HIV **S**ELF-**T**ESTING **AFR**ICA **(STAR)** INITIATIVE

COSTS OF IMPLEMENTING HIV SELF-TESTING IN SWAZILAND AND LESOTHO

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I. Abbreviations

AF: Allocation Factor

AHF: AIDS Health Foundation

ANC: Antenatal Clinic

CITC: Client-Initiated HIV Testing & Counselling

DHIS2: District Health Information System 2

FP: Family Planning

HIVST: HIV Self-Testing

HTS: HIV Testing Services

ICER: Incremental Cost-Effectiveness Ratio

IEC: Information, Education and Communication

LOE: Level Of Effort

LOP: Life Of the Project

LSHTM: London School of Hygiene and Tropical Medicine

M&E: Monitoring and Evaluation

MNCH: Maternal Neonatal Child Health Services

MoH: Ministry of Health

NCD: Non-communicable disease

NGO: Non-Governmental Organization

NIAID: National Institute of Allergy and Infectious Diseases

NSF: National Strategic Framework

PITC: Provider-Initiated HIV Testing & Counselling

PMTCT: Prevention of Mother-To-Child Transmission

PreP: Pre-exposure Prophylaxis

PSI: Population Services International

RDT: Rapid Diagnostic Test

SNAP: Swaziland National AIDS Program

STAR: HIV Self-Testing AfRica

TAG: Technical Advisory Group

TB: Tuberculosis

UNAIDS: The Joint United Nations Programme on HIV/AIDS

VMMC: Voluntary Medical Male Circumcision

WHO: World Health Organization

II. Project summary

Summary of the Cost analysis – Swaziland and Lesotho

The HIV epidemic remains high in Swaziland and Lesotho with an estimated prevalence among those aged 15 to 49 years old of 27% and 25% respectively. While there have been tremendous efforts to close the HIV testing gap, only an estimated 62% of people living with HIV (PLHIV) in Southern Africa (84, 7% in Swaziland, 77.5% in men, 88.7% for women) know their status (1). For those living with HIV who are still undiagnosed, this means further delaying their access to treatment and maintaining a substantial risk of transmission to others. Limited access to HIV testing also prevents high-risk HIV negative individuals from accessing effective HIV prevention services such as voluntary medical male circumcision (VMMC) and pre-exposure prophylaxis (PrEP). HIV self-testing (HIVST) is a relatively new approach that provides an opportunity to reach, test, and diagnose or prevent infection among populations who were previously considered unreachable. HIVST, when used as test for triage, also has the potential to reduce costs and time savings for the health delivery system and to the end use. Economic evaluations, costing by model of distribution and economic modelling of a mix of distribution models are needed to increase the evidence base on different programme implementation options for policymakers. The overall goal of this costing analysis is to estimate the costs associated with the distribution of HIVST kits through various delivery models. The project aims to determine the costs of introducing and running HIVST kits distribution for the following models:

- ✓ Swaziland:
    1. Secondary distribution through Antenatal clinic at public hospitals
    2. Fixed HTS "New Start" franchise and AIDS Health Foundation Centres
    3. VMMC fixed site
    4. VMMC community mobilisers
    5. Workplace distribution (through private public partnerships)

- ✓ Lesotho:
    1. Secondary distribution through Maternal Neonatal Child Health Services at public hospitals
    2. "New Start" franchise HTS centres
    3. "New Start" HTS outreach services
    4. Uniformed Forces Health facility

We will conduct a full economic costing, using a provider perspective and capturing start up, capital and recurrent costs. The analysis aims to estimate the full cost of introducing HIVST and assess cost drivers within each distribution model. We will estimate total and unit costs per HIVST kit distributed and per HIV positive person linked to care. Our comparator will be the existing HIV testing services in these countries.

III. General information

Title: HIV SELF-TESTING AFRICA (STAR) INITIATIVE - COSTS OF IMPLEMENTING HIV SELF-TESTING IN SWAZILAND AND LESOTHO

Date: JANUARY 2018

Funder: The funding body for the UNITAID/PSI HIV STAR project is UNITAID, is a global health initiative housed within WHO that supports the development and optimisation of robust, high-quality and low-cost products specifically intended to meet the diagnostic and pharmaceutical needs of HIV, tuberculosis (TB) and malaria programmes in low-resource countries. The physical address is: Chemin de Blandonnet 10 – BIBC III – 8th Floor, 1214 Vernier, Switzerland.

Global and local investigators' role, institution and contact information are presented in **Table 1**.

Table 1. Global and local investigators' role and contact information

Investigators	Institution	Role
Fern Terris-Prestholt, PhD (Principal Investigator)	London School of Hygiene and Tropical Medicine, 15-17 Tavistock Place, Kings Cross, London WC1H 9SH, United Kingdom	Responsible for the overall design and supervision of cross country cost studies including design, analysis and dissemination of results
Karin Hatzold, PhD	Population Services International/Society for Family Health 2nd Floor, Block B, Metropolitan Office Park, 8 Hillside Road, Parktown, Johannesburg 2193, South Africa	Principal Investigator on the multi-country STAR Initiative and oversights research implementation. Karin contributes to the development of protocols, study design, technical oversight and will coordinate data collection, interpretation and dissemination of results
Marc d'Elbée, Pharm.D.	London School of Hygiene and Tropical Medicine, 15-17 Tavistock Place, Kings Cross, London WC1H 9SH, United Kingdom	Developed the research protocol and will coordinate data collection, analysis and dissemination of results.
Cheryl Johnson	World Health Organization Avenue Appia 20, 1202 Genève, Switzerland	WHO lead for the STAR project
Professor Liz Corbett	Queen Elizabeth Central Hospital College of Medicine P.O. Box 30096 Chichiri Blantyre 3, Malawi	STAR Research Director

Investigators	Institution	Role
Ayanda Sikhondze (Co-Principal Investigator - Swaziland)	Population Services International, Mbabane PO Box 170, Swaziland	Contributed to the development of the research protocol, study design and will support coordination of data collection, interpretation of results and dissemination.
Makhosazana Dlamini	Population Services International, Mbabane PO Box 170, Swaziland	Overall supervisor of the HIVST program in Swaziland
Alysha Beyer	Population Services International, Mbabane PO Box 170, Swaziland	PSI Swaziland Country representative
Munyaradzi Pasipamire	Swaziland National AIDS Program, PO Box 1119, Mbabane, Cooper Centre Building, H100, Swaziland	Head of research and coordinates all research activities
Lenhle Dube	Swaziland National AIDS Program, PO Box 1119, Mbabane, Cooper Centre Building, H100, Swaziland	Focal for National HTS activities and is the point of contact for the Ministry and for facility entry for data collection
Knowledge Chipango (Co-Principal Investigator - Lesotho)	Population Services International, 138 Moshoeshoe Road Maseru, Lesotho 100	Focal point STAR Initiative in Lesotho. Contributed to the development of the protocol, study design and will support coordination of data collection, interpretation of results and dissemination
Makhahliso Jubilee	Population Services International, 138 Moshoeshoe Road Maseru, Lesotho 100	Contributed to development of the protocol, study design and will support coordination of

Investigators	Institution	Role
		data collection, interpretation of results and dissemination

IV. Rationale & background information

HIV context in Swaziland and Lesotho

An estimated 220,000 people are living with HIV in Swaziland. The national population level HIV prevalence is 27.2% among those aged 15-49 years old (2). Of those who are HIV positive, 79% are on Antiretroviral Therapy (ART) (2). Populations greatest affected by HIV in Swaziland include women (35% of all women are living with HIV, compared to 20% of men), orphans due to AIDS (24% of all children aged 0-17 years are orphans and 45% are either orphans or vulnerable) and key populations (3). HIV Testing Services (HTS) are outlined as one of the critical priority interventions aimed at addressing HIV/AIDS to reduce the HIV incidence rate to a threshold level. Currently 84% of PLHIV in Swaziland know their HIV status; there are gender discrepancies with only 77.8% of male PLHIV and 84.8% of females knowing their status. As Swaziland is intending to reach its 95/95/95 to end the epidemic in Swaziland, HIVST has been seen an important game changer in achieving these ambitious goal. Swaziland now includes HIV self-testing (HIVST) as one of the options for HIV testing and has incorporated HIVST in its national policy (4).

In Lesotho, the latest HIV estimates show that the HIV epidemic stabilized at 25% while the epidemic is higher in urban than rural areas with the prevalence at 27% and 21%, respectively (5). Lesotho is characterized by low uptake of HIV testing among men. Amongst women, 85% have ever been tested for HIV and received their results as opposed to 65% of men (5). Disclosure is very low. During this survey, only 25% of HIV+ individuals reported disclosing their status to significant others, often attributed to very high levels of stigma and discrimination (5). Innovative strategies are needed to reach those with low diagnoses, particularly the undiagnosed 25% of the male population. The country has therefore adopted HIV Self Testing and Assisted Partner Notification strategies as strongly recommended by WHO to complement and strengthen existing HTS and achieve even higher coverage (4).

HIV self-testing

Historically most countries implement a provider-based approach to HTS (6). The provider-based model requires that individuals present at an HIV screening location staffed by a dedicated provider either at the health facility, in the community, or in the home. The provider-based model for HIV testing is therefore costly (7). The

development of HIV rapid diagnostic tests (RDT) has enabled highly accurate results from HIVST even carried out by untrained lay clients (8). As HIVST requires lower human resource requirements, it could provide more cost-effective community-based HTS in comparison to current community-based models (9).

HIVST kits are already available for purchase over-the-counter in several countries, including the United States, United Kingdom and Kenya and have recently been introduced in Malawi, Zambia and Zimbabwe (10). Since December 2016, WHO has provided guidelines on HIV self-testing and partner notification to facilitate HIVST inclusion in national policies (11). National HIV programmes have adapted policy and programme documents, including algorithms and training materials, to fully accommodate HIVST.

Costs and cost-effectiveness of HIV testing and HIV self-testing

HIV self-testing is an emerging technology in Swaziland and Lesotho, and it is important to determine cost and cost-effectiveness to inform the national strategy and identify potential financial savings and efficiencies. First, it is crucial to assess previous studies' findings on costs and cost-effectiveness analyses of HTS. Multiple studies assessed facility-based HTS and reported cost per person tested and cost per HIV positive case detected. From studies conducted in Nigeria, South Africa, Kenya, Rwanda, Zambia, Malawi, Uganda, Swaziland and Zimbabwe, the facility-based HTS cost per person tested and cost per HIV positive case detected ranged between $7.40 to $12.18 and $22.78 to $1057, respectively (12-21). In 2015, a study in Swaziland reported on costs per person tested of $34.10 and cost per HIV positive detected of $133.01 when testing was delivered through integrated HIV and sexual reproductive health services (18).

Regarding HIVST costs, a cluster randomised trial study in Malawi showed the health provider cost for attending HIV positive individuals for ART initiation were lower for HIV self-testers ($19.92) compared to facility-based HTS ($22.79) (21). A cost analysis study in Malawi showed that though the provider cost per individual HIV self-tested ($8.78) was higher than the regular facility-based HIV testing service ($7.53), the mean societal costs, which includes users' costs, for HIV self-testers ($9.23) was lower than facility-based HTS $11.84 (15).

Cost-effectiveness studies on HIV testing have also been carried out. One study in South Africa applied the costing study in high and low HIV prevalence areas, and findings showed the cost of $522 per person tested and 4 gained QALYs in high HIV

prevalence areas, and cost of $635 per person tested and 5 gained QALYS in low HIV prevalence areas (22). A clinical impact study in South Africa showed the incremental cost-effectiveness ratios of $1570/QALY for HIV screening every five years and $1720/QALY for annual screening (23). A recent model-based study showed 20-year net saving of $75 million from introducing a $3 HIVST in Zimbabwe (24).

These results show that decentralisation of HTS by bringing HIVST to the community has the potential to reduce societal costs for accessing HIV testing, increase efficiency gain by not having to pay for provider costs of conducting the test and to reach people who would otherwise not test. However, there is a need to better understand how estimated costs per person tested for HIV and person identified HIV positive compares between HIVST and HIV standard of care. Provider costs for distributing HIVST need to be evaluated to inform Swaziland and Lesotho national HIV prevention strategy. Our study aims to fill these gaps by estimating incremental costs of providing HIVST in addition to existing HTS services at the various distribution channels in both countries.

V. Study goals and objectives

Between 2015 and 2017, the UNITAID/PSI HIV STAR project conducted HIVST implementation research in Malawi, Zambia and Zimbabwe to generate the evidence base required for WHO to introduce its guidelines on HIVST (10). As part of phase 2, the STAR Initiative, this study will investigate different models for distributing oral and blood based HIVST kits in Swaziland and Lesotho and their costs. Collaborators include Population Services International (PSI), the London School of Hygiene and Tropical Medicine (LSHTM), the Ministry of Health in Swaziland, the Ministry of Health and Social Welfare in Lesotho and WHO. PSI is responsible for HIVST implementation, while LSHTM is responsible for the economic evaluation and costing.

The funding body for the UNITAID/PSI HIV STAR project is UNITAID, a global health initiative housed within WHO that supports the development and optimisation of robust, high-quality and low-cost products specifically intended to meet the diagnostic and pharmaceutical needs of HIV, tuberculosis (TB) and malaria programmes in low-resource countries.

1. Overall project goal

Swaziland and Lesotho are preparing to introduce HIVST to their national HIV prevention strategy in order to reach the UN 90/90/90 and 95/95/95 goals. Cost estimates from program initiation and scale up are needed to increase the evidence base on different implementation options for policymakers. In a context with scarce resources, this costing study aims to present the total and unit costs incurred in routine HTS as compared with delivering HIVST at the distribution channels presented in **Table 2**.

Table 2. HIVST distribution models in Swaziland and Lesotho

Swaziland	**Lesotho**
Secondary distribution through Antenatal clinic at public hospital	Secondary distribution through Maternal Neonatal Child Health Services at public hospital
Fixed HTS "New Start" franchise and AIDS Health Foundation Centres	"New Start" franchise HTS centres
Integration of HIVST with VMMC services offered at a fixed site	"New Start" HTS outreach services
HIVST offered as part of VMMC community mobilisation	Uniformed Forces Health facility (Military personnel and police officers)
Workplace distribution (through private public partnerships) - mining and manufacture industry, labour and corporate institutions	

2. Overall project objectives and research questions

Research question

What are the costs of introducing and scaling up different delivery models of oral and blood based HIVST compared to the conventional HTS approaches at facility and district level?

Research objective

The primary objective of this activity is to estimate the incremental costs of distributing HIV self-testing to the general population in Swaziland and Lesotho.

This secondary objective is to model scale up costs of a combination of cost-effective models of HIVST distribution in the medium term (3 to 5 years) and longer term for purposes of financial planning, based on observed programme costs.

3. Summary of UNITAID/PSI HIV STAR activities

Between 2018 and 2020, PSI plans to provide a total of 72,224 HIVST kits to general population adults in Swaziland using multiple distribution channels in all four regions (Manzini, Hhohho, Lubombo and Shiselweni) where HIVST is currently being piloted and at provider-initiated sites in all four regions. In Lesotho, PSI plans to provide a total of 60,025 HIVST kits to general population adults using multiple distribution channels. **Table 3** provides a summary of the HIVST distribution activities in Swaziland and Lesotho. Standard operating procedures (SOP) for each HIVST distribution model can be found in **Appendix**.

Table 3. Summary of HIVST kits distribution in Swaziland and Lesotho

Swaziland						
Target populations	**Target Number of Self-Tests**				**Districts**	**Distribution model**
	2018	**2019**	**2020**	**Total**		
Adult men	3,500	3,411	4,400	11,311	Shiselweni	- Antenatal clinic at public hospital

All target groups	8,400	10,500	12,800	31,700	Manzini, Hhohho	- Fixed HTS "New Start" franchise - AIDS Health Foundation Centres
Adult men	3,000	3,200	3,500	9,700	Manzini	- PSI VMMC fixed sites
Adult men	3,641	4,800	4,600	13,041	Manzini	- PSI VMMC mobile team in demand creation activities
Workers	2,400	2400	1,672	6,472	Manzini	- Workplace through public and private partnership
TOTAL	**20,941**	**24,311**	**26,972**	**72,224**		
Lesotho						
Target populations	**Target Number of Self-Tests**				**Districts**	**Distribution model**
	2018	**2019**	**2020**	**Total**		
Pregnant women and their male partners	3,933	2,045	2,289	8,267	Thaba-Tseka, Maseru	- Maternal Neonatal Child Health Services at public hospital
All target groups	6,554	4,091	4,578	15,223	Maseru, Berea, Leribe, Mafeteng & Mohale's Hoek	- "New Start" franchise HTS centres
Young people (15-24), adult men and other highly vulnerable groups	10,487	6,136	6,867	23,490	Maseru, Berea, Leribe, Mafeteng & Mohale's Hoek	- "New Start" HTS outreach services
Adult men	5,243	3,682	4,120	13,045	Maseru, Mafeteng, Qacha's Nek, Mokhotlong, Leribe,	- Uniformed Forces Health facility

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TOTAL	**26,217**	**15,954**	**17,854**	**60,025**		

VI. Study processes

Training and study initiation

The LSHTM team will conduct a follow-on visit as soon as IRB approval is obtained to support the local team to pilot instruments and train data collectors. This will be a 1-2 week visit. Thereafter the LSHTM team will start data collection with the local partner. This will include 2 to 3 in country visits to supervise and participate in data collection which may take up to six months and 3 months for data cleaning. One local research assistant will be hired by PSI in each country to collect cost data. The research fellow based in London will coordinate and support the data collection between Lesotho and Swaziland.

Analysis of results

The analysis of results will be done collaboratively between the Swazi, Lesotho and the LSHTM based economist via Skype call and workshops where the LSHTM and local teams will meet and analyse the data together. These workshops will likely be attached to wider STAR Consortium meetings expected to happen once or twice a year. Additional workshops will be planned as necessary. Data analysis will be completed at the end of the first year. The scale up cost model will be developed during the second year of the study.

VII. Study Design and Methodology

1. Study design

The cost analysis follows the Global Health Costing Consortium (GHCC) reference case which sets standards for global health costing studies (25). The purpose of this

costing is to estimate the incremental economic costs of introducing HIVST to existing health promotion services using alternative delivery model.

Estimated costs will be incremental to existing HIV testing services (PITC and CITC) which is our comparator. Incremental costs will be measured at public hospital, "New Start" and AHF centres and VMMC fixed sites. Full costing will be conducted when no HTS services exists such as the workplace and VMMC community mobilisation. The primary outcome is the total and unit cost per HIVST kit distributed among the various distribution channels.

The perspective describes which payers' costs are included in the estimate. For our analysis, to inform budget consideration, we will estimate the costs that fall on the government as payer (provider perspective). Both government and non-government providers are included. The main non-government provider will be PSI.

Costing period – HIVST kits distribution

The costing study will analyse data expenditures for one year following HIVST kits distribution in each model.

In Swaziland, fixed site at New Start and workplace through private public partnership started distribution in November 2017 while AHF sites, ANC sites, VMMC centres and VMMC demand creation teams will be starting in February 2018.

In Lesotho, New Start distribution and mobile outreach started in November 2017, uniformed forces health facility started in January 2018 and secondary distribution through MNCH sites will be starting in February 2018.

2. Cost data collection

a. Scope of the costing

We will estimate financial and economic costs for providing HIVST among the different models with a data analysis of overhead expenditures complemented by an ingredient-based approach (top-down and bottom-up costing).

The costing activities will include the three following activities:

1/ Top down costing (macro-costing) only applies to PSI expenditure data analysis and will ensure:

- All financial costs are captured
- High comparability with accounts

2/ Bottom up costing (micro-costing) for non-PSI and non-AHF run distribution sites to obtain costs data and allocation factors across distribution models as well as economic costs (donated goods and services).
3/ Scale up modelling to consider budget impact after scaling up.

Table 4 summarizes the sources of cost data for each model:

Distribution model	Source of cost data
Swaziland	
"New Start" centres, PSI VMMC fixed sites, VMMC Demand creation team, workplace	PSI expenditure data analysis supplemented by site observations
AIDS Health Foundation site	AHF expenditure data analysis supplemented by site observations
ANC site at public hospitals	Micro-costing
Lesotho	
"New Start" centres, PSI mobile outreach	PSI expenditure data analysis supplemented by site observations
Uniformed Forces Health facility, MNCH service at public hospitals	Micro-costing

Table 4. HIVST distribution models - Source of cost data

Any costing data gap will be complemented by additional bottom-up costing data. AHF and PSI have a long experience of working together; we will obtain AHF expenditure data from our PSI partners in Swaziland.

b. Unit costs

In Swaziland and Lesotho, we will estimate total and unit cost per HIVST kit distributed and per HIV positive person identified and linked to care within the models presented below:

Table 5. Total and unit cost estimates in Swaziland and Lesotho

Models	Total and unit costs	Smart Indicator
Swaziland		
ANC at public hospital Fixed site HTS ("New Start" and AHF) VMMC fixed site VMMC demand creation Workplace	Per HIVST kit distributed	# of test kits distributed by model
	Per HIV positive person identified and linked to care	# of people who test positive with an HIVST, enrolled into treatment
Lesotho		
MNCH services at public hospital "New Start" HTS fixed site "New Start" outreach Uniformed Forces Health facility	Per HIVST kit distributed	# of test kits distributed by model
	Per HIV positive person identified linked to care	# of people who test positive with an HIVST, enrolled into treatment

The smart indicators will be reported by the PSI Monitoring & Evaluation team. Based on these cost estimates, we can model the budget impact of scaling up HIVST under the range of the distribution models part of the study.

These unit costs will be presented by distribution model to allow for comparison across the distribution strategy. Observed costs will be collected prospectively over year 1 and feed into the scale up cost model.

c. Time horizon

The time horizon will be of 1 year following HIVST distribution, and will include both start-up and implementation phase of HIVST.

Costs will be disaggregated into those in the 'start-up' phase (all costs incurred before the first service is delivered) and those in the 'implementation' phase. The timeframe for the costs will be annual, with annualization of capital resources that provide benefits for more than one year.

The costing activities will run over 2018 (Year 1) and 2019 (Year 2):

- Year 1: We will use short term observed costs of HIVST distribution models, to estimate total and unit costs.
- Year 2: Longer term cost analysis for the duration of the project, which will be the full first year plus additional months depending on how long start up took. We will use the latest period of observed costs as input into the scale up cost model.

d. Identification and measurement of resource use

As a first step, we need to identify all the relevant providers and activities involved in the delivery process of HIVST. For each distribution model, this will include an analysis of expense records of each provider, interviews with key informants and observations of testing distribution. This in turn will guide the any adaptation of the cost data collection tools.

The research team will combine "top-down" and "bottom-up" costing approaches to estimate the overall costs of distributing HIVST. The main objective of the bottom-up costing is to identify cost allocation factors for PSI delivery systems. For government clinics, we will need to do the full micro-costing. We will also conduct time and motion studies with health care workers to estimate their allocated time to provide HIVST, where shared across various activities. We will then model scale-up costs nationally.

i. Extraction of financial data from expenditure reports – "top-down" costing

The data analysis plan aims to ensure that all costs are identified. It will be fully transparent for programmes as all expenditures are tracked and will provide insights into programme budgeting. Due to the timelines, our costs analysis will capture early programme costs, thus requiring modelling to estimate changes attributable to economies of scale and programme learning.

Our expenditure analysis will follow 3 steps: by phase (1), by ingredient (2) by activity (3).

1. Project phase. All expenditures prior to the first training or implementation will be classified as start-up and treated as capital costs with a life span of the project.

2. Expenditure analysis by ingredients. Line items in expenditure data will be categorized by type of input used, e.g. supply, equipment, etc., staff. This is useful to understand the types of resources required for future role out.

3. Activity based costing. This refers to costing by HIVST distribution model disaggregated by cost category at different level ((distribution point and district level). This expenditure analysis will be complemented with the bottom-up costing method to collect quantities and prices of items that were not part of PSI expenditures.

Costs will be allocated across HIVST distribution models, cost category and level using:

- Overhead costs
- District level costs
- Number of HIVST kits distributed
- Number of HIVST distributor trained
- Geographical distance between storage and distribution points

A summary of the tentative allocation factors is presented in **Appendix.**

ii. Recording of resource use – "bottom-up" costing

In collaboration with providers at distribution sites, resources quantities and unit costs will be assessed. Data to be collected include capital costs (building, vehicle, start-up (training and other)) and recurrent costs (staff, testing supplies, other supplies, etc.). The cost data collection tools presented in **Appendix** will be used for government facility costing; we will then adapt them for different model. These costs will be allocated based on the estimated proportion of visits for HIVST clients versus other clients. Each cost will be determined for the different categories as indicated in the following sections. Our comparator will be HIV standard of care.

Capital costs and start up

Land and Buildings

Buildings costs or annual rent equivalent, where applicable, will be estimated by using current replacement values based on Ministry of Health building costs. The information on annual rent equivalent will be obtained from facility managers or partners where applicable. If this information is not available, information will be collected locally about the cost of buildings and land. In addition, the physical space utilised by each department, including specific room allocated for HIVST, will be measured and allocated to HIVST according to use. For government clinics, the cost of building will be obtained from the MoH, private housing agents or estimated based on current housing rates. Specific information includes purchase price or construction cost of each capital good (such as facility buildings, generators, vehicles, etc.). This information will be used to estimate the cost of constructing the facility.

Start up and training

In addition, information on the cost of training of service providers, peer educators, counsellors and other personnel or volunteer involved in HIVST kits delivery will be obtained from PSI and Swaziland/Lesotho MoH supporting the training of service providers at the national and district level. This information will include the number of participants attending the training (opportunity cost of their time will be based on their salary), the total cost of organising a workshop and the number of workshops held. The cost per person trained should take into account expenses related to refreshments, office supplies, facilitator, etc.

Furniture and Equipment

The furniture, equipment and other asset data will be obtained from the asset register of the service providers. The cost of each piece of equipment, medical and non-medical, will be obtained from the price lists from PSI, the partner supporting HIVST distribution. Alternatively, the cost of furniture and equipment will be obtained from local markets. The locally appropriate life of each item will be applied to calculate annual costs.

HIVST kits and other supplies

Information on the HIV self-test kits, including kits price, will be obtained from PSI as actual purchase price. The full list of supplies used for HIVST will be included in the data collection form.

Recurrent Utilities and recurrent transport costs

Utility costs include telephone, water, gas and electricity, maintenance of vehicles, and transport costs. The invoices for each utility will be obtained from the accounts or the in-charge on site where applicable.

Volume of services

Information on volume of kits distributed in different sites will be obtained from the PSI and from Swaziland and Lesotho MoH facility outpatient registers.

Personnel and time and motion study

Personnel

Personnel salaries will be obtained from PSI accounts as well as national salary scales and will be used to value staff time. Any contribution to living allowance, subsidies as well as number of working day per year will be collected during the site visit. Staff time allocated to providing HIVST services will be captured in the time and motion study.

Time and motion study

Time and motion studies will be completed in all distribution models. The aim of this sub-study is to observe how much time HIVST distributors (health care workers and VMMC demand creation team) spend on delivering HIV testing services to their clients, differentiating time allocated to HIVST and to standard HTS. This usually includes activities such as time to ask previous HIV testing history and last HIV test results, explain how the self-testing device work and other type of counselling on HIV prevention, STI prevention or family planning depending on the provider and distribution model. Results from the time and motion study will be used to allocate direct personnel costs in settings where HIVST is provided along with other health care services.

The time and motion data collection form is presented in **Appendix**. To collect time on the provision of HIV services, the data collector will be waiting outside of the room and will time the length of the consultation. The consent forms and participant information sheet for the HIVST distributor can be found in **Appendix**. A summary of the data resource is presented in the **Table 6** below.

Table 6. Cost data sources

Type of Data	Source of Data
Direct project resources	Project Expenditures: The starting point for the analysis will be the PSI project expenditures, extracted from the financial accounts. These accounts contain project codes as well as input type and location.
Programmatic and non-financial operational data	Programme data will be collected from routine M&E data as well as data on numbers of staff for service delivery.This will be supplemented through key informant interviews at the service delivery sites. Informants will include the facility managers, doctors and nurses responsible for HIVST service delivery. In all the sites, the number of clients receiving HIVST will be obtained from the HIVST/HTS register at the site, if not already obtained from central level M&E data.
Staffing and time spent	Information on time taken in providing HIVST with counselling will be obtained through the time and motion study, evaluating time required to deliver HIVST. Staff salaries will be obtained from PSI expenditures and official Government pay scales for each cadre (in the case of public health facilities), while salary for workers at New Start and AIDS Health Foundation clinics will be obtained from the head offices directly.
Equipment, commodities, and consumables and supply chain management	The cost of equipment, commodities, and consumables will be extracted from official invoices provided by partners supporting HIVST in each site. Alternatively, the information including the cost of supply chain management (e.g., logistics, warehousing, and distribution to the sites) will be obtained from PSI, AHF or MoH.

Type of Data	Source of Data
Training costs	The training costs will be the actual training expenditure for HIVST service providers including doctors, nurses, counsellors or peer educators. Information to be collected include per diems for the trainers, trainees, and counsellors; training materials; cost of the training venue; transport reimbursement for the trainees and trainers; and the cost of refreshments. The cost per person will be obtained by dividing the total cost of training HIVST providers by the number of participants.
Overhead and operational costs	The overhead and operational costs (utilities and maintenance) for each distribution site will be derived from the facility general ledger or summary ledger reports. In addition, information on the type and number of support staff will be obtained through interviews with key informants at each site or managers of organizations supporting HIVST.
Administrative and program costs	This expenditure item refers to facility overhead costs. We assume that each medical officer (in the case of public health facilities) or manager/in-charge in the other service delivery models, though not directly involved in the provision of HIVST, plays a key role in overseeing the delivery of services including HIVST in the facility. In each site, the team will collect information on the salaries of the medical officer in charge and the hospital administrator. Their contribution will be based on the facility share of HTS/HIVST to the other services provided at the facility.
Land and buildings	The cost of each facility or site will be estimated using information from the MoH. The ministry has estimates of the cost of construction per square meter. Information on land and buildings will be obtained from the county government relevant department. Information on the lifespan of the building will be based on previous studies.
Volume of services	Information on client services will be extracted from the facility registers. The nature of data to be collected will include patient admission for the overall facility (where applicable), HTS and HIVST clients.

Type of Data	Source of Data
Demand-creation costs	Information on demand-creation will be based on estimates to be obtained from PSI for the VMMC model.

Data on logistics

The costs both within the PSI supply chain management as well as the government system will be estimated. The following information will be collected from PSI or from service delivery points when government services are being utilized: cost of transporting the HIVST commodities, cost of storage (warehousing), cost of waste disposal and cost of personnel for supply chain management.

Data on waste disposal

To obtain the unit cost of waste disposal that accrues to services related to HIVST delivery, the following information will be collected: 1) total cost of waste disposal in the site delivery points, 2) the number of sharp bins disposed of in each department and the total number of clients receiving services in the site. In this way data on waste disposal can be allocated proportionally to the HIVST services.

Data collection on demand creation

Information on demand creation will be obtained from PSI and other partners supporting demand creation and advocacy. The specific information, education and communication (IEC) data to be obtained will include the cost of IEC communication strategy as well as cost of IEC campaigns in the selected sites.

e. Valuation of resource use

Capital goods

We will take into account depreciation of equipment and building (cost allocation of a tangible asset over its useful life) using a discount rate of 3% following guidelines, while using country specific discount rates in the sensitivity analysis.

Currency conversion

We will report total costs in USD2018 –i.e. US dollars valued at 2018 prices— and in Swazi Lilangeni/Lesotho Loti, using a 3% discount rate where costs need to be adjusted over time. Costs incurred in Swazi Lilangeni/Lesotho Loti will be adjusted for local inflation, and converted in USD at the base year (2018) using the current

exchange rate. PSI expenditure data are presented in USD reported in real time and will be used as this.

3. Sampling method

HIVST distribution sites are presented in **Appendix**. For the costing studies, if the number of clinical sites for the HIVST distribution model is less than six, then all sites will be cost. If a model has more than six sites, then purposive sampling of clinical sites will be done to capture a range of clinical characteristics, including rurality, catchment size, and if large variation in prevalence this will also be considered when developing a sampling frame. A maximum of six health care providers will be included in the time and motion study per HIVST distribution site.

4. Cost data analysis

Cost analysis

We will determine the unit costs per HIVST kit distributed and per HIV positive person linked into treatment or care within each model. This analysis will inform decisions on allocative efficiency for the distribution of the kits among the different models and the investment in HIV testing and HIVST distribution across model. We will report on cost breakdowns by intervention phases, input category, at facility and district level within each distribution model.

The table below present a summary of our cost data analysis for Lesotho:

Table 7. Example - Cost analysis summary table for unit cost estimation by alternative distribution models in Lesotho

	Overheads	**ANC clinic**	**New Start fixed site**	**New Start outreach**	**Uniformed Forces Health facility**	**Total**
Capital						
Training						

Sensitisation						
Building & storage						
Equipment						
Personnel						
Supplies						
Vehicle maintenance/transportation						
Building operation/maintenance						
Other recurrent						
Not implementation						
Start-up other						
Other capital						
Total Capital						
Recurrent						
Recurrent training						
HIVST kits						
Sensitisation						
Building & storage						
Personnel						
Supplies						
Vehicle operation & maintenance						
Building operation/maintenance						
Other recurrent						
Not implementation						
Total recurrent						
Over all total						
% cost by model						
Total with overheads distributed across models						
Unit cost= (total by model distributed)						

VIII. Data Management and Statistical Analysis

Expenditure data will be received from relevant finance departments (PSI and AHF organizations), or collected on site and will be analysed in Microsoft Excel software by the LSHTM team. All expenses will be converted to US dollars 2018 for analysis, capital costs will be annualised. Data will be disaggregated per distribution site and per model.

M&E data will be provided by the coordinator responsible for data processing, analysis and reporting. The data will be managed and stored using the secured system District Health Information System 2 (DHIS2). Data from the M&E plan will answer the following question relevant for the costing studies and within the relevant distribution model:

- How many HIVST kits were distributed?
- What is the linkage to care rate after HIVST?

Further analysis of mean and median costs across sites will be estimated where there are multiple sites implementing the same model. Cross country analysis of unit costs and their drivers will be undertaken where possible, though full analyses of cost functions is not feasible due to sample size constraints.

IX. Data Quality control and storage

Data quality control

Financial and other cost data will be validated on entry through a range of consistency checks. For instance, excel checks will identify where allocation factors do not add up to 100%, project accountant will be invited to jointly revise the analysis. Logical and consistency data checks will also be performed across data types, to ensure that the narratives reported in the interviews with the in-charges are consistent with the accounting data and that both form a realistic picture of activities. Errors will be reviewed and corrected on a quarterly basis.

For the time and motion study, the local research assistant will be timing the HIVST distributor. This will ensure there is no reporting bias regarding participants' time allocated to the delivery of HIVST.

The M&E team will conduct routine visits to sites to supervise data collection and compilation of reports. Data checks are conducted to verify correctness and completeness of data recorded on paper forms against data entered on the database (DHIS2). There will be dedicated staff to check on data quality. DHIS2 also has a mechanism for logical checks which are in built in DHIS2 to assist in data validation.

STAR has also formed a TAG to review data and provide expert opinion on ongoing and planned research studies.

Data storage

Study records (consent forms, cost data spreadsheets, etc.) will be kept in a secure location accessible only to authorised study staff. All records will be archived in a secure storage facility for at least five years after the completion of the study. Security of data access and storage and discussed in more details in the "Ethical considerations" section.

All anonymised cost data will be analysed by a Swazi and Mosotho researcher and a research fellow at LSHTM, under the supervision of the principal investigators on the study. Results will be fed back to local team and discussed before inclusion in the final analyses. However costs will be identifiable by study site.

X. Dissemination of Results and Publication Policy

The results of this research will be used to guide the formation of national and international policies around HIVST. Findings will also be distributed internationally to global health policy makers, nationally to the Swazi and Lesotho governments, including HTS technical working groups. Research will be published in international journals and presented at international conferences.

STAR consortium partners have also established HIVST and STAR technical websites where updates and outcomes are shared on a regular basis as soon as new evidence is available. Research findings will be discussed with members of the STAR Technical Advisory Group (TAG), which brings together public health experts, scientists and policy makers to guide research and programme implementation as well as with the HIVST technical working group established by WHO.

XI. Study timelines

Table 8 describes the expected timelines in both Swaziland and Lesotho. The study will be implemented in the second quarter of 2018.

Table 8. Study timelines in Swaziland and Lesotho

Quarters (2018-2019)	Q1				Q2				Q3				Q4				Q5				Q6		
Month (2018-2019)	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J				
Ethical approval of the study			x	x																			
Costing: data collection-start up and training					x	x	x	x															
Costing: ongoing prospective data collection					x	x	x	x	x	x	x	x	x	x	x	x							
Costing: data cleaning									x	x	x	x	x	x	x	x							
Costing: expenditure primary analysis					x	x	x	x	x	x	x	x											
Cost modelling: model scale up & unit costs													x	x	x	x	x	x	x				
Dissemination at conferences and publications												x	x	x	x	x	x	x	x				

XII. Limitations and Problems Anticipated

Data collection progress at the various distribution sites can sometimes be delayed due to logistical issues (e.g. planning of the visit, absence of the key staff personnel at the clinic, etc.). In this situation, members of the team (from LSHTM or in-country team) will support each other, for example by providing additional human resources to help with the data collection. Delay in starting of models will reduce the costing follow up period, which may make generalisation from some models less valid. Problems with surveys capturing testing and linkage to care would reduce our ability to estimate cost per person linked and reduce the ability of estimating cost effectiveness.

XIII. Ethical considerations

Ethical approval for the study will be sought from the National Health Research Review Board Ethics Committee in Swaziland, Lesotho Ministry of Health Ethics Committee and the Research Ethics Committees of the London School of Hygiene and Tropical Medicine. The study has been discussed with and has the support of senior staff at the implementing partner organization Population Services International.

The study may be subject to audit by UNITAID, the funding body for the STAR project, and inspection by regulatory authorities, to ensure compliance to the protocol, and all applicable regulatory requirements.

Confidentiality of data

Sensitive information from individual provider resource use (e.g. salary information) and information collected from the time and motion study will be kept confidential. All hard copies of the records will be stored by the local health economist in locked filing cabinets. Electronic copies data will be stored in password protected computers on the LSHTM approved secured server "OneDrive". Access to the records will be restricted to the local health economist, and to STAR team members as required.

Data on patient linkage to care will be obtained from our partner implementer Society for Family Health as part of their M&E reporting system. M&E data will be provided by the coordinator responsible for data processing, analysis and reporting. The data will be managed and stored using the secured system District

Health Information System 2 (DHIS2). The research team will not have access to individual level patient information and data on linkage to care will be obtained at distribution site level. Therefore, there is no risk for breach of patient anonymity.

Time and motion study

Sensitization of district health officers and clinic heads will be done by the local project team prior to the time and motion study. No incentive will be given to compensate the time of health care workers and PSI staff taking part in the study as the Swaziland and Lesotho MoH do not allow that and it is not part of PSI policy.

The health care workers willing to participate in the time and motion study will give a written consent.

An information sheet describing the purpose of the study globally and the time and motion study will be provided to the participant. It clearly states why we ask them to participate in the study, what it entails, and is free of technical language. The information sheet clearly states that there will be no consequences if providers decide not to participate in the study and that they can withdraw at any time during the study. The information sheets will be translated into local languages (isiZulu and Sesotho). The data collector will allow time to answer any questions the participant may have. If the HIVST provider does not wish to participate in the time and motion study, the data collector will only proceed to cost data collection at the distribution site.

To collect time on the provision of HIV services, the data collector will be waiting outside of the room and will time the length of the consultation. The patients of the health care worker taking part in the time and motion study will be informed that their consultation has been timed; the researcher will read a brief information sheet specifying that no other information has been collected.

Informed consent forms will be obtained from the HIVST distributor in order to conduct the time and motion study. A copy of the written consent form, participant and patient information sheets can be found in **Appendix**. These three documents will be translated into local languages (Swazi and Sotho).

XIV. References

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XV. Appendix

I. Standard Operating Procedures for the HIVST distribution models

Distribution models in Swaziland

1. **Secondary distribution in ANC units at public hospital (high volume facility)**

HIVST will be distributed at public health facilities and at different HTS entry points within the high-volume facility. For phase 1, HIVST kits will be distributed at ANC clinics for partners of pregnant and lactating woman. Individuals who test both negative or positive during the ANC visit will be offered a self-test kit for their regular partner/s. Participants will be encouraged to check with their partner if they may want a self-test kit, and to check if the partner is happy to have their contact details passed on to program staff. In addition to the kit and instructional materials (a WhatsApp version of the video will be shared with the participant if he/she has WhatsApp) that are given as per clients taking the kits themselves, an invitation slip that is addressed to partners will be enclosed as well as IEC material on HIVST.

Clients will be told that a positive self-test result necessitates a confirmatory test, which must be provider-delivered. They will be told about possible places where confirmatory testing can be accessed if needed. At two weeks after collection of kit, the client will be telephoned to ask if he/she gave the kit to the partner, whether the partner accepted it, whether the partner self-tested, and the result of the self-test if known. If the self-test was positive, they will be asked whether, when and where the partner sought confirmatory testing.

2. **Integrated HIVST at "New Start" and AIDS Health Foundation sites**

The rationale behind this approach is to triage out HIV negative clients out of the health system at the same time emphasising on access to preventive services. At fixed sites, clients will be given a choice between testing using standard HTS and or HIVST. Those who opt for self-testing will have the choice of testing on site or taking the kits away for testing at their convenience. Clients who choose to self-test on-site will be given a self-test package and access to a cubicle or room where they can self-test in private. The self-test package will consist of the HIVST kit and validated testing instructions. At the time of receiving the package participants will be shown an instructional video on a computer, tablet, smartphone or television screen. They will also provide information that "New Start" routinely collect from clients seeking HIVST, including demographic information and history of HIV testing; these data are collected using paper based

tools initially with plans to migrate to DHIS 2by April 2018. Clients will be encouraged to disclose their self-test results to the counsellor. However it will be emphasized that should they obtain a positive self-test result, confirmatory HIV testing is necessary and will be available on-site on the same day. Confirmatory testing will be offered according to the national algorithm. If they are HIV negative, there are HIV prevention interventions that they may wish to consider.

Clients choosing to test off-site will be given not more than 2 self-test packages and will be shown the instructional video, as those testing on site. In addition, they will be given detailed instructions on how to seek post-test support services, including confirmatory testing if needed. To restrict the use of self-test kits to the intended purpose, clients eligible for taking kits away must be willing to provide a demographic information which will be verified and must be willing to receive follow up calls. At the time of collecting the self-test kit, participants will be asked to think about the date and time they are likely to self-test.

Clients choosing to test off-site will be given the self-test package and will be shown the instruction video and written step by step guide on how to perform an HIV self-test. All clients who opt for out of "New Start" HIV self-testing will be provided with counselling on the importance of linking to a health facility after taking the test. Clients who test positive out of "New Start" will be encouraged to link to health care facilities of their choice, for confirmatory provider delivered HIV testing and possible enrolment into on-going care. Clients who test negative by self-test out of "New Start" are encouraged to present at health facilities for HIV prevention services as applicable.

Clients who opt to test out of the site will be offered telephonic follow-up by the HTS provider to find out the outcome of the test. At the time of collecting the self-test kit, participants will be asked to think about the date and time they are likely to self-test. Once they decided on date they want to test, they will be provided with a client held appointment card that serves as a reminder to the client. An appointment date for the facility visit after the test will also be entered on the card.

Clients will be encouraged to return used kits when they follow at the facility for services outlined above. The returned are only used to assess use of distributed kits. Clients who self-test out of facilities will be followed with a phone call randomly (systematic random sampling, taking every third client served) to check use of the test and linkage to appropriate services. Calls to clients who opt to test at home will be made within a month of collecting the kit. This telephonic follow-up will be implemented for the first six months of implementation and then reviewed. Clients will also be asked to report if they visited a health facility after taking an HIV self-test for services outlined above.

3. **VMMC in Fixed sites**

At static VMMC centres, distribution will be done at Litsemba Letfu Clinic. Clients will be given the choice of standard HTS or HIVST. At static Litsemba Letfu sites clients who opt for self-testing will be given access to a room/cubicle where they can self-test in private. Clients will not be given the option to take the self-test kit away. Clients will be told that should the self-test result be positive, confirmatory with the standard HTS following the national algorhythm is necessary and will be available on the same day. Clients who get a negative self-test result will show their test device to VMMC health care workers who will then proceed with provision of VMMC services. Outcomes from programmatic data at VMMC centres is the proportion of males who opt for HIVST at the site before undergoing a VMMC procedure as well as those who screen positive and require a conformation test on site. The target for VMMC will be men aged 16 and above.

4. **VMMC in Demand creation**

Counsellors will distribute HIVST kits to men interested in VMMC at community level during the recruitment process. The HIVST kits are offered to the men as part of the recruitment process and motivation for VMMC. HIV self-testing has been identified as a barrier for men accessing VMMC and studies done in countries like Zimbabwe show that with the introduction of HIVST, uptake of VMMC is improved. Men screening HIV negative will be fast tracked during the procedure day at the VMMC site. The rationale is that HIVST will Improve uptake of HIV testing and circumcision among VMMC eligible men. This will also reduce waiting time for the procedure at the site for those men already tested. Outcomes from programmatic data from community mobilisers will be the proportion of potential VMMC clients accepting HIV self-test kit, go on to self-test and those who eventually take up VMMC.

5. **Workplace distribution through private public partnerships**

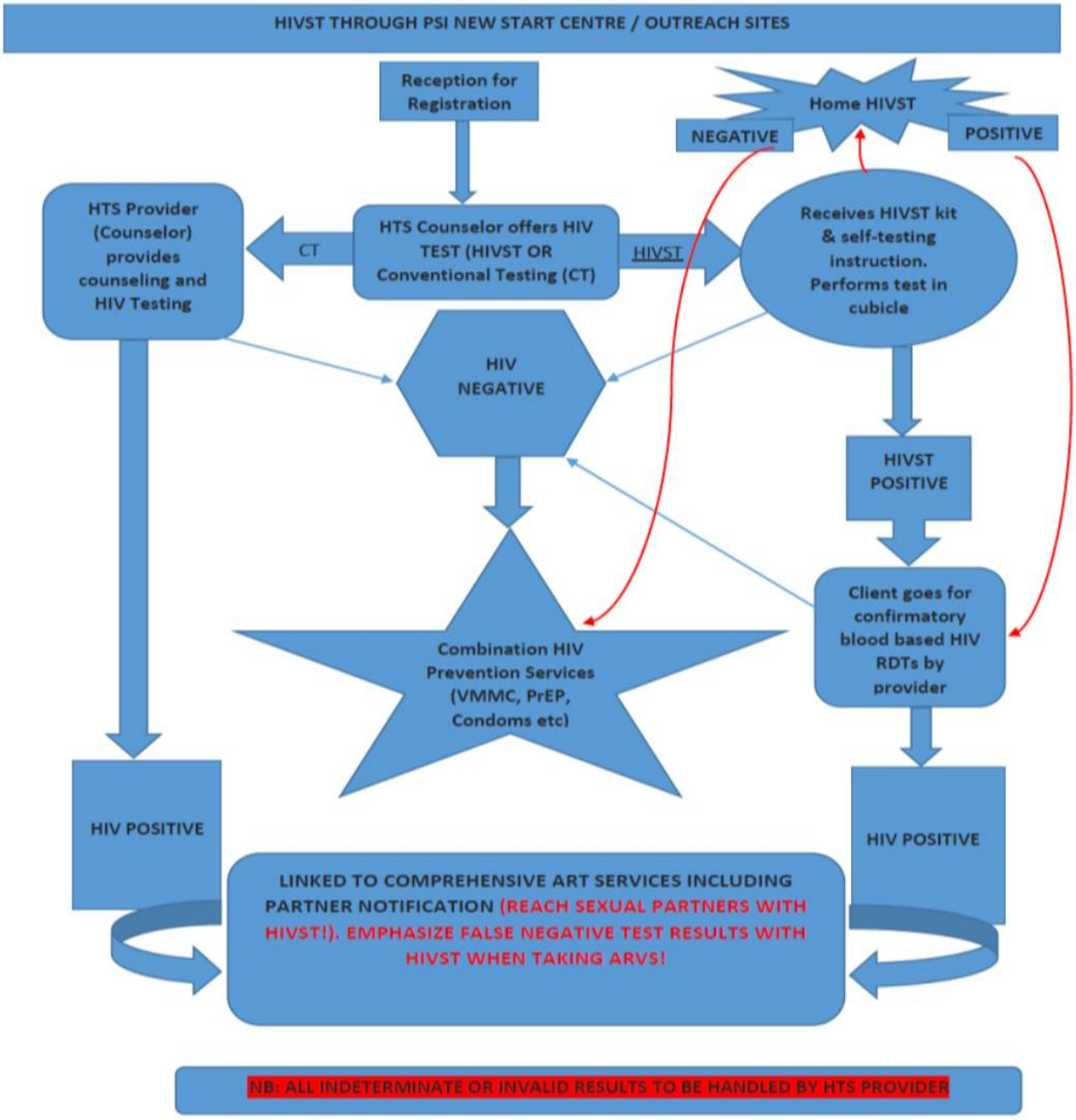
HIVST will be distributed at male dominated workplaces in Matsapha in both hard labor (mining and manufacture industry) as well as corporate institutions. Distribution will be done by trained counsellor agents during outreaches to these workplaces. Clients will test at home by themselves and then if the screen test is positive, confirmation will be done at the PPP outreach mobile unit. During the outreach, clients will be offered the option of standard HTS and HIVST which will be fully integrated within the outreach with a Gazebos partitioned for HIVST clients who wants to self-test during the mobile outreach. If clients screen positive, confirmation will be done on site at the mobile unit using the national algorithm.

Distribution models in Lesotho

1. **Integrated HIVST at "New Start" sites**

The "New Start" fixed site distribution model is the same as for Swaziland. A client who comes to the "New Start" Centres or accesses HTS services at the "New Start" outreaches will follow below client flow (see **Figure 1**).

Figure 1. Client Flow at the "New Start" Centres and Outreaches



2. **Targeted HTS outreach services integrated within "New Start" outreach**

Clients who test at the New Start mobile outreaches will follow the client flow indicated above (**Figure. 1**). The clients will be offered option to self-test or to receive provider delivered HTS at the mobile outreach. The HTS provider collects client data based on the HIVST register. Clients who opt for self- testing will have the choice of testing on site or taking the kit away for testing at their convenience. Clients will be encouraged to test at mobile outreach where possible to maximize review of test result with HTS provider.

Clients who choose to self-test on-site will be given a self-test package and access to testing tent where they can self-test in private. The self-test package will consist of the kit and testing instructions in English and Sesotho.

If the result is positive, the client is offered confirmatory HIV Testing by the HTS provider at the site. If confirmatory results are positive, then client will be initiated at the collaborative community ART initiation with Elizabeth Glaser Paediatric AIDS Foundation (EGPAF). For HIV positive clients who may not be willing to initiate at the community ART initiation, then they will be referred to the preferred nearby health facility. All confirmed clients living with HIV will be offered HIV self-test kit for secondary distribution to their sexual partner(s) or home visit for index HIV testing.

If HIV self-test is negative, the client is counselled on HIV prevention and offered preventive methods including VMMC for males, PrEP if eligible according to guidelines and consistent & correct condom use. The client with a negative HIV status will also be counselled on need for subsequent repeat testing according to risk profile outlined in the national guidelines. Clients who will opt to do self-test off site will also follow similar processes for clients who test off site at New Start.

3. **Distribution at uniformed forces health facility**

HTS providers working in the military health facilities will be trained on HIVST prior to distribution. A target of 40 providers will be trained on HIVST per national training curriculum.

Distribution Points

Uniformed Forces Health Facilities (Thomas Wellness Centre, Makoanyane Military Hospital and AHF facility (for LMPS)

The clients will be offered option to self-test or to receive provider delivered HIV testing. The HTS provider collects client data based on the HIVST register.

Clients who opt for self- testing will have the choice of testing on site or taking the kit away for testing at their convenience. Clients will be encouraged to test at facility where possible to maximize review of test result with health care provider. Clients who choose to self-test on-site will be given a self-test package and access to room where they can self-test in private. The self-test package will consist of the kit and testing instructions in English and Sesotho.

Clients are encouraged to discuss the result with an HTS provider after self – testing within the facility. If the result is positive, the client is offered confirmatory HIV Testing by the provider. If confirmatory results are positive, then client is referred for on-going HIV care & treatment. All confirmed clients living with HIV will be offered HIV self-test kit for secondary distribution to their sexual partner(s) or home visit for index HIV testing.

If HIV self-test is negative, the client is counselled on HIV prevention and offered preventive methods including VMMC for males, PrEP if eligible according to guidelines and consistent & correct condom use. The client with a negative HIV status will also be counselled on need for subsequent repeat testing according to risk profile outlined in the national guidelines.

Clients choosing to self-test off site

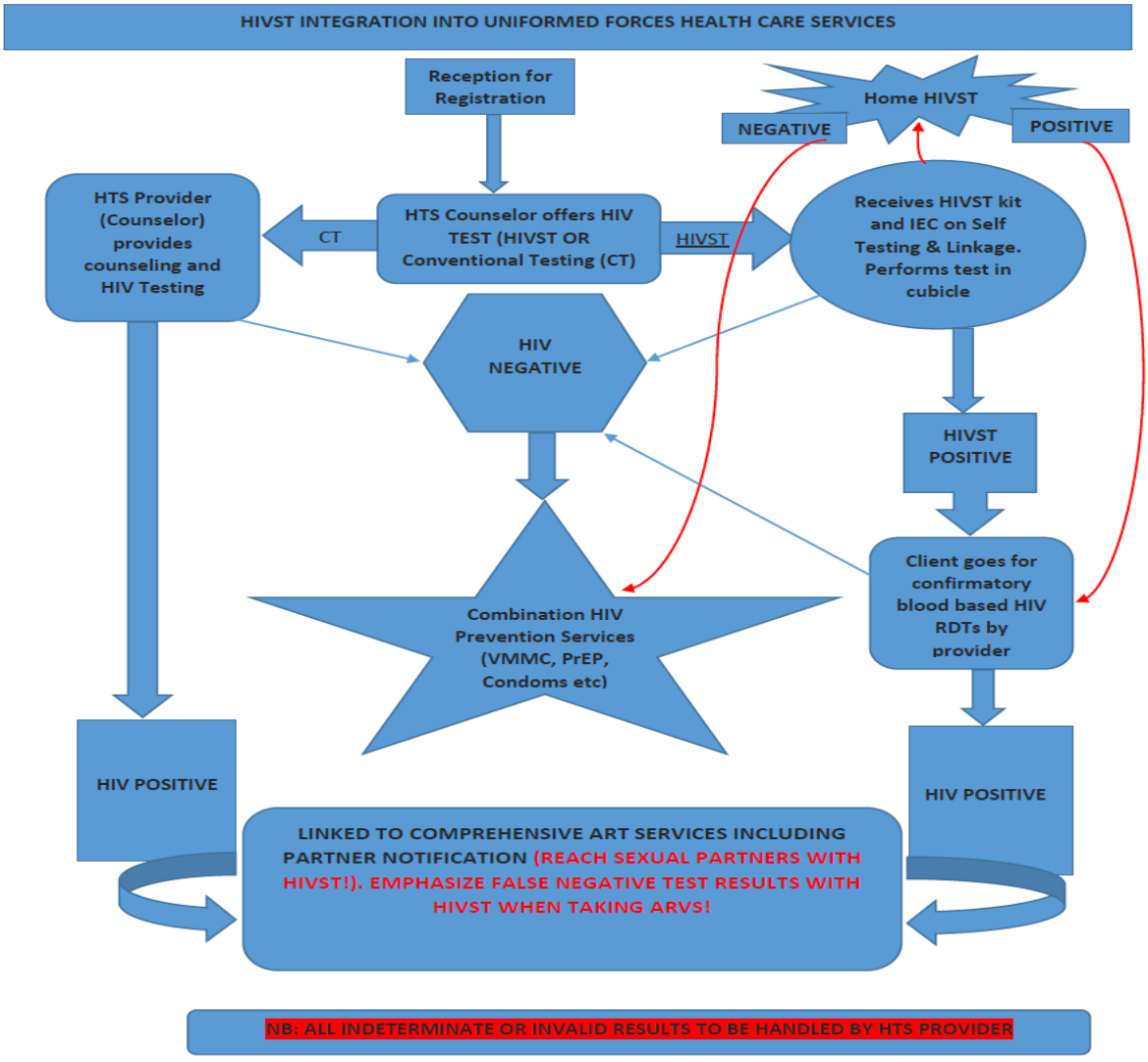
Clients choosing to test off-site will be given the self-test package and will be shown the instruction video and written step by step guide on how to perform an HIV self-test. All clients who opt for out of facility HIV self-testing will be provided with counselling on the importance of linking to a health facility after taking the test. Clients who test positive out of facilities will be encouraged to link to health care facilities of their choice, for confirmatory provider delivered HIV testing and possible enrolment into on-going care. Clients who test negative by self-test out of facility are encouraged to present at health facilities for HIV prevention services as applicable.

Clients who opt to test out of the facility will be offered telephonic follow-up by the HTS provider to find out the outcome of the test. At the time of collecting the self-test kit, participants will be asked to think about the date and time they are likely to self-test. Once they decided on date they want to test, they will be provided with a client held appointment card that serves as a reminder to the client. An appointment date for the facility visit after the test will also be entered on the card.

Clients will be encouraged to return used kits when they follow at the facility for services outlined above. The returned are only used to assess use of distributed kits (see **Figure 2**).

Clients who self-test out of facilities will be followed with a phone call randomly (systematic random sampling, taking every third client served) to check use of the test and linkage to appropriate services. Calls to clients who opt to test at home will be made within a month of collecting the kit. This telephonic follow-up will be implemented for the first six months of implementation and then reviewed. Clients will also be asked to report if they visited a health facility after taking an HIV self-test for services outlined above.

Figure 2. Integration of HIVST at Uniformed forces Health Facilities



Peer Distribution of HIVST among uniformed forces

Thirty peer distributors will be trained to distribute HIVST kits in military bases. HIVST kits will be given to peer distributors together with HIVST registers and relevant IEC material for provision to members of the Lesotho Defence Force stationed at military based in the different districts of Lesotho.

4. Integration of HIV Self-Testing into Maternal Neonatal Child Health Services (MNCH).

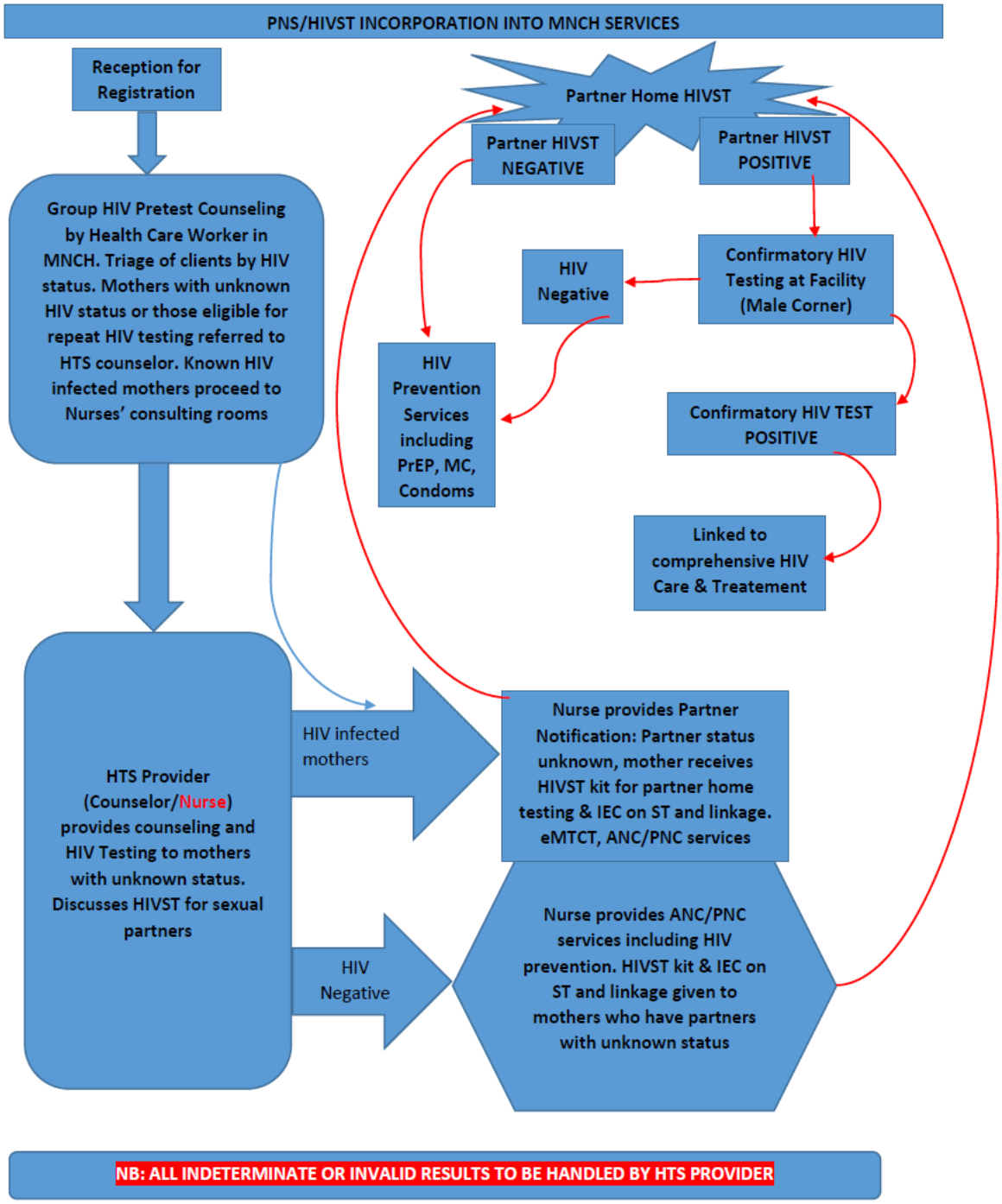
Clients are registered at the reception upon arrival. Health care provider will conduct group HIV pre-test counselling to mothers who present for MNCH services. MNCH clients are triaged based on HIV status into known and unknown status in a confidential manner. Mothers who are eligible for HIV testing according to guidelines are offered HTS by health care provider. All pregnant and breastfeeding mothers will be tested with consent using blood based HIV rapid diagnostic tests. Clients with known status including those living with HIV proceed to consult with the MNCH nurse provider.

The HTS provider will establish the HIV status of sexual partner(s) of mothers attending MNCH through history taking. Mothers with sexual partner(s) whose status is unknown will be offered HIVST kits to take home and give to the partner(s). The HIVST register will be completed.

HIVST kit with instructional leaflet will be provided by the nurse to the mother to give to the partner(s), additionally instructional video on self-test will be shared with mothers who have Whatsapp. Clients will be told that a positive self-test result requires a confirmatory test, which must be done by the provider at the nearest health facility or testing centre.

At subsequent MNCH visit, the HTS provider or MNCH nurse will ask if the partner(s) self-tested for HIV or not and document in HIVST register and client records. Mothers who do not come for follow-up visits will be phoned to ascertain if the partner(s) self-tested. Information on whether the sexual partner(s) linked to facility for further management will also be obtained during the call. If the self-test was positive, mother will be asked whether the partner received confirmatory HIV test and linked for on-going care & treatment. If not linked yet, then support to link to health facility of choice will be given. Mothers whose male partner(s) self-test result is negative will be asked when and where the partner (s) reported for HIV prevention services including VMMC and PrEP if applicable per national guidelines. Integration of HIVST into MNCH services is presented in **Figure 3**.

Figure 3. Integration of HIVST into MNCH services



II. Tentative cost allocation factors for the cost data analysis

Input type	Central (PSI-HQ)level	District Level	Health Facility level	Model level (New Start, VMMC, Public facility)
Training	Costs allocated to training directly from PSI expenditure cost description.	Like at HQ, costs allocated to facilities by number of distributor trained	Like at HQ, costs allocated to facilities by number of distributor trained	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
Sensitisation	Treated as overhead/program shared costs and allocated to districts by district level direct expenditure.	Allocated to facilities by number of HIVST kits distributed.	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
Other Start up	Treated as overhead/program shared costs and allocated to districts by district level direct expenditure.	Allocated to facilities by number of HIVST kits distributed.	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
Building and storage	Treated as overhead/program shared costs and allocated to districts by district level direct expenditure.	Allocated to facilities by number of HIVST kits distributed.	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care

Equipment	Treated as overhead/program shared costs and allocated to districts by district level direct expenditure.	Allocated to facilities by number of HIVST kits distributed.	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
Personnel	Treated as overhead and allocated to districts by district level direct expenditure. Program shared costs by distributors.	Allocated to district by number of distributor trained	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
HIVST Kits	Allocated by kits distributed. Remove % of warehouse remaining stock at end of year.	Allocated to models by number of HIVST kits distributed.	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
T-shirts, bags, flipcharts	Allocated by number of distributors trained	Allocated by number of distributors trained	Allocated by number of distributors trained	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
Other supplies	Allocated to districts by number of HIVST kits distributed.	Allocated to models by number of HIVST kits distributed.	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care

Vehicle maintenance and transportation	Allocated by distance (km) to district	Allocated by distance (km) to facilities	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care
Building operations and maintenance	Treated as overhead/shared program costs and allocated to districts by district level direct expenditure.	Allocated to district by number of distributers trained by district	Allocated to models by number of HIVST kits distributed.	Unit costs calculated by dividing cost by HIVST kits distributed or per HIV positive person identified linked to care