ SOCIAL HARMS

1. Stigma or discrimination from family or community
2. Problems with personal relationships
3. Gender based violence
4. Suicide
5. Self-harm
6. Other (specify) _____

****NOTE:** Definitions - Serious incident refers to suicide, gender based violence. The distributor will indicate the nature of incident whether serious or not serious and may imply difficulty in personal relationships/stigma or discrimination from family or community.

RECORDING AND REPORTING OF INCIDENTS/ SOCIAL HARMS

Non serious incident

Community:		Month:	
Name of person Reporting:		Date generated:	
		Date received by Supervisor:	
Type of incident	Date of incident	Reported by	Serious or non-serious

SERIOUS INCIDENT (To be completed by the person compiling the incident report)

Name of person Reporting	Date:
Site:	
Date of Event:	
Approximate time of event:	
Description of event	
Action Taken (To be completed by supervisor) (Provide referrals as needed to other organizations, agencies, and service providers that may be able to help address the problem.)	

ANNEX IV: HIV SELF- TESTING REGISTER






Society for Family Health
Better Choices. Better Lives.

HIV SELF-TESTING REGISTER

Distributor Name: District: Health Facility (Name)

Distribution Channel (Tick one): VMNC Health Facility Community

SN	Verbal Consent given?	Client details						Stock Balance			Remarks
		Name	Home address	Age	Sex	Distribution Date DD/MM/YYYY	Barcode (Attach Barcode slip here)	Stock Received	# Issued	Balance	

Date (DD/MM/YYYY)	Number of People reached with HIVST Messages

