UNITAID

MID-TERM EVALUATION OF THE PSI HIV SELF-TESTING AFRICA (STAR) PROJECT

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FINAL REPORT

Submitted by:

Cambridge Economic Policy Associates Ltd

CEPA

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Annexes are included as a separate document.

ACRONYMS AND ABBREVIATIONS

Acronym	Full description
ARV	Antiretroviral
BMGF	Bill & Melinda Gates Foundation
CBD	Community-Based Distribution
CBDA	Community-Based Distribution Agent
CDC	U.S. Centers for Disease Control and Prevention
CE	Conformité Européenne
CeSHHAR	Centre for Sexual Health and HIV/AIDS Research
CIFF	Children's Investment Fund Foundation
CSO	Civil Society Organisation
ERPD	Expert Review Panel for Diagnostics
FSW	Female Sex Workers
GAD	Grant Agreement Development
GHTF	Global Harmonization Task Force on Medical Devices
HIVOFT	HIV Oral Fluid Test
HIVST	HIV Self-Testing
HMIS	Health Management Information Systems
HTS	HIV Testing Services
IRB	Institutional Review Board
LMIC	Low and middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
LSTM	Liverpool School of Tropical Medicine
M&E	Monitoring and Evaluation
MCAZ	Medicines Control Authority of Zimbabwe
MoH	Ministry of Health
MoHCC	Ministry of Health and Childcare of Zimbabwe
MSM	Men Who Have Sex With Men
NGO	Non-governmental Organisation
NIH	U.S. National Institute of Health
PDHTS	Provider-delivered HIV Testing Services
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLHIV	People Living With HIV
PSI	Population Services International

Acronym	Full description
RDT	Rapid Diagnostic Test
SADC	South African Development Community
SFH	Society for Family Health
SRA	Stringent Regulatory Authority
STAR	PSI HIV Self-Testing Africa Project
TOR	Terms of Reference
TWG	Technical Working Group
UCL	University College London
UNAIDS	Joint United Nations Programme on HIV and AIDS
USAID	United States Agency for International Development
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

EXECUTIVE SUMMARY

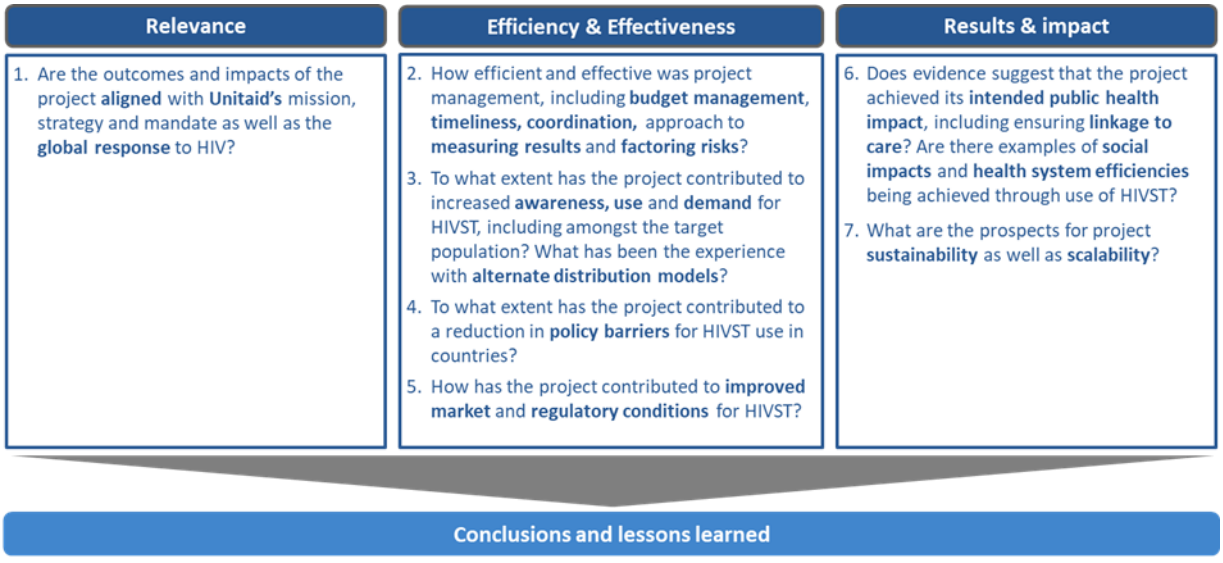
Project background

The Self-Testing Africa (STAR) project, approved by the Unitaid Board in October 2014 and signed in August 2015, aims to address key evidence gaps and catalyse the market for HIV self-testing (HIVST). The project was set up in two phases: Phase I, from September 2015 to August 2017, for a total budget of US$23.7m, implemented in Malawi, Zambia and Zimbabwe by a consortium led by Population Services International (PSI) and including the London School of Hygiene and Tropical Medicine (LSHTM), the Liverpool School of Tropical Medicine (LSTM), University College London (UCL), the World Health Organization (WHO) and local research partners; and Phase II (or the STAR Initiative), which builds on the foundation laid in Phase I and involves scaling up self-testing in the Phase I and additional southern African countries (South Africa, Swaziland and Lesotho). Phase II will be implemented from August 2017 to July 2020 and will be delivered by a new consortium, with additional grantees specifically for South Africa.

Evaluation objectives and methodology

The purpose of this mid-term evaluation is to carry out an assessment of the programmatic implementation of Phase I. The evaluation framework is structured around three key dimensions (Figure A), and is based on document review, data analysis, consultations with Unitaid, the project grantee, manufacturers, global partners, as well as country-level consultations with government officials, members of the HIVST Technical Working Groups health workers and beneficiaries through a field visit to Zimbabwe and telephone consultations for other countries.

Figure A: Evaluation Framework



Key findings by evaluation dimension are presented below, followed by overall conclusions and lessons learned.

Dimension 1: Project relevance

In terms of project relevance to Unitaid's strategy/mandate and the global response to HIV, our review found that the STAR project is a much needed and highly relevant initiative, representing a "bold move" from Unitaid given the early stage of the HIVST market, underscoring its role and comparative advantage in the global health architecture. The project's relevance is brought about by the fact that it represents the largest demonstration and evaluation project on HIVST, serving as the needed push to create momentum in the market.

While not reducing the relevance of the project per se, specific gaps in the project scope include the absence of private sector distribution models and the extent to which key aspects of the project (particularly the delivery of self-testing through community-based distribution (CBD)) are relevant for countries where there isn't a general epidemic.

Dimension 2: Efficiency and effectiveness

Project management and coordination

With regards to project management and coordination, our review found the following:

- Out of a total **project budget** of US$23.7m for STAR Phase I, US$19.9m or 84% has been spent as of the end of Phase I. The main reasons for the underspend have been delays in obtaining ethical approvals for research that held up project implementation (i.e. a challenge), as well as the lower than planned price obtained for HIVST kits (i.e. a positive).
- In terms of **project timeliness**, the noted delays in obtaining ethical approvals (which perhaps could have been better planned for) resulted in programmes having to be scaled down in terms of kits distributed and communities reached, with some distribution models only being tested for a few months in Phase I. Another key delay was in terms of the project approval process by Unitaid which took nearly two years and presents scope for efficiency. While the phased approach for the project is viewed as reasonable from the Unitaid funder perspective, additional transaction costs posed on the grantee suggest a "lighter touch" approach could be beneficial.
- **Project coordination and management** has been highly effective, with a pivotal role played by the STAR Core Team/PSI. The approach to measuring results and accounting for risks has generally been done well by the project grantee.

Extent of project progress towards increased awareness, use and demand for HIVST

During Phase I, a total of 643,276 kits were distributed across the three project countries, predominantly through the CBD model, representing 83% of all kits distributed. The total

distribution represents 88% of the planned target, although stakeholders view the volume of kits distributed as significant, especially given this was a pilot project. However, while overall distribution was not significantly different from targets, individual models (particularly those other than CBD) were far below their planned targets (e.g. female sex workers (FSW, 35%) and voluntary medical male circumcision (VMMC, 31%)).

Implementation experience across distribution models has been positive, and self-testing has widely been accepted by beneficiaries, distributors, health professionals and policymakers alike, with all noting its distinct positive benefits. Key results emerging from implementation of the distribution models suggest that:

- **HIVST is increasing access to testing for previously untested groups, particularly men and adolescents:** Between 42%-49% of kits distributed through the CBD model in the three countries were to males. Based on survey data taken in 2016 for the three countries, an average of 37% of individuals tested through conventional means in the past 12 months were male, suggesting that the CBD model was effective in targeting males. For younger people, figures on the proportion for Malawi (50%) and Zambia (47%) suggest that the CBD model reached a relatively higher proportion of younger people than conventional testing had done in these countries over a 12-month period (34%) while figures for Zimbabwe were slightly lower (31%). Figures on first-time testers for all countries were relatively comparable to proportions reached through conventional means of testing. Our review of the methodology to obtain the project data suggests that these findings are reasonably robust.
- **There has been an increased uptake of HIV testing, to which HIVST made available through the CBD model could have contributed:** Based on preliminary survey data, HIVST has had a significant and positive uptake on testing in regions where it was implemented, particularly for males and younger people. However, we note that at the time of writing endline surveys were being conducted, and these would provide more credible findings, given larger sample sizes.
- **The yield through HIVST can be higher or at least in line with provider-delivered HIV testing services (PDHTS):** Data from late-reads of self-test kits suggests that the yields obtained from self-testing are higher or at least in line with those obtained from conventional HIV testing. However, issues associated with late-reading of test kits means that such figures should be interpreted with caution.
- **There is positive evidence on increased awareness and demand through the project – in project countries and globally:** Preliminary data from surveys suggest that awareness and acceptability of HIVST is high across the three project countries. One of the key strengths of the STAR project has been raising awareness of HIVST at the global level, based on the extensive knowledge management, marketing and dissemination the activities of the project.

In general, positivity towards HIVST was a common response across our consultations with global partners and country-level stakeholders, and was also emphasised in research conducted under the project. Table A presents CEPA's assessment of the available evidence under the project, in terms of the acceptability, feasibility, targeting, and linkage aspects of the different distribution models employed (with linkage also being discussed further below), as well as an assessment of the strength of evidence (with red font in the table depicting limited strength of evidence). As the table shows, the evidence is more positive in terms of acceptability, somewhat lower (but still positive) in terms of feasibility (recognising limited work conducted in terms of costings and cost-effectiveness analyses) and less positive in terms of targeting and linkage (where there are also more gaps in evidence). Please note that this represents CEPA's subjective assessment, with more details on the approach presented in the report, including on the strength of evidence.

Table A: Summary of key dimension findings for different distribution models[1]

Model	Acceptability	Feasibility	Targeting	Linkage
CBD	High	Medium	Medium	Low
Facility-based	Medium	Medium	Medium	High
VMMC	High	Medium	Low	Medium[2]
FSW	High	High	High	High[3]
Secondary distribution	High	High	No evidence	No evidence

Source: CEPA analysis based on review of evidence.

Notwithstanding the positive results noted above, there are a number of key project-specific implementation issues and remaining gaps at the end of Phase I. These include: (i) tension between the project objectives of establishing a robust evidence base and of encouraging greater uptake of HIVST, suggesting the need to clearly establish the Unitaid strategy and prime objective for the project; (ii) more attention needs to be paid to "negative" research findings amongst the general "euphoria" on HIVST (e.g. accuracy findings from Zambia); (iii) the limited strength of evidence on distribution models other than CBD (and possibly FSW) generated through this project; and (iv) the need to conduct greater research in key areas of interest to other donors and policymakers. Key areas of further research include linkage to care and prevention, cost and cost-effectiveness, and blood-based interventions, the majority of which we understand are being picked up under Phase II. Whilst Unitaid has questioned the need for a large amount of additional research, our review finds that this is

[1] Note that the categorisations of high-medium-low are defined relative to the different distribution models, as opposed to being absolute categorisations.
[2] Note that linkage for the VMMC model refers to linkage to circumcision.
[3] It should be noted that this only applies to FSW models where individuals are tested at sites, as opposed to models where FSW can test away from health facilities.

necessary, although it is to be determined whether or not Unitaid would fund this, in line with its catalytic function within the global aid architecture.

Extent of project progress towards reduction in policy barriers for HIVST

The project has been able to contribute to alleviating policy barriers for HIVST, both within the project countries and globally.

At the **project country level**, all three countries have policies supportive of HIVST, while Zimbabwe and Zambia have included HIVST in their testing algorithms and will soon be launching HIVST operational frameworks. In Malawi, progress in securing a supporting policy environment has been less pronounced, primarily as a result of leadership changes in the Ministry of Health (MoH) affecting the level of engagement that the project has had with the government. Based on consultations with in-country stakeholders (government, civil society organisations (CSOs), other partners) and an assessment of the situation prior to the project being implemented, the STAR project has been pivotal in mobilising political commitment in project countries (primarily Zimbabwe). This has largely been due to the evidence generated through implementation, as well as the formal and informal dialogue between project partners and governments.

One of the key deliverables under this project has been the development of WHO guidelines on self-testing, with the STAR project being pivotal to their development. Stakeholder feedback has overwhelmingly stated that without the STAR project, the guidelines would have been produced a few years later. The release of the WHO guidelines has been accompanied by a **rapid increase in policy uptake of HIVST globally**. As of October 2017, 41 countries had national HIVST policies, 23 of which are in low and middle income countries (LMICs). Policy uptake has been particularly pronounced in high-burden countries in Sub-Saharan Africa, while progress in Asia and the Pacific, and Latin American regions has been less pronounced.

Extent of project progress towards improvements in HIVST market and regulatory conditions

The project has played a key role in supporting the HIVST market through its demand-generation activities and by demonstrating the acceptability of self-testing in the project countries. During Phase I, 1 million oral fluid test kits were procured to support project distribution – a substantial amount given the size of the HIVST market.

As such, the supply base has progressed considerably from the start of the project.[4] Our consultations with select manufacturers and other stakeholders indicates that the main

[4] At the end of Phase I, one HIVST product had obtained WHO PQ approval, and three additional products had obtained Global Fund Expert Review Panel for Diagnostics (ERPD) approval. Five products also had approval by founding member countries of the Global Harmonisation Task Force (GHTF), and six products had obtained approval from national regulatory authorities in four low and middle-income (LMIC) countries. Additionally,

contribution of the project has been in terms of the momentum created in the market. While the project has supported WHO with the PQ process, direct support to manufacturers has been more limited mainly due to mistiming between availability of project data and PQ submission by OraSure.

Regarding forecasted procurement, while there is widespread policymaker and donor interest, 2.2m of the currently estimated 4m kits to be procured to December 2018 across 39 LMIC countries is attributable to Phase II of the STAR project, suggesting that a large proportion of 2018 demand will be driven by the STAR project.

As regards prices, while the project was able to reduce prices for the OraSure product to US$3.15 per kit by the end of the project, in mid-July 2017 the Bill and Melinda Gates Foundation (BMGF) agreed to support a buy-down arrangement with OraSure that would allow the OraQuick Self-test to be supplied for US$2 per kit in 50 LMIC countries over the next four years, including those under STAR Phase II. While the STAR project was not directly involved in the negotiations, our review has found that the decision to implement this arrangement was influenced by the activities of the STAR project.

Regulation of HIVST is one of the areas where a considerable amount of work is needed going forward. For example, manufacturers remain concerned that capacity in all countries remains limited and that regulation and registration of HIVST products is still unclear. They also noted that even with WHO PQ, in-country validation and registration is needed, and regulatory processes between countries are yet to be harmonised. However, it should be noted that these are problems that go beyond HIVST, and that are not unique to project countries.

Dimension 3: Results and impact

Public health and wider impact

As regards **linkage to care,** we note that current evidence is limited and mixed with regard to uptake of care and treatment services following HIVST positive testing. For example, project data suggests in some instances linkage for CBD range from 50% (3/6) to 80% (20/25) in Malawi and Zimbabwe; however these proportions are based on survey data with low absolute numbers, therefore are not robust. For Zambia, project data suggests that only 8% (697/8,389) of those testing positive had linked to care, though such data was collected relatively soon after distribution. A number of ongoing challenges remain with regards to improving linkage, including appropriate methods to monitor linkage, as well as more general challenges of linking HIV testers to care.

Regarding **linkage to prevention,** project data regarding the impact of introducing HIVST into VMMC programmes in Zimbabwe suggest that it had a positive impact on increasing

there was a strong pipeline of HIVST products being developed, and three products were in advanced stages of the WHO PQ process.

the proportion of males who tested negative when reached through the VMMC programme to circumcision. Anecdotal evidence from our consultations also suggests that there has been an increase in demand for male circumcision following the introduction of HIVST programmes. However, data on males circumcised in areas when HIVST were implemented remain low in the project countries, suggesting that ongoing challenges remain with increasing VMMC in the general population, though we recognise that these may not be resolved by HIVST alone. In addition, while there is some evidence that individuals who self-tested had linked to HIV prevention programmes, several respondents noted that one of the missed opportunities in Phase I is the limited integration of HIVST with other health assessments/interventions during implementation of the CBD models.

Our review has also found several positive **social impacts** that self-testers and other stakeholders find particularly important from self-testing, including the empowerment and ownership obtained by conducting a self-test, the anonymity it allows, and the wider choice and relative innovativeness of self-testing, making it a useful and exciting prospect if it were to be scaled up. Many also noted that self-testing provides those less willing and able to test at health facilities (particularly males) with a more convenient option, whilst also benefiting health workers by reducing the requirements on health facilities to test all individuals, with community-based self-testing acting as a screening tool to triage negative individuals out of the health system (i.e. offering **health systems efficiencies**).

Sustainability and scalability

The STAR project is starting to lay the foundation to support the scalability and programmatic and financial sustainability of the project activities in the three project countries. Funding commitments are in place from Global Fund and the US President's Emergency Plan for AIDS Relief (PEPFAR) for the three project countries, although national scale-up is only likely to be in place in the next couple of years. Outside of project countries, pilot programmes are being initiated in several regions, and some countries (particularly Kenya and Uganda) are planning to distribute a significant number of kits over the coming years.

One of the main risks to scale up of HIVST is that funding for HIV is plateauing globally, and therefore donors and country governments may need to utilise funding elsewhere in their HIV programmes to support HIVST, highlighting the importance of demonstrating the cost-effectiveness of different HIVST distribution models. Sustainability risks also arise with the limited domestic non-governmental organisation (NGO)/CSO engagement by the project to date.

Conclusions and lessons learned

The Unitaid-funded PSI-led STAR project is a highly relevant intervention that has been very well-delivered and extremely well-received by global and country-level stakeholders. Whilst the project is still in relatively early stages in terms of measuring results and success,

stakeholder feedback strongly suggests the "game-changing" value add of the project, indicating that a number of achievements under the project would not have happened in the absence of the project, or at least as quickly. The project has served as the necessary push to create momentum for HIVST, in a context where testing gaps are large, the HIVST evidence base limited, and policy and market conditions unfavourable. Key contributions of STAR Phase I include: i) demonstrating acceptability, demand, and uptake of HIVST; ii) significant contributions to global and country-level HIVST policy; iii) stimulating demand for HIVST products, thereby generating greater interest from manufacturers in supplying HIVST in resource-limited settings; and iv) strong information sharing and dissemination through the project that has generated significant interest in HIVST. These are all significant achievements given the short project timespan, and are reflective of the strong consortium, effective management by PSI, and good coordination within the consortium and with the range of HIVST stakeholders.

Key areas of further work include: i) establishing the public health impact of HIVST, given that current data is relatively limited on the extent to which patients are able to link to care and prevention; ii) addressing key evidence gaps required by donors and policymakers to increase support for HIVST, including the cost-benefit impact of HIVST and further evidence on the acceptability and feasibility of blood-based tests; iii) increasing the evidence base for non-CBD models; iv) addressing regulatory barriers associated with HIVST; vi) considering the practical policy implications of national HIVST rollouts, in terms of supporting development of national operational plans specifying how HIVST will be integrated into HIV testing services (HTS), as well as ensuring appropriate monitoring and evaluation (M&E) and surveillance mechanisms are in place; and vii) ensuring political engagement and advocacy across countries, beyond policymaker engagement – for example, further engagement with advocates such as those who work with young people, CSOs for demand creation and sustainability of CBD models, etc.

1. INTRODUCTION AND EVALUATION APPROACH

Cambridge Economic Policy Associates (CEPA) has been appointed by Unitaid to conduct a mid-term evaluation of the PSI Self-Testing AfRica (STAR) Project Phase I. This report presents our evaluation findings and conclusions.

In this section, we provide a brief background to the project (Section 1.1), the evaluation objectives and methodology (Section 1.2) and the structure of the report (Section 1.3).

1.1. Project background

HIV testing, and awareness of HIV status, is an essential component of the HIV response. However HIV testing rates have been low, with only one quarter of African adults tested in 2012 and fewer than half of African people living with HIV (PLHIV) being aware of their status.[5,6] In 2014, WHO and the Joint United Nations Programme on HIV and AIDS (UNAIDS) issued a *Technical Update of HIV Self-Testing* (HIVST) and WHO incorporated technical guidance and considerations into the *March 2014 Supplement to the WHO Consolidated Guidelines on the use of antiretroviral drugs (ARVs)*. These documents synthesised experiences, research and policy issues for countries interested in integrating HIVST as part of national programmes. Despite these developments, there were a number of knowledge gaps and key policy questions that needed to be answered, including additional evidence required for WHO to develop normative guidance.[7] In addition, there was a need to transform the global market for HIVST in terms of normalising HIVST in resource-limited settings and leveraging the existing HIV rapid diagnostic test (RDT) market for HIVST scale-up. This required informing and shaping policy at the national and global levels, demonstrating demand for quality-assured products for HIVST, and facilitating market entry for manufacturers in order to drive down prices in resource-limited settings.

In response to this need, the Unitaid /PSI STAR Project was approved by the Unitaid Board in October 2014 and the grant agreement was signed in August 2015.[8] The project has been set-up in two phases - Phase I and Phase II, with the latter being branded as the "STAR Initiative" requiring separate approval from the Unitaid Board, and dependent on the successful completion of Phase I. In particular:

[5] Cohen, Myron S., Ying Q. Chen, Marybeth McCauley, Theresa Gamble, Mina C. Hosseinipour, Nagalingeswaran Kumarasamy, James G. Hakim et al. *Prevention of HIV-1 infection with early antiretroviral therapy.* New England Journal of Medicine 365, no. 6 (2011): 493-505.

[6] Staveteig, Sarah, Shanxiao Wang, Sara K. Head, Sarah E.K. Bradley, and Erica Nybro. 2013. *Demographic Patterns of HIV Testing Uptake in Sub-Saharan Africa.* DHS Comparative Reports No. 30. Calverton, Maryland, USA: ICF International.

[7] Mavedzenge, M., Baggaley, R., Corbett, E. (2013). *A Review of Self-Testing for HIV: Research and Policy Priorities in a New Era of HIV Prevention.* Clinical Infectious Diseases, Oxford University Press, 57 (1).

[8] Unitaid and PSI, (2015) *HIV Self-Testing Africa (STAR) Grant Agreement Face Sheet*.

Phase I, from September 2015 to August 2017, for a total budget of US$23.7m, was implemented by a consortium with Population Services International (PSI) as the lead grantee and the London School of Hygiene and Tropical Medicine (LSHTM), the Liverpool School of Tropical Medicine (LSTM), University College London (UCL) and the World Health Organization (WHO) as lead partners. The project also include local research partners the Malawi-Liverpool Wellcome Trust, Zambart in Zambia and the Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) Zimbabwe. This first phase of work aimed to pilot and evaluate the acceptability and feasibility of HIVST among different target populations in Malawi, Zambia, and Zimbabwe, and generate information about how products for HIVST can be distributed effectively, ethically, and efficiently. Phase I also planned to focus on generating essential multi-country public health evidence to inform development of interim WHO guidance and support national-level policy formulation. It also aimed to support HIVST manufacturers interested in pursuing WHO Prequalification (WHO PQ) or stringent regulatory authority (SRA) approval and registration at the national level in project countries and aimed to achieve a reduction in the wholesale price of the HIVST included within a kit. Procurement and distribution of HIVST kits were planned through pilot distribution models.[9]

Table 1.1 below outlines the project goal, outcomes and outputs, as set out in the Logical Framework (logframe).

Table 1.1: Project goal, outcomes and outputs

Result level	Description
Goal	Catalysing the HIVST market in resource-limited settings through effective use of HIVST RDTs
Outcome	Increased effective use of HIVOFT for self-testing among target populations in the three target countries of Malawi, Zambia, and Zimbabwe
Outputs	1. Established distribution models for quality-assured HIV RDTs for self-testing in each project country. 2. Increased informed consumer demand for quality-assured HIV RDTs for self-testing 3. Reduced policy barriers to market entry for quality-assured HIVST products 4. Reduced structural barriers to market entry for quality-assured HIVST products

Phase II (i.e. the STAR initiative), which will be implemented from August 2017 to July 2020, will be delivered by a new consortium of PSI, LSHTM and local and international research partners in five countries (Lesotho, Malawi, Swaziland, Zambia and Zimbabwe), alongside work in a sixth country, South Africa, where the Initiative will be delivered by the Society for Family Health (SFH) South Africa, University of Witwatersrand-Reproductive Health Institute, and international and local partners. It will aim to build on STAR Phase I to facilitate HIVST scale-up and transition in these six Southern African countries. The STAR initiative aims to achieve direct public health impact by reducing the number of new HIV

[9] Unitaid/PSI HIV Self-Testing Africa (STAR) Project Plan

infections and averting deaths due to HIV infection by increasing demand for and access to HIVST and onward treatment and prevention services. The project will support national governments in establishing an enabling environment for HIVST scale-up and integration into national health systems by ensuring the adoption of cost-effective distribution models that reach vulnerable, underserved and key populations effectively.[10]

1.2. Evaluation objectives and methodology

1.2.1. Evaluation objectives

Based on the Terms of Reference (TOR), the purpose of this mid-term evaluation is to carry out an assessment of the programmatic implementation of the project with a particular focus on the project's overall market and public health impact. Drawing on the areas highlighted in the TOR as well as discussions with the Unitaid Secretariat, the following are priority areas for the evaluation:

- progress made against the project objectives, including an assessment of the distribution models, targeting approach and the potential to close the testing gaps;
- contribution of the project to country policy change and the market supply situation, including an assessment of what may have been the case in the absence of the project;
- assessment of project impact in terms of linkage to treatment and other areas of public health impact;
- assessment of social impact through human impact stories of the beneficiaries including evidence of positive change in the community; and
- an assessment of the project progress viewed through the lens of the Unitaid Strategy KPIs and healthy market dimensions.

1.2.2. Evaluation framework

Figure 1.1 presents the evaluation framework, structured as three core and inter-related dimensions of:

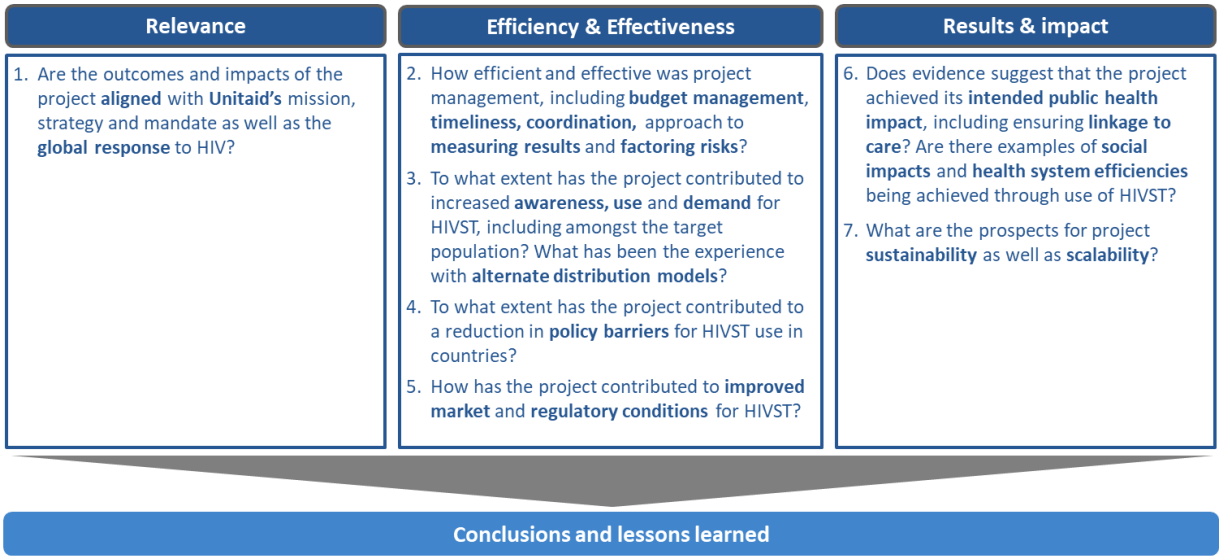
- **Project relevance** – encompassing a review of the alignment of the project objectives and scope in relation to Unitaid's strategy and mandate as well as the global needs and response to HIV.
- **Efficiency and effectiveness** – assessing project implementation in terms of overall management, and critically, how effective the project has been in achieving desired

[10] Population Services International and Society for Family Health (2017) HIV Self-Testing In Africa (STAR) Phase II Annex 1 Project Plan.

outputs relating to increased awareness, use and demand, reduction in policy barriers and improvements in market conditions.

- **Results and impact** – examining the impact the project is achieving on ground to date as well as *potential* impact, plus the prospects for sustainability and scalability.

Figure 1.1: Evaluation framework



1.2.3. Evaluation methods and limitations

The key methods employed for the evaluation include:

- **Desk-based document review and data analysis:** Key reference documents include project documents (e.g. the project plan, M&E framework, progress reports, research outputs from the project, etc.) and other broader documentation (e.g. the 2017-21 Unitaid Strategy, WHO guidelines on HIVST, etc.). In addition, we have also undertaken a basic data analysis of how the project is performing in relation to its logframe targets as well as the budget. Other data relevant for analysing the Unitaid Strategy KPIs and healthy market dimensions have also been reviewed. Annex A provides the list of key references.
- **Stakeholder consultations:** As part of the inception phase, CEPA had a kick-off meeting with the Unitaid Secretariat. In addition, CEPA participated in the STAR All Partners consortium meeting in South Africa. Our attendance at this meeting provided an opportunity to hear detailed information about project progress and to engage on a one-to-one basis with the stakeholders present at the meeting (around the formal meeting schedule and agenda). During the core evaluation phase, we have consulted with the full Unitaid project team (programmes, M&E, strategy), the project grantee consortium members (globally and in country), and other relevant stakeholders (e.g. WHO, the Global Fund, the United States Agency for International Development (USAID), the US President's Emergency Plan for AIDS Relief (PEPFAR),

the Bill and Melinda Gates Foundation (BMGF), the Children's Investment Fund Foundation (CIFF), HIVST manufacturers, etc.). Annex B provides a list of consultees.

- **Country reviews through a field visit and telephone consultations:** The evaluation has been supported by a field visit to Zimbabwe, which has enabled a better understanding of what has been achieved at a country level and the extent to which this project has contributed/will contribute to any results being realised. Consultations have been conducted with the project partners, government officials, members of the HIVST Technical Working Group (TWG, including civil society organisations (CSOs)), health facility personnel, community-based distribution agents (CBDAs) and beneficiaries. We have also consulted with select country stakeholders by telephone for the remaining two project countries to gather more comprehensive project-wide evidence. Annex B also provides a list of country consultees.

The use of a mixed-methods approach for the evaluation provides robustness to our evaluation conclusions. We note certain limitations to the evaluation methods in terms of lack of complete data on project results given that the planned endline survey has not been concluded, greater detail on Zimbabwe as compared to other project countries that were not visited for the evaluation, as well as the challenge in attributing results directly to the project given other ongoing work in HIVST and changing country and market contexts. However, we have employed considerable diligence in our assessment of conclusions by, for example: (i) carefully reviewing the quality of underlying data and noting caveats if any; (ii) conducting a number of telephone consultations with stakeholders in Zambia and Malawi, including with stakeholders outside of the project such as the government and CSOs; (iii) more generally, including a balance of perspectives by interviewing the project funder (Unitaid) and implementer (PSI, academic institutions) alongside external stakeholders (e.g. manufacturers, donors, government, CSOs); (iv) critically considering where feedback may have the potential for bias (e.g. project implementer commenting on project progress) and balancing this the available evidence and external stakeholder feedback; and (v) noting where the conclusions are specific to one country or a particular aspects of the analysis.

1.3. Structure of the report

The report is structured as follows: Sections 2-4 present analysis and findings across each of the three evaluation dimensions of relevance, implementation efficiency and effectiveness and results and impact. Section 5 presents the evaluation conclusions.

The main report is supported by the following annexes, which are included in a separate document:

- Annex A presents the bibliography/list of references;
- Annex B presents the list of consultations and interview guides;
- Annex C presents a summary of risks identified by the project;

- Annex D summarises the implementation experience of the various distribution models across the project countries based on evaluation consultations, including an assessment of the strengths and weaknesses of the models;
- Annex E presents a summary of evidence from the project countries on acceptability, feasibility of scale-up, targeting of different models and linkage to care and prevention, as well as an assessment regarding the overall strength of evidence in these areas;
- Annex F presents a list of distribution models not tested under STAR Phase I; and
- Annex G presents a listing of the project research outputs included in the WHO guidelines.

2. PROJECT RELEVANCE

The first evaluation dimension is on project relevance where we have sought to assess the extent to which the project is aligned with Unitaid's strategy and mandate and the global needs and response to HIV.

The specific evaluation question is as follows:

1. Are the outcomes and impacts of the project aligned with Unitaid's mission, strategy and mandate as well as the global response to HIV?

Testing gap and HIVST potential

In support of the efforts to end the AIDS epidemic by 2030, UNAIDS issued the ambitious 90-90-90 targets of 90% of PLHIV knowing their status, 90% diagnosed to receive antiretroviral therapy (ART), and 90% of these having viral suppression by 2020. Despite progress in scaling up HIV testing services, in 2016 30% of all PLHIV did not know their status, reflecting the large testing gap.[11] Further, the yield of current testing approaches is not very high – for example, of 150m HIV tests performed in 2014 in 122 low and middle income countries, 81 of these countries reported that only 3% of the tests were positive.[12] The testing gap is larger for men, adolescents and key populations because of the limited reach of existing testing services to these population groups, also on account of stigma and discrimination associated with HIV.

As such, scale-up of efficient and effective HIV testing approaches is needed, that can improve the yield and reach populations that are not being traditionally tested. HIVST offers a new and innovative additional approach towards this end, with the potential to improve the reach and efficiency of testing, by offering private testing and serving as a first step screening/test for triage. Whilst HIV treatment is a critical tool to end the AIDS epidemic, prevention strategies and a concerted effort to reduce the stigma, discrimination and social exclusion are also critical, both of which have the potential to be supported through HIVST.

HIVST context and project response/relevance, including Unitaid comparative advantage

From 2010 onwards, the concept of HIVST has been explored through small research projects mainly by using professional use RDTs, however there has been limited evidence and knowledge on its effective use. As such there was a need to create a body of evidence on HIVST (e.g. on acceptability/feasibility, impact, cost effectiveness, etc.), also to support WHO normative guidance and wider policy shaping. There was also a need to create a market, with demonstration of demand and encouragement of supply. The STAR project, with its goal to catalyse the HIVST market through increasing the effective use of HIVST

[11] Ending AIDS: Progress towards the 90-90-90 targets. Joint United Nations Programme on HIV/AIDS; 2017.
[12] Factsheet to the WHO consolidated guidelines on HIV testing services. World Health Organization; 2015.

RDTs, was therefore a highly relevant intervention in response to the global needs to combat the epidemic. Indeed, several of our consultations have highlighted the following that exemplify the relevance of this project, both in terms of the global response to HIV and Unitaid's mandate:

- The project represents a "bold move" given the early stage of the HIVST market, which is precisely where Unitaid's comparative advantage lies. The state of the HIVST market was nascent/undeveloped, such that large funders like the Global Fund and PEPFAR/USAID would not fund countries until the evidence base was established.
- Whilst other programmes on HIVST have been implemented globally, the scope and scale of the Unitaid-STAR initiative is much more extensive, serving as the largest demonstration and evaluation project in resource-limited settings and thereby the "needed push to create momentum" for HIVST.
- Despite delays in starting-up (see Section 3.1.2), the project was introduced at the right time to create the needed momentum for HIVST, and could not have been as catalytic if commenced later, given the growing momentum in the market.

Our consultations with governments and other actors also highlighted the relevance of the project. Some examples include: in Zimbabwe many stakeholders noted the high level of commitment to implementing HIVST, with government representatives noting that they have been closely involved in the project throughout implementation; WHO Zambia and PSI implementing partner in Zambia – SFH – specifically noted that previous HIVST research in the country was mainly formative in nature, and the government wanted to know how HIVST can be used effectively and at scale.

Broader fit with Unitaid strategy

The project was approved during the period of Unitaid's 2013-16 Strategy, where the challenge of access to HIV diagnosis lagging behind access to ARV treatment was a noted issue. While the focus of Unitaid's planned interventions (active and potential), as noted in the Strategy document, appear to relate to point-of-care diagnostics in the most part, exploratory interventions include those aimed at increasing access to improved rapid HIV diagnostic products for use in decentralised HIV care and treatment programmes, where it can be assumed this project fits. More generally, the project can be viewed to be directly aligned with Unitaid's overall mission and role within the value chain for health commodities.

Further, the new and ongoing Unitaid Strategy 2017-21, emphasises Unitaid's strategic objective on innovation, including its role in "game changing" innovation such as self-tests and other products. The project fits well within the context of the Unitaid HIV portfolio encompassing the test-prevent-treat-monitor spectrum, with several projects on early

infant diagnosis testing and this HIVST intervention representing an important intervention targeted at a different population group (i.e. adults and adolescents).[13] The supporting HIV disease narrative also emphasises the importance of self-testing and existing market barriers, with the PSI STAR project as a contribution to the solution.

It is generally noted that operational research projects are not core to Unitaid's mandate and portfolio (as indicated in a number of our consultations with the Unitaid Secretariat). However, Phase I was much more than operational research, with a significant amount of focus also being placed on the distribution of self-testing kits to encourage demand. This first phase represents an important initial step for demonstrating self-testing as a concept and laying the foundation for activities to be continued and scaled up in Phase II. Indeed, the several pieces of operational research included in Phase I are viewed as critical to developing the evidence-base for a previously untested/limited use product.

Some gaps in project design/scope

Some specific scope/design aspects of the project are however worth noting – which while do not reduce the relevance of the project, reflect the need for further work in the area:

- The PSI STAR project focuses on public-sector delivery models, and does not encompass private pharmacy based distribution which is also viewed as an important distribution channel with many critical areas for research including monitoring and linkages to programmes.
- The project covers the three southern African countries of Malawi, Zambia and Zimbabwe, selected due to their "fertile" base for policy change to help set the stage for HIVST. Whilst many have commented that this southern African focus is useful to demonstrate proof of concept and catalyse the market, the emerging lessons from models such as community-based distribution (CBD, which has been the primary focus of the project to date) that target the general population may be of less relevance to other parts of the world where there isn't a generalised epidemic.[14]

These aspects notwithstanding, we conclude that the project is a highly relevant intervention, emphasising Unitaid's role and mandate.

[13] Unitaid (2017), *Unitaid and HIV – A brief history and steps into future: brainstorming with partners*. Working slide deck.

[14] Recognising this, we understand that Unitaid is currently considering additional investments in Western Africa where the epidemic is concentrated in specific target groups.

Summary findings:

The STAR project is a much needed and highly relevant initiative, representing a "bold move" from Unitaid given the early stage of the HIVST market, underscoring its comparative advantage in the global health architecture. The project's relevance is brought about by the fact that it represents the largest demonstration and evaluation project on HIVST, serving as the needed push to create momentum in the market. Whilst the public sector delivery focus of the project represents a missed opportunity given the potential expected from the private sector, this does not reduce the relevance of the project per se, and rather highlights areas for further work.

3. EFFICIENCY AND EFFECTIVENESS

The second dimension of the evaluation focuses on the efficiency and effectiveness of project implementation. First, we consider project management with regards to budget management, timeliness and coordination (Section 3.1). Then we consider the extent to which the project has achieved planned results, in terms of project outputs of increased use, demand and awareness (Section 3.2), reduction of policy barriers (Section 3.3) and improvement of HIVST market and regulatory conditions (Section 3.4).

3.1. Project management and coordination

2. How efficient and effective was project management, including budget management, timeliness, coordination, approach to measuring results and factoring risks?

We consider below the extent to which implementation of the project has been efficient and effective, focusing on budget management (Section 3.1.1), timeliness (Section 3.1.2) and overall management and coordination including approach to measuring results and managing risks (Section 3.1.3).

3.1.1. Budget management

Out of a total project budget of US$23.7m for STAR Phase I, US$19.9m has been spent as of the end of Phase I, representing 84% of the total budget. The main reasons for a lower than planned spend have been:

- delayed implementation on account of delays in approval of research protocols and thereby delayed distribution of HIVST kits and associated procurement, training, and staff expenditure (see next section on project timeliness for further details); and
- lower than planned price obtained for the HIVST kits.

Data on expenditures until the end of July 2017 indicate that actual expenditure in Zambia amounted to 95% of budgeted expenditure, but was lower in Zimbabwe and Malawi, where 82% of the budget was expended in each case.

Staff accounted for the largest share of the expenditure (as can be expected for an operational research project), representing 36% of cumulative expenditure for 2015 and 2016, which is close to the budgeted share of 38% of expenditure for staff costs. According to PSI, the main driver of staff costs was research partner staff costs (including UK and country-based staff), which had higher salaries relative to country-based implementers. For Phase I, research partner staff costs accounted for 46% of all staff costs, while country implementers accounted for 36% of staff funding and STAR Core staff costs accounted for 18%.[15]

When compared with logframe targets, expenditure is relatively aligned with what was achieved. For example, a financial absorption of 84% compares relatively well with the target set for number of kits distributed, in which 88% of the overall target was achieved (see Section 3.2.1 for further details).

3.1.2. Project timeliness

In terms of project timeliness, we note three key aspects:

Lengthy project approval process

As noted in Section 1.1, the timeline for Phase I was September 2015 to August 2017. However we understand from PSI that the project concept was discussed long before, with the original project proposal being developed in September 2013. The proposal received a go-ahead by the Unitaid Board over a year later in October 2014, with the Unitaid Grant Agreement Development (GAD) process taking another ten months.

A recent internal review of the timelines for 18 Unitaid grants submitted for go-ahead suggests an average timeline between proposal submission and GAD kick-off of less than six months, while the average time between GAD kick-off and grant signature being slightly less than nine months i.e. a total of 15 months in comparison to 22 months for the STAR project. Based on our consultations with consortium members, the main reason for the lengthy timeframe between submission and GAD commencement was due to several changes in the project structure, including changes in lead consortium partner from LSHTM to PSI, the removal of additional partners and countries and some concerns from the Proposal Review Committee, given the limited use of self-testing in resource limited settings at the time of review.

This total of nearly two years from submission of project proposal to commencement was viewed as heavy by the grantee (especially in comparison to its other projects). More generally we comment that having shorter project approval processes is important to ensure Unitaid maintains its “first-mover” or early funder advantage in the global aid

[15] Source: STAR Project data.

architecture. That said, the broader stakeholder community has noted that the project was timely in relation to where HIVST had got to (as also noted in Section 2).

Delays in receiving ethical approvals with knock-on effects on project activities

During the initial stages of the project, key activities included obtaining necessary ethical approvals to carry out research activities for each distribution model, both from institutional review boards (IRBs) in the countries and from LSHTM Ethics Committee. While ethical approval was eventually obtained, in many cases this took a considerable amount of time to obtain approval. In particular, according to the first semi-annual progress report and the Project Plan, ethical approval was expected for all countries and LSHTM by Q1 2016, but in most cases all were achieved towards the end of Q2. Zimbabwe was noted for being particularly delayed in receiving ethical approval, although project partners were able to begin some of the formative research due to receiving approval for activities funded by the UK Department for International Development (see Section 3.2.1 for further details).[16]

While project partners were unable to control delays linked to obtaining ethical approvals (and this is a recognised challenge with research projects, and as such, may have been better planned for), these delays had knock-on effects for the implementation of the project. Planned programmes in all three countries had to be scaled down, with fewer than planned kits distributed and number of communities reached. While the CBD model could be rolled out over a 12 month period across the countries, other models were implemented over a much shorter period of time. While other distribution models were not scheduled to be implemented over the same time period nor at the scale of the CBD model, the limited time for implementation has made it difficult to draw definitive conclusions on their applicability (further discussion on this is provided in Section 3.2.5).

Pros and cons of the phased approach

The original proposal was to be implemented over a continuous four year period (i.e. not in two phases as was finally agreed). We understand that a phased approach was introduced as Unitaid was concerned about committing funds for a long time period, given there was little evidence of the acceptability and feasibility of HIVST in resource-limited settings.

In general, the phasing has not impeded project activities and progress, and the transition to Phase II has also been reasonably smooth. However, it has entailed additional transaction costs for the grantee (as a new proposal has to be submitted to Unitaid after only a year of implementation given initial delays) as well as losing some of the unspent budget in Phase I, given that a new budget was developed for Phase II with no funds being rolled over. While the phased approach was useful for allowing changes to be made to project design following lessons learned from Phase I, it would have been beneficial for all parties involved if the

[16] In addition, the project experienced delays due to time required for sub-contracting research staff.

requirements on PSI for obtaining Phase II approval were lower, for example with the application process only requiring a smaller application and shorter approval process.

3.1.3. Project coordination and management

We review three aspects here, including: (i) overall management by PSI as the lead and coordination amongst implementing partners and other stakeholders; (ii) approach to measurement of results; and (iii) approach to risk management.

Overall management/coordination

The general consensus has been that project management and coordination has been very effective.[17] In particular:

- Project partners and Unitaid have been overwhelmingly positive about the work of the STAR Core Team, and have generally felt well informed about the different project developments and future steps. Indeed, many individuals who have had experience working on other Unitaid projects have noted that the coordination and management under this grant has been among the most effective.
- The role of LSHTM as lead research partner has worked well and the project research networks have been noted as being useful mechanisms for exchanging thoughts and ideas, as well as learning lessons from experiences in other countries.[18] Many stakeholders have noted the impressive level of South-South collaboration and capacity building that has taken place as a result of this collaborative approach.
- The role of WHO in coordinating the inputs from project partners and the findings from the research into the HIVST guidelines, as well as the support it has provided to countries adopting policies for HIVST has been noted positively (see Section 3.3 for further details).
- Coordination between country implementers and research partners has also been effective, and has been important for ensuring that useful findings could be drawn from the project.

[17] Some partners reported the view that the project structure has meant that communications between Unitaid and sub-grantees has been difficult, given that messages would be channelled through PSI to the various sub-grantees, which for the research partners could also need to be communicated through LSHTM. This "top-down" approach to communication meant some delays in communication (resulting in the need to respond to very tight deadlines in some cases). Some partners noted that they found it difficult to suggest specific ideas to other members of the consortium, both because of the time lapse in receiving communications and (related to this) not being able to attend All Start Partners meetings as only a short amount of notice has been given for the dates that these would occur. However, it should be emphasised that these are isolated points in what overall has been seen as a positive experience by different project partners.

[18] (i) The Quantitative and Epidemiology Research Network; (ii) the Qualitative Research Network; and (iii) the Economics Network.

- Key mechanisms for project coordination have included bi-annual All STAR Partners Meetings, regular discussions within research networks and fortnightly catch-ups between country implementers and researchers, with less formal discussions and contact taking place more often than this between all project partners.

More generally, we also note that the project was well coordinated with other stakeholders in the HIVST landscape, primarily through the HIVST TWGs that were established as a result of the project (further discussion on these are provided in Section 3.3.1), but also close contact between the STAR partners (particularly the Project Director and individuals in WHO) and external donors and manufacturers through STAR implementation. STAR partners have also been in contact with external stakeholders at key international events, which has enabled them to showcase the project to the international community (see Section 3.2.3 for further details). Many external stakeholders have noted that this communication has been helpful and has contributed significantly to key institutions maintaining their interest in HIVST throughout Phase I implementation.

To conclude, management and coordination of partners and activities has been an important success factor driving the results of the project.

Approach to measurement of project results or logframe

Regarding the logframe, we note in general that this has been well designed, with the following aspects working well:

- Generally easy to follow with appropriate levels for goal, outcome, output and impact.
- Mostly appropriate, verifiable indicators.

However, we note that there are some aspects which do not work as well with the logframe, and measurement of project results more generally, including:

- The logframe does not fully capture project results, which are much more than the logframe indicators. Some examples include: (i) linkage is limited to treatment and voluntary medical male circumcision (VMMC) and not additional prevention interventions such as those for female sex workers (FSW), and broader prevention interventions for TB, cervical screening etc.; (ii) the age of testers has been measured but is not included in the logframe; (iii) the logframe has not been able to fully capture the market impact of the project.
- Activities in Output 1 contributed to results achieved under Output 2 and vice versa. This is not an issue per se but it would be helpful to have a theory of change to inform the flow of activities and results, especially given that this was a pilot project to demonstrate feasibility for scale up.
- In the Unitaid context, key market terms such as “demand”, “supply”, “use”, “adoption”, “uptake”, etc. have specific definition, and some of the terminology in

the logframe does not use these market terms in a strict sense e.g. difference between "use" in the Outcome and "demand" in Output 2.

Effectiveness of risk management approach

Risks associated with the STAR project were highlighted in the initial Project Plan as well as in the semi-annual progress reports provided to Unitaid, which are summarised in Annex C. Our review of these documents suggests that major project risks were identified either at project initiation or during implementation. For example:

- risks associated with uncertain demand/acceptability of HIVST were identified in the initial project plan, while negative results coming from other bodies of research was also identified in early progress reports;
- risks associated with not obtaining WHO PQ were identified throughout the project;
- delays associated with IRB approval were identified early in project implementation, specifically risks associated with delays in Zimbabwe; and
- risks regarding social harms were highlighted both at project initiation and throughout implementation.

Our only comments on the above is that the risk associated with the project producing evidence for OFT only (and not blood-based tests) was considered later in the 2016 Annual Report, and the risk in delays associated with obtaining ethical approval was only first considered in the 2015 Semi-Annual Report. Given their significance, both should have been noted at the outset.

Summary findings:

The STAR project has been very well managed and coordinated, being one of the key success factors driving its results. The main challenge with management has been with regards to timeliness where delays in obtaining ethical approvals (recognized as a challenge for most research) have had knock on effects on implementation of project activities, implying a lower than planned scale of activities and inadequate implementation time for testing of some models.

3.2. Increased awareness, use and demand for HIVST

3. To what extent has the project contributed to increased awareness, use and demand for HIVST, including amongst the target population? What has been the experience with alternate distribution models?

Under this evaluation question, we consider the extent to which the project has delivered against the logframe Outputs 1 and 2 ("established distribution models for quality-assured HIV RDTs for self-testing" and "increased informed consumer demand for quality-assured HIV RDTs for self-testing" respectively), the project activities for which contribute to increasing awareness, use and demand for HIVST. Output 1 in particular forms the core of

STAR Phase I, aimed at demonstrating the feasibility, acceptability and applicability of alternate distribution models for HIVST.

Our assessment encompasses:

- A review of the key activities including implementation of different HIVST distribution models, supporting qualitative and quantitative research as well as marketing activities – this is covered in Sections 3.2.1- 3.2.3 below, encompassing an assessment of what has worked well and less well during implementation and key findings from the research;
- A review the emerging results in terms of increased access, uptake, yields and general awareness of HIVST (Section 3.2.4); and
- An assessment of the overall evidence on HIVST through the project as well as project-specific key issues and remaining gaps (Section 3.2.5).

3.2.1. Implementation of distribution models

We first describe the extent to which the different distribution models were implemented, followed by an assessment of their relative advantages and disadvantages. A more detailed analysis is provided in Annex D.

Extent of implementation of distribution models

HIVST kits were distributed through a range of different models in Phase I, including CBD, facility-based distribution, linked to VMMC services, female sex worker (FSW) distribution, amongst others.

Table 3.1 below summarises the extent to which the different distribution models were tested in the project countries, in terms of number of kits distributed. As can be seen from the table:

- **The CBD model was the main model employed in all three countries**, accounting for 83% of the total distribution. Discussions with stakeholders indicates that this was the model of choice at the time of project design, to establish the feasibility of HIVST and reach a reasonable scale, also given the generalised nature of the HIV epidemic in the project countries.
- **While distribution targets were not achieved for Zambia and Zimbabwe, overall volumes are regarded as significant for the pilot phase.** Targets were not met on account of delays in obtaining IRB approvals, as mentioned above in Section 3.1.2. However the overall scale of distribution has been regarded by country stakeholders as significant and relevant for a project aiming to test the HIVST concept.
- **Although overall volumes were significant, the number of kits distributed relative to targets for non-CBD models was low.** For example, across the three countries

only 71% of the overall target was met for public sector distribution, while for FSW (35%) and VMMC (31%) the proportions were significantly lower. This is largely attributable to the delays in implementation previously mentioned.

Table 3.1: Distribution of kits by model for each country (September 2015-August 2017)[19,2021]

Model	Malawi	Zambia	Zimbabwe	Total	Total as % of target
CBD	175,991 (94%)	156,806 (82%)	199,552 (83%)	**532,349 (83%)**	**98%**
Facility based - New Start/Tunza[22]	2,518	-	52,254	**54,773 (8.5%)**	**109%**
Facility-based - Public sector	1,056 (0.6%)	18,588 (9.7%)	2,595 (1%)	**22,239 (3.5%)**	**71%**
VMMC[23]	2,581 (1.4%)	15,092 (7.9%)	7,142 (2.7%)	**24,815 (3.9%)**	**31%**
FSW	5,255 (3%)	-	3,548 (1.3%)	**8,803 (1.4%)**	**35%**
Workplace	-	298 (0.2%)	-	**298 (0.05%)**	**No target set**
Total	**197,401**	**190,784**	**265,091**	**643,276**	**88%**
Target	**172,054**	**200,478**	**360,890**	**732,422**	**N/A**
Total as % of target	**110%**	**95%**	**73%**	**88%**	**N/A**

Source: PSI project data. Targets based on figures from final logframe (dated 21st June 2016). Figures in parentheses for individual models refer to proportion of total kits distributed in the project country.

Implementation experience and advantages/disadvantages of distribution models

As regards the implementation experience of different models, our review of project documentation and feedback from consultations (particularly through our field visit in Zimbabwe) has indicated that, despite initial delays limiting the extent to which kits have been distributed, the **experience across models has been positive**. In particular, **self-testing has widely been accepted by beneficiaries, distributors, health professionals and policymakers alike**, with all noting its distinct positive benefits. For example:

- For **CBD,** individuals often preferred this model as it they do not need to spend time going to the health facility and avoid the risk of being tested/seen being tested by others in the community. People also appreciated the support provided by CBDAs,

[19] The outputs achieved for CBDAs trained also display similar results to kits distributed, namely that overall targets were not met primarily as a result of the targets for Zimbabwe not being met (with the number of wards visited being reduced from 80 to 44), as well as initial delays in implementation.
[20] Data from secondary distribution is included within the other models, and was not reported explicitly.
[21] We do not discuss the workplace model below due to limited implementation.
[22] The social franchise distribution models include distribution via fixed sites and outreach activities.
[23] VMMC distribution includes fixed site as well as distribution via Interpersonal Communication (IPC) agents.

who are often known individuals in the community and able to provide useful advice. Significant awareness of self-testing was generated through the use of this model.

- For **facility-based models**, self-testing was integrated relatively easily into existing health facilities, and also had the benefit of freeing up staff time to perform other tests. In New Start facilities in Zimbabwe, patients were initially given the choice between self-testing and PDHTS testing, and during project implementation, we understand that the proportion opting for self-testing rose from 40% to 60%.[24] More recently, the New Start facilities began offering self-testing on an "opt-out basis", and since then the proportion of people taking self-tests has increased to 98%.
- For **VMMC,** implementers saw self-testing as being a useful tool for supporting their demand creation activities and facilitating greater linkage to circumcision.
- Similar benefits to facility-based models were also found for models focusing on **FSW**, where availability for HIVST freed up staff time for other tests. Evidence from the project also found that sex workers in Zimbabwe liked self-testing due to the privacy and convenience it allows, inculcating a sense of empowerment and control on their test results.

Alongside the benefits, some key challenges that need to be considered as HIVST is rolled out included:

- In a number of countries linkage to care and treatment (including its monitoring) continued to be an issue, particularly for **CBD** and other models that were not linked to a specific facility (Section 4.1 and Annex E elaborates further).
- Another key issue from the **CBD** model in Zimbabwe was that follow-up activities were taking place two weeks after initial distribution, which was found to be too long for those who were testing positive. In addition, kits were only distributed to eligible individuals present in the household at the time of kit distribution, meaning that some people would be missed by CBDAs.
- Further, while the **CBD** model has strong support from communities, it is considered to have the largest sustainability risks due to the costs of the CBDAs in addition to the cost of test kit distribution. Further, to date there has been limited integration with communities and CSOs/community-based organisations also undermining sustainability going forward. We note that a community-led model is to be trialled in Phase II in order to reduce costs (Zimbabwe).

These benefits and challenges are further elaborated upon in Annex D, alongside a more detailed consideration of the social impact of HIVST in Section 4.1.2.

[24] *Source: Consultations with project partners.*

3.2.2. Quantitative and qualitative research

Whilst the implementation of the distribution models was the primary focus of the project, this was supported by a range of quantitative and qualitative research to establish the feasibility and acceptability of HIVST. We provide a brief summary of the main areas of research and high-level findings.

Initial formative research

Initial research was conducted by the consortium on the extent to which the OraQuick self-test kit could be used by individuals to obtain **accurate** results across project countries. Key findings from these studies were as follows:

- Each study confirmed the need for clear and well-defined instructions for use (IFUs) that needed to cater for local contexts (i.e. language and significance of pictures in different cultures). In addition, ideally, instructions should be complemented with videos/demonstrations to ensure greater accuracy of results.
- In Zambia, results from accuracy studies suggested that compared to "gold standard" laboratory testing, sensitivity fell to 87.6% overall, or 76.6% in rural communities.[25][26]

This initial work was important for ensuring that appropriate IFUs were developed for the implementation phase of the project and also directly informed the IFUs included in the OraQuick HIVST kits. The studies also highlighted that confirmatory testing following positive HIVST results was important. The Zambia findings in particular highlighted the importance of repeat testing (i.e. every three months) for high-risk populations and confirmatory testing if tested positive, as noted in the WHO guidelines.

Formative research studies also included a number of focus group discussions (FGDs) and discrete choice experiments (DCEs) on how HIVST should be distributed. Key findings from these studies (which were consistent across countries) included: (i) respondents were strongly against any form of pricing for HIVST; (ii) respondents would prefer to self-test in their own home as opposed to undertaking self-tests in clinics or mobile facilities; and (iii) post-testing support via a follow-up call and meeting with those distributing the kits was believed to be most appropriate.

[25] Based on a sample size of 2,552 overall (604 in rural communities, 1,031 in urban communities and 917 in urban health facility). While this was a significant improvement on the 29% sensitivity prior to optimising IFUs, this is still relatively low by testing standards

[26] Aside from this study, sensitivity in the three countries was above 93%, while specificity results were often above 99%. However, it should be noted that sensitivity numbers (especially for studies conducted in Malawi and Zimbabwe), are based on low sample sizes (13 for Malawi and only four for Zimbabwe).

Cluster randomised trials on distribution models and impacts

In addition to this research, each country conducted cluster randomised trials (CRTs) to analyse the **impact** of HIVST. For example:

- In Zimbabwe, the CRT tested the extent to which incentives to CBDs resulted in greater levels of linkage to post-test services.[27] Findings from this trial suggest that financial incentives on CBDs were not significant in increasing linkage. However, many have noted that the size of the financial incentive was relatively low (US$0.20). As regards general findings on post-test linkage, preliminary findings from the CRT appear to be positive.
- In Zambia, the PopART trial has been investigating whether a combination HIV prevention package including universal HIV testing and treatment can reduce HIV incidence in communities, as well as testing the impact of HIVST of populations knowing their status. This trial has received funding from a range of sources, while the self-test kits used within the trial were funded by the STAR project. Current findings from the study suggest that HIVST has a positive and significant impact on people knowing their HIV status, particularly among men (further details regarding the study are provided in Annex E).
- In Malawi, the CRT evaluated the effectiveness of introducing HIVST on HIV testing coverage and ART initiation rates. Findings from the CRT on testing coverage are included in Section 3.2.4, and suggest an increase in uptake, while findings regarding ART initiation were not available at the time of writing.

Further details on the findings from all these studies can be found in Sections 3.2.4 on uptake/demand and 4.1 on public health impact.

Cost and cost-effectiveness studies

Another area of study is on the **cost and cost-effectiveness** of distribution models. Analysis has been undertaken in Zimbabwe by modellers at UCL and LSHTM (as part of the Economics Network), while more general research has also been undertaken on costs of HIV testing services across the three countries.

Based on costing studies, researchers have found that HIVST distribution via CBDs is relatively comparable to those of facility-based HIV testing, although costs of HIV testing vary substantially between countries. In terms of cost-effectiveness, findings from modelling of HIVST in Zimbabwe suggest that generalised models such as CBD are unlikely to be cost-effective due to higher prevalence rates in these countries making the incremental cost in

[27] There were initial plans to provide incentives to patients to link to care (for example, by providing vouchers for bus fares in order to visit facilities), but this was subsequently dropped as the project did not obtain government approval. An assessment of the impact of HIVST on ART initiation was also conducted.

finding those that already know their status high. However, it was noted that i) such models could be more cost effective with lower commodity prices (with prices reducing significantly since the analysis was carried out); and ii) this was an issue associated with any form of HIV testing and not specific to HIVST. The analysis also suggested that models targeted at FSWs and secondary distribution to male partners of pregnant women, as well as pharmacy based models could be relatively cost-effective given the potential high yields found as well as marginal incremental costs of such models. Further details on the findings from cost and cost-effectiveness studies can be found in Annex E.

Social harms

Social harms was a major concern at the start of the project in terms of whether self-testing would result in increased domestic violence, marriage/relationship break-up and family members being coerced into taking tests. Of the three countries where distribution models were implemented, Malawi had a particular focus on assessing the impact of HIVST in this regard.

According to reports from the project, there were no instances of social harm relating to HIVST in Zambia or Zimbabwe, while Malawi had 13 reports of social harm as of July 2017.[28] This was explained by the intensive follow-up system in place in Malawi. In addition, community groups working in the countries and PSI noted that there was evidence of social harm, but this was not often specifically linked to HIVST.

From consultations with government stakeholders in Zimbabwe, social harms appeared to be less of a concern for them as a result of the evidence from the STAR project. However, other stakeholder groups felt that it would be unwise to ignore potential issues around social harm should self-testing be rolled out more widely. This was especially the case given different local contexts and potential risks of being diagnosed HIV positive, which may be magnified when individuals find out their results on their own.

3.2.3. Marketing research and campaigns

Under Phase I, marketing research was conducted to obtain a greater understanding of consumer preferences and motivation for self-testing, as well as implement effective marketing campaigns to increase consumer demand. This was informed by the formative research undertaken, including DCEs that analysed user preferences with regards to how kits are distributed, their price, timing of delivery/collection, as well as cognitive interviews and FGDs, and was closely integrated with the research work described above. It was also informed by activities related to observing the implementation of distribution models.

The market research helped identify distinct consumer groups or 'archetypes' that would have differing motives for using self-testing, which in turn informed the overall programme

[28] Source: TAG meeting summary note, July 2017.

design in terms of training CBDAs on the way they should approach clients and support them with self-testing, how to sensitise communities and which models would be most appropriate for different archetypes. It also helped inform the marketing campaign of the project, which was implemented by PSI staff regionally, with support from external marketing consultants, as opposed to being a national activity. This included disseminating posters depicting different archetypes, participating in local radio dramas as well as docu-dramas that were broadcast in clinics and on social media. Local events were also launched in the communities to raise awareness of self-testing.[29]

PSI noted that the regional marketing approach, plus HIVST being a new product category with substantially less awareness than other products used in HIV testing and preventions services (such as condoms), resulted in the processes involved in designing and refining campaign materials taking longer than expected. This was due to having to involve a broad range of stakeholders in the design of the regional campaign and the fact that the external marketing agency that supported PSI needed a large amount of guidance on the messages they were trying to portray and the nature of the product. Such learnings may be important for informing project partners in the new countries, particularly those in South Africa where implementation is being led by Society for Family Health (SFH), as well as other programmes using HIVST such as the recently approved Unitaid grant for introducing HIVST in West Africa.

3.2.4. Emerging results on uptake and demand

Data has been collected during project implementation directly by CBDAs during distribution, through clients filling out questionnaires and individuals returning used kits to CBDAs and in drop-boxes in health facilities. In addition household surveys have been undertaken by project researchers, and to date baseline (Q4 2016) and midline (Q1-Q2 2017) surveys have been completed on the CBD model, with endline surveys expected to be completed in February 2018. As such, data presented in this sub-section is likely to change once the final endline results are available.

Key findings are as follows:

There is emerging evidence that HIVST is increasing access to testing for previously untested groups, particularly men and adolescents.

One of the key objectives of Phase I was to demonstrate that HIVST could reach those less likely to be tested through traditional forms of testing, including males and younger adults. According to the Phase I Project Plan, the CBD models in particular targeted these groups.

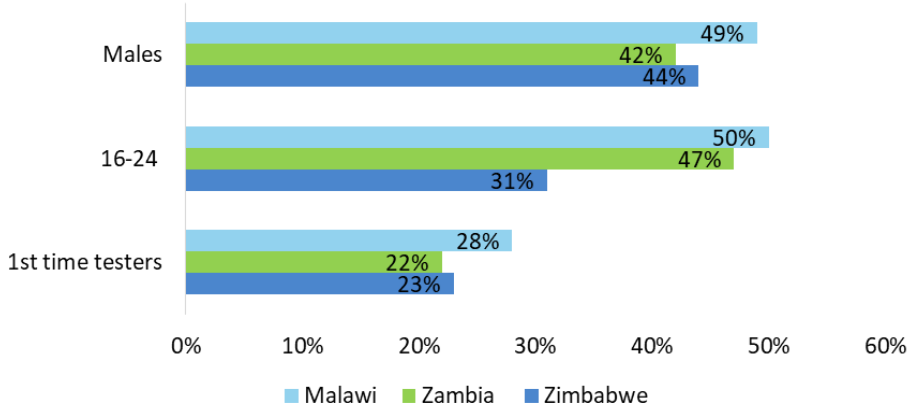
[29] While the marketing activities were implemented regionally, it should be noted that in-country campaigns were primarily focused on generating awareness and demand at the local level where distribution activities were being undertaken, given that both PSI and government partners in country did not want to raise awareness at a national level in Phase I due to being unable to meet this potential demand.

Figure 3.1 shows the preliminary results in this regard, which can be viewed as positive. In particular, as can be seen in the figure:

- Between 42-49% of kits were distributed to males in the three countries. Given that females normally account for 70% of those tested for HIV, these figures suggest that the CBD model was effective in increasing the proportion of men tested for HIV.[30] Further, based on the recent Population-based HIV Impact Assessments (PHIAs) undertaken by the ministries of health in the three countries (supported by PEPFAR and CDC), around 37% those surveyed who had tested for HIV in the past 12 months across the three project countries in 2016 were male. This suggests that self-testing was able to reach a larger proportion of males compared to conventional forms of testing.[31]
- For younger people, the proportion of kits distributed were 50% for Malawi and 47% for Zambia, while for Zimbabwe relatively low at 31%. Compared to 34% of 15-24 years olds noted in the PHIA studies as having tested for HIV over the past 12 month through conventional testing, as such, the project was able to reach a relatively higher proportion of this age group, at least Malawi and Zambia.[32]
- The proportion of kits distributed to first-time testers was between 22%-28% depending on countries. This is in line with the proportion of people found to have never tested for HIV in the three project countries as part of the PHIA assessments (25% for Malawi, 27% for Zambia and 25% for Zimbabwe), suggesting comparable additionality for this group.[33] However PSI informed us that they were expecting this to be around 10%, suggesting that the extent to which first-time testers were reached was higher than expected.

[30] WHO (2016). *Overview of the New Guidelines on HIV Self-Testing and Partner Notification*. Presentation at BMGF Workshop, September 2017.
[31] Individual country proportions were 37% for Malawi, 38% for Zambia and 35% for Zimbabwe. Sources: MoH Malawi (2017), Malawi PHIA; MoH Zambia (2017), Zambia PHIA; MoHCC Zimbabwe (2017), Zimbabwe PHIA.
[32] Ibid.
[33] Ibid.

Figure 3.1: Percentage of kits provided to key target groups through CBD models



Source: STAR project data. Sample sizes: Malawi: 163,300; Zambia: 140,024; Zimbabwe: 123,192

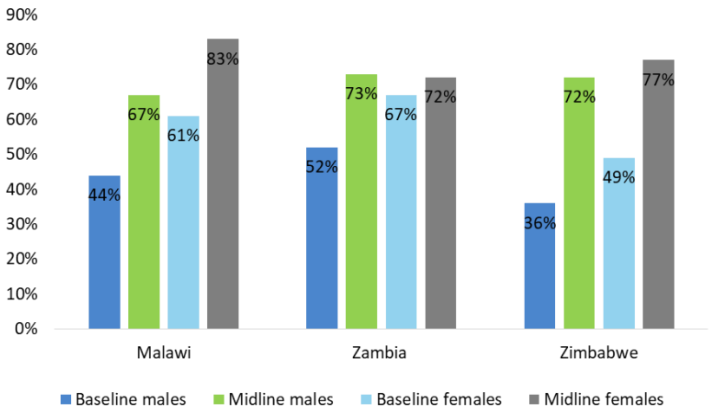
These figures are based on demographic data collected by CBDAs during the distribution of kits. Given the nature of this data and the method used to collect it (with fairly large sample sizes), we view the data to be reasonably robust.

Evidence also indicates an increased uptake of HIV testing, which could potentially be contributed by HIVST made available through the CBD model.

The project estimated increases in testing (including self-testing and other forms of testing) following the implementation of the CBD models. These figures are based on responses from baseline and midline surveys in Malawi and Zambia. The baseline surveys included a sample size of 4,800 participants for both Malawi and Zambia, 2,400 of which received self-testing while 2,400 were in control groups (i.e. no HIVST were received). For the midline surveys, the sample size in Malawi was 436 while in Zambia it was 620. A slightly different methodology was used for Zimbabwe, which compared DHS survey data from 2015 with surveys undertaken after HIVST testing was introduced in communities via CBD (with a total sample size of 2,400 for these surveys). These are reasonable sample sizes given the project context and hence the data may be viewed as robust, although a more credible comparison would be between the baseline and endline surveys.

The emerging evidence is presented in Figure 3.2, which shows that the extent to which people were testing for HIV rose considerably in all three countries, particularly among men where the increase averaged 26 percentage points. While these figures are not directly attributed to self-testing, it is likely that HIVST contributed to the increase given the project and survey design. For example, mid-line survey data suggests that a high proportion of the target population tested in Malawi (48% males, 52.5% females) and Zimbabwe (69.6% males, 71.5% females) had used self-testing (although figures for Zambia were considerably lower, with only 14.8% males and 14.6% of females tested, partly due to the timing of the surveys in Zambia meaning that implementation in some districts had only just started, so may not fully capture the impact of introducing HIVST).

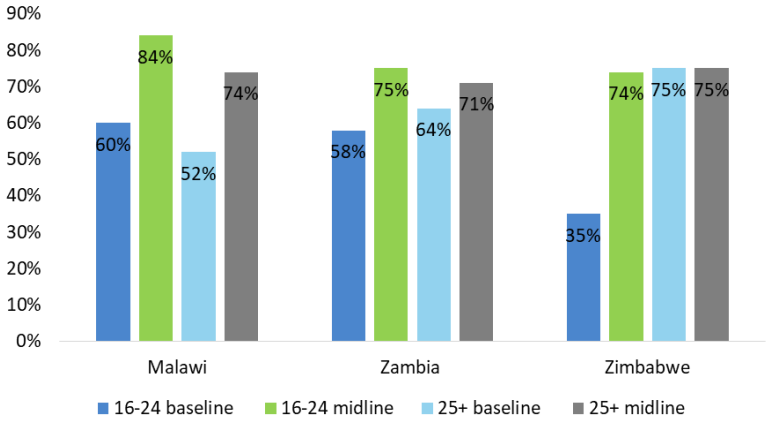
Figure 3.2: Proportion of male and females testing for HIV over the last 12 months in project areas – CBD model



Source: PSI End of Project Progress Report (2017).

Project data also suggests that there was a considerable increase in younger people being tested following the introduction of HIVST, as shown in Figure 3.3 below. This data suggests that there was on average a 27 percentage point increase in HIV testing among younger adults following the activities of the project, with Zimbabwe showing a particularly high increase among young people (39 percentage points).

Figure 3.3: Proportion of 16-24 and 25+ individuals testing for HIV over the last 12 months in project areas – CBD model



Source: STAR project data.

Preliminary findings from public sector facility-based distribution in Zimbabwe also shows that the introduction of self-testing resulted in the total number of tests being conducted at health facilities more than doubling.

Preliminary findings suggest that yield through HIVST can be higher or at least in line with provider-delivered HIV testing services.

The project also collected self-reported data on the proportion of HIV positive individuals identified through self-testing. This information was based on reading the results of test kits anonymously dropped into collection boxes located either at convenient places in the

community or health facilities where people returned for confirmative testing or post-test support. People were also asked to complete a questionnaire, asking what the result was of their self-test and whether they had previously tested for HIV. The late reading of self-test kits was undertaken 1-2 months after the distribution of test kits or when boxes were full. Previous research analysing the stability of self-test kits have found that results can change from negative to faintly positive when read after extended periods of time. For example, a study by LSTM under the STAR project found that 30% of 148 HIV non-reactive (negative) test results turned faintly positive.[34] Given these issues, PSI noted that the figures reported may over-estimate the extent to which people were tested as HIV positive, and therefore should be interpreted with caution. In addition, the yield for all the distribution models was not available at the time of writing.

Further, the sample sizes used for analysing the late-reads varied by model and was relatively small for some models. These are summarised in Table 3.2 below, which shows that for some of the models (particularly FSW and VMMC) sample sizes were considerably smaller than others (for example, the CBD model).

Table 3.2: Sample size used to measure yield of different models

Distribution model	Malawi	Zambia	Zimbabwe
CBD	81,232	68,943	71,198
Facility-based	968	11,724	24,375
FSW	3,611	-	325
VMMC	957	10,580	1,361

Source: STAR project data.

As such, the findings cannot be considered definitive and should be interpreted with caution.

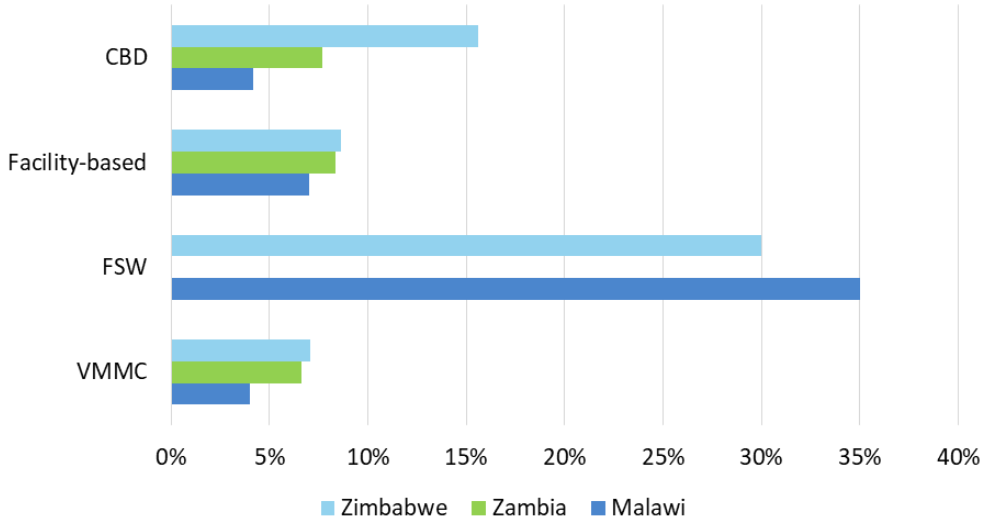
Figure 3.4 presents the available data on yield by countries and distribution models, reflecting the following:

- As expected, yield among FSW, a key HIV population, were particularly high.
- On the other hand, the yield among those tested through the VMMC model were relatively low. This reflects the relatively low prevalence of HIV among younger men, which are targeted for male circumcision in PSI programmes.
- For CBD, we have been informed by PSI that they expect the yield to be around 8-10% for Zimbabwe and Zambia, which is in line with the facility-based models, whereas for Malawi preliminary data is lower at around c.3%. Numbers for these

[34] Watson et al. (2017), *Determination of OraQuick HIV self-test result stability with delayed visual re-reading: An external quality assurance analysis.*

models targeting general populations are either above (Zimbabwe and Zambia) or in line (Malawi) with the yield found for HIV testing overall, as noted in Section 2.

Figure 3.4: Yield by distribution model



Source: STAR project data; FSW estimates based on studies conducted by Cowan (2016) and Mavedzenge (2017) under the STAR project.

One important thing to note on the data on yield for the CBD model is that even if yields are not higher than in other models, the project data presented previously suggests that it is reaching those not tested through other means, therefore helping to reach the first 90 target by identifying additional PLHIV, as opposed to simply testing those that would otherwise find out their status.

There is positive evidence on increased awareness and demand through the project – in project countries and globally

Table 3.3 summarises the extent to which the project has been able to achieve its logframe targets under Output 2 (using a red-green coding to reflect less than or greater than planned achievement). It should be noted that actual figures are based on the midline survey (with a relatively small sample size) undertaken for the project at the beginning of 2017, therefore should be interpreted as preliminary findings.

From these figures, the following observations can be made:

- **Malawi and Zambia** were able to achieve **all their logframe targets** for under Output 2, far exceeding these targets on several occasions.
- **Zimbabwe** was unable to achieve logframe targets set out under Output O2.2, which was specifically related to awareness of access to treatment and prevention services (including VMMC). An explanation for these results in Zimbabwe was how CBD was implemented relative to other countries, with a six week resource intensive campaign not allowing for sufficient time to disseminate all relevant information on

linkage to care and prevention following testing. While we cannot confirm this is the reason, PSI noted that this will be looked at in further detail going forward.

Table 3.3 Summary of project performance against Output 2 logframe targets

	Malawi	Zambia	Zimbabwe
O2.1: % of target population who ever heard of HIVST as a method of testing			
Target	**70%**	**65%**	**75%**
Female	98%	99%	82%
Male	97%	99%	81%
O2.2: % of target population aware of how to access testing/care and treatment services			
Target	**70%**	**70%**	**75%**
Female	85%	88%	54%
Male	83%	85%	50%
O2.2: % of target population aware of how to access VMMC for HIV prevention			
Target	**60%**	**65%**	**70%**
Actual	70%	85%	43%
O2.3: % of target population who would recommend HIVST to a peer/family member			
Target	**60%**	**60%**	**65%**
Female	98%	99%	97%
Male	99%	100%	95%

Source: PSI (2017).

Further, while not reflected in the logframe targets per se, one of the key strengths of the STAR project has been raising awareness of HIVST at the global level, based on the extensive marketing and dissemination the activities of the project. This is reflected in the number of research outputs and evidence generated – 28 abstracts and four research papers have been funded under the STAR project to date, with an additional 6 abstracts and 24 papers being written by STAR authors and funded by other organisations.[35] It is also particularly reflected in the fact that, as many stakeholders have noted, PSI has done an excellent job in disseminating the findings from the project as well as generally raising awareness of HIVST with key stakeholders in international fora. For example, results from the STAR project implementation and research have been disseminated at five International conferences, including ICASA 2015, AIDS 2016 in Durban, CROI 2017, the International HIVST Symposium in Nairobi in 2017 and at IAS in Paris in 2017. This, combined with the close collaboration with external partners during project implementation, is likely to have significantly contributed to the increased interest in HIVST compared to when the project was initiated,

[35] PSI (2017), *STAR End of Project Report*.

including the adoption of HIVST policies and pilot programmes in non-project countries (further discussion regarding this is provided in Section 3.3).

3.2.5. Overall evidence on HIVST, key project issues and remaining gaps

As presented above, the experience across distribution models has been positive, with self-testing being widely accepted and emerging positive trends in terms of access and uptake amongst population groups with limited reach through traditional testing approaches.

Reviewing the evidence-base across distribution models on their acceptability, feasibility, targeting and linkage (with linkage also being discussed in more detail in Section 4.1), we find the evidence is more positive in terms of acceptability, somewhat lower (but still positive) in terms of feasibility (recognising limited work conducted in terms of costings and cost-effectiveness analyses) and less positive in terms of targeting and linkage (where there are also more gaps in evidence). Table 3.4 provides a summary assessment, which is explained in detail in Annex E. Note that the categorisations of high-medium-low are defined relative to the different distribution models (e.g. linkage to care under the CBD model relative to the facility-based model), as opposed to being absolute categorisations, and reflect CEPA's subjective assessment. Please also note that entries with red font refer to areas with relatively limited strength of evidence. Annex E provides further details on the strength of the evidence base across the dimensions for each distribution model.

Table 3.4: Summary of key dimension findings for different distribution models

Model	Acceptability	Feasibility	Targeting	Linkage
CBD	High	Medium	Medium	Low
Facility-based	Medium	Medium	Medium	High
VMMC	High	Medium	Low	Medium[36]
FSW	High	High	High	High[37]
Secondary distribution	High	High	No evidence	No evidence

Source: CEPA analysis based on review of evidence.

Some project-specific implementation issues and remaining gaps at the end of Phase I are as follows:

- **There has been a degree of tension between the project objectives of encouraging uptake and demand versus establishing the evidence base.** For example, during consultations, implementing partners stressed that the former was the primary objective of the project, while researchers noted it was important to use the project as an opportunity to collect robust evidence. The two-pronged objectives of the

[36] Note that linkage for the VMMC model refers to linkage to circumcision.
[37] It should be noted that this only applies to FSW models where individuals are tested at sites, as opposed to models where FSW can test away from health facilities.

project have created a degree of tension with PSI keen to distribute as many kits as soon as possible, but having to also align with the research protocols and methods. Going forward, it would be important to clearly establish the strategy and prime objective for the project.

- **Some researchers have expressed caution with inadequate emphasis on research findings in the context of the "euphoria" around HIVST.** An example is the accuracy findings from Zambia, which indicated lower sensitivity compared to the current gold standard for testing. We also note the issues associated with the validity of findings on the yield of different models, given issues associated with late-read kits previously mentioned. While these do not negate the value of HIVST, also given its many other benefits, there was a view that adequate attention was not heeded to these findings within the context of the positive momentum for HIVST. The research findings have been largely positive, but it is important to objectively consider the evidence base being generated, especially to inform scale-up plans and approaches.
- **Substantial emphasis on CBD alongside limited testing of other models.** As noted above 83% of the kits were distributed through the CBD model and in some of our global stakeholder consultations there was limited awareness of testing and results from other models being implemented under STAR Phase I. The initial delays in obtaining ethical approvals for the research meant that the CBD model (which was planned as the pioneering model in all project countries) was the only model with a good number of months of implementation, while a number of the other models in countries were implemented for a few months only.[38] As such, the strength of evidence for these other models is also not adequate to make strong programmatic conclusions. This is also reflected in our review of the strength of evidence across the distribution models described above in this section and in Annex E. There are mixed views as to whether the CBD focus has been appropriate given the utility of this model and the objective of reaching a base level of scale, as compared to the need for testing alternate models for a wider evidence base.[39] The emerging view from our consultations is that this focus on CBD was appropriate for Phase I, although additional models could have been better incorporated, and that going forward, there is merit in testing additional models, although balancing appropriately with the project objective and Unitaid mandate of catalysing the market. The FSW model can be viewed as the other model that was reasonably well tested during Phase I. Annex

[38] In addition, in Malawi the project plan noted that slightly over 3,000 kits would be distributed via men who have sex with men (MSM) peer educators, but this was not taken forward due to legal complexities with MSM in the country. In Zambia and Zimbabwe, distribution via pharmacies was envisaged in the project plan, however we understand that these were not pursued due to no WHO prequalified (PQ) product being available.

[39] Many noted that while the CBD model has been important for demonstrating applicability and acceptability, it is not likely to be a sustainable model, especially after the project concludes in 2019 when funding will need to be provided by countries and other partners (see Section 4.2 for further discussions on sustainability).

F provides details on models to be tested in Phase II as well as others that are not being tested under the STAR programme as a whole.

- **Unitaid questioning extent of research conducted/planned, although key evidence gaps remain, as specifically requested by policymakers and global funders.** Our consultations with Unitaid indicated the view that the evaluation should test whether the extent of research conducted/planned has been excessive in relation to needs. All of our consultations for the evaluation have emphasised the importance of the research conducted, noting that this has been of high quality reflecting the credible institutions that have been involved. The only contrary feedback has been that with the benefit of hindsight, and given where we are on HIVST today, there needn't be extensive research on CBD across all project countries. Some questions have also been raised in terms of the extent of detailed sub-questions being approached through the research and the need to prioritise and streamline research questions. These comments notwithstanding, we note that our discussions with policymakers and global funders (as well as other project stakeholders) have identified a number of ongoing research gaps that require focus going forward. These are summarised in Box 3.1.

Box 3.1: Further areas of research on HIVST requested by policymakers and global funders

With regards to key evidence gaps on HIVST, our review found the following:

- Greater work is needed on ensuring that appropriate systems are in place to ensure that **linkage to care and prevention** is achieved, particularly for models such as CBD where individuals are less likely to be integrated into the health system. Formative project research across countries has suggested that follow-up phone calls with clients is seen as the most appropriate and feasible approach to helping to improve linkage.
- Related to this, many believe further work is needed to identify how to integrate self-testing into country Health Management Information Systems (HMIS) in order to assess how self-testing is contributing to increase knowledge of HIV status (without compromising the anonymity benefits of HIVST). Related to the above, further evidence is likely to be needed on **quantifying the health systems impact** of different interventions. This includes the net benefit of triaging individuals out of the health system using HIVST, as well as how it improves the allocation of staff resources within health facilities.
- Feasibility of models in terms of their **cost and cost-effectiveness** remains a key area for several stakeholders (although we note that this will be a key component of Phase II). While some research on cost-effectiveness has been undertaken in Zimbabwe as previously mentioned (as discussed in Annex E), many feel that not enough evidence has been generated in this regard. These assessments have also been noted as being more academic in nature, as opposed to being targeted specifically for governments and policymakers, yet this is an area that governments and key donors (Global Fund and PEPFAR) are particularly interested in better understanding. To ensure that this work is more targeted at these audiences, it may be more appropriate to structure them as cost-benefit analyses as opposed to being focused on cost-effectiveness.
- Phase I was able to test the acceptability of OFT on a large scale (as detailed in Sections 3.2.4 and Annex E, but limited evidence on **blood-based interventions** has been generated to date, making it difficult to generalise the conclusions on feasibility and acceptability coming out of Phase I.

- While limited evidence of **social harm** may have been found in Phase I, stakeholders noted that this still remains a concern for many governments that have not implemented HIVST on the scale in the project countries. Even in Zimbabwe, some non-project stakeholders were concerned about overlooking social harms going forward, particularly with regards to young people.
- The **formative research on accuracy and usability** of self-test kits was important for informing the implementation during Phase I. However, PSI and others recognise that similar formative research will be needed when rolling out into other countries to determine their applicability in different country contexts.

Summary findings:

The experience across distribution models has been positive, with self-testing being widely accepted by beneficiaries, distributors, health professionals and policymakers alike and emerging positive trends in terms of access and uptake amongst population groups with limited reach through traditional testing approaches. As regards the yields of distribution models, despite some methodological issues associated with late-reading of test kits, rates from general models appear to be at least as high as yields for through traditional testing and higher in some of the countries, while yields for FSW are particularly high. The evidence base on acceptability of the different distribution models is more positive than for other dimensions such as feasibility of scale-up, targeting and linkage, with key evidence gaps remaining with regards to linkage to care and prevention, cost and cost effectiveness of different distribution models and feasibility and use of blood based self-tests.

3.3. Reduction in policy barriers for HIVST

4. To what extent has the project contributed to a reduction in policy barriers for HIVST use in countries?

This section provides a review of the extent to which the project has contributed to the development of policies for HIVST in the project countries and beyond, as well as global policy (i.e. WHO guidelines), as reflected in Output 3 of the project logframe.

Specifically with regards to the achievement of Output 3 indicators, we note the following:

- Output 3.1 on "number of countries with HIVST integrated into national testing frameworks/guidelines in all intervention countries" has a target of all 3 project countries and a reported end of project achievement of having met this target. We argue however that this is not a fully exact representation of the achievements, as there are several nuances in terms of the state of policy on HIVST in each of the three countries, as described below in Section 3.3.1.
- Output 3.2 on "number of national testing algorithms adapted to include HIVST in all intervention countries" has a target of 1 of 3 project countries and a reported end of project achievement of 2 of 3 countries.

- Output 3.3 on "availability of interim WHO guidance for HIVST" was achieved in advance with the full guidance being released in December 2016. We assess the contribution of the project in this regard in Section 3.3.2, alongside a review of policy developments in non-project countries.

3.3.1. HIVST policy in project countries

This section presents the policy situation for HIVST in the project countries at the start of the project, project activities and the current policy status, and the extent to which the project may have contributed to a reduction in policy barriers.

HIVST policy situation at the start of the project

At project outset, none of the three Phase I project countries had policies explicitly allowing or prohibiting HIVST. There was also limited evidence on the legal, ethical, gender, human rights and public health aspects of HIVST.[40] However, there was evidence of policymaker interest in possible HIVST scale-up, for example:

- The Zimbabwe *National Guidelines on HIV Testing and Counselling Guidelines 2014* included HIVST as one approach for increasing HIV testing coverage, and HIVST was included in the *National HIV Strategic Plan (III) 2015-2018* as of March 2015.[41]
- The Malawi *National HIV Prevention Strategy* (2014) included self-testing as a possible intervention to increase testing rates and the development of a national HIVST plan was under consideration.

Further, PSI and research partners had been working in the project countries for several years prior to the project, and thus had an ongoing relationship-building with policymakers. This is particularly the case in Zimbabwe, where PSI (in particular the STAR Project Director) has had a close working relationship with the Ministry for over twenty years.

Project activities and current policy status

The principle mechanism for mobilising government commitment for self-testing was through the HIVST TWGs. These were specifically established to facilitate national policy development during project implementation. The TWGs were chaired by the ministries of health and included representatives from the project consortium, national regulatory bodies, WHO, in-country donors supporting national HIV programmes and civil society organisations. The TWG in Zimbabwe was established ahead of plan in Q2 2016 and the Zambia TWG was established in line with expected timeframes. For Malawi, there were some challenges in establishing the TWG, with a self-testing focused TWG not established during Phase I, mainly on account of changing Ministry leadership.

[40] PSI (2015) Project Plan.
[41] http://hivst.org/policy/zimbabwe

Outside of the TWGs, we understand that the project implementers also interacted with government on a less formal basis in order to keep them updated on project related findings. In addition, while not directly funded under this project, WHO country offices have been supporting the development of HIVST policies, and coordinated their activities with WHO at the global level (some of whom were funded under STAR), as part of the core work of WHO in the global health landscape.

Progress in securing political/government commitments and addressing policy barriers has been made in all three project countries, with some inter-country variation:

- In **Zimbabwe**, since the introduction of the STAR Project, the government has become supportive of HIVST scale-up, with relevant policy and guidelines established.[42] Further to the *National HIV Strategic Plan* mentioned above, in December 2016, the Ministry of Health and Child Care (MoHCC) launched new *Guidelines for Antiretroviral Therapy for the Prevention and Treatment of HIV in Zimbabwe*, which included HIVST for the first time. They were supplemented in February 2017 by the MoHCC release of (i) an *Operational and Service Delivery Manual* and (ii) a '*Job Aide*' to help healthcare workers in implementing the new guidelines. Discussions with the MoHCC in Zimbabwe indicate that they are currently in the process of developing an operational framework that will guide the scale-up of HIVST in the country. These discussions also emphasised the government's keenness to scale-up HIVST as soon as possible.
- In **Zambia**, policy uptake and government ownership of HIVST has increased significantly over the course of the project. Self-testing has obtained presidential and ministerial support, with HIVST featuring in a presidential speech in August 2017. Several policy milestones have been reached, including the formation of the HIVST steering committee and inclusion of HIVST in the national HIV testing services guidelines released in December 2016.[43] The Zambian Ministry of Health (MoH) is leading on the development of an Operational Framework on HIVST which will seek to address, among other areas, regulatory issues, distribution models, human rights concerns, HIVST monitoring, and target age groups (currently expected to be ready to launch by March 2018).
- In **Malawi**, progress in securing policy uptake for HIVST has been less pronounced than in the other project countries. While this may have been influenced by changes in MoH leadership, our consultations with individuals in the ministry and CSOs indicate that they would have liked to have seen more dialogue between themselves

[42] Source: Unitaid (2017) Market Landscape Report, p.42. Excerpt is based on Karin Hatzold correspondence from June 2017.

[43] The December 2016 *HIV Testing Services: National Guidelines* include HIVST, with the proviso that HIVST 'does not provide a definitive diagnosis' and that further testing to confirm a positive self-test result is necessary. Zambia (2016) HIV Testing Services: National Guidelines, p.10.

and project partners on the developments and findings of the project. MoH also wanted to be more directly involved in project delivery so they could have more hands-on implementation experience of the distribution models. As a result, while HIVST importance is agreed within the HIVST TWG, there is still the need for greater ministerial support. The STAR team have been working on obtaining this support, through meetings with the Ministry, and more recently we understand that a Research Task Force has been established, led by the MoH demonstrating their ownership, which will oversee the generation of the HIVST evidence base. We also understand that government officials will be involved in the implementation of distribution models in Phase II.

Project contribution and remaining gaps

It was argued by in-country stakeholders that the project has been pivotal to generating policy momentum in all three project countries, notwithstanding the issues in Malawi. In our consultations in Zimbabwe, this was emphasised not only by PSI, but also by the government, CSOs, and other external partners.

Prior to the project, work on HIVST had been small scale and formative only, whereas the STAR project has generated evidence relevant to a number of key policy questions, including on social harm, usability, acceptability, preferences and user demand. That said, a number of outstanding evidence gaps will need to be addressed in the Phase I countries in order to support wider scale up, including further evidence on cost-effectiveness of HIVST, the feasibility and acceptability of alternative distribution models (including facility-based, community-led and workplace distribution) and further evidence on ensuring appropriate linkage to care and treatment.

Going forward, it will be important to complement policy adoption of HIVST with national operational plans specifying how HIVST will be integrated into HIV testing services (HTS) nationally. As noted above, from our consultations in Zimbabwe and Zambia, we understand that an operational plan for HIVST is currently being developed and is expected to be finalised early in 2018.

3.3.2. HIVST policy globally and in other countries

One of the key objectives of the project was to inform the development of WHO guidelines on HIVST, which were released in December 2016 – being the flagship achievement of the project. The project contributed to the development of these guidelines through:

- **Funding:** Unitaid was the primary funder of the WHO self-testing guidelines, along with funding provided by other partners.[44] This included fully funding WHO team members who were coordinating guideline development, as well as funds to support evidence review, compilation and development, editing and printing of guidelines.
- **Evidence generation:** Project research outputs addressed a number of critical policy concerns, specifically regarding feasibility, applicability and usability of HIVST. We understand that research activities were planned with the goal of informing WHO and country-level guidance, and the methodologies adopted were explicitly designed to provide relevant and appropriate evidence to inform the guidelines. Based on a review of the references in the WHO guidelines, we find that STAR research outputs comprise a significant share of the low- and middle-income country studies that were referenced in the guidelines (specific research outputs discussed in the WHO guidelines are outlined in Annex G).
- **Direct engagement of STAR consortium members:** Many members of the STAR consortium, including PSI, research partners and WHO staff, joined the working groups that contributed to the development of the WHO guidelines.

Overall, the contribution of the project in the development of guidelines was critical, with stakeholder feedback indicating that without this, the guidelines may have been produced a few years later.

The release of the WHO guidelines has been accompanied by a rapid increase in policy uptake of HIVST globally. The number of countries with policies explicitly supporting self-testing at project outset was limited to three (Kenya, UK and US). According to the WHO data presented at the STAR All Partners Meeting in Johannesburg, as of October 2017, 41 countries have national HIVST policies, 11 of which were introduced following the publication of the WHO guidelines in December 2016.[45,46] In particular:

- Policy uptake has occurred in all WHO regions, and many of the countries contributing the most towards the number of people living with HIV globally have adopted supportive HIVST policies since 2015. Out of the 41 countries with policies supportive of HIVST, 18 are high-income countries, and 23 are low- or middle-income countries.
- Out of ten high HIV burden countries in Sub Saharan Africa on which there are data, nine have policies which are supportive of HIVST, which includes Botswana, Kenya,

[44] Funding for the development of the partner notification aspect of the guidelines was provided by the Gates Foundation. Gates also funded evidence compilation related to values and preferences in African countries, with PEPFAR and USAID also providing funding to support this in countries with high prevalence.
[45] WHO presentation on global HIVST policy uptake from the STAR All Partners Meeting, Johannesburg (October 2017).
[46] Population Services International and Society for Family Health (2017) HIV Self-Testing in Africa (STAR) Phase II Annex 1 Project Plan, p.9.

Lesotho, Malawi, Namibia, South Africa, Swaziland, Zambia and Zimbabwe. Uganda has a policy supportive of HIVST under development.

- In the Asia and the Pacific region, progress on the adoption of policies supportive of HIVST has been less rapid. Among six high-burden countries on which there are data, two (China and Vietnam) have policies which are in place, three (Indonesia, Myanmar and Cambodia) have policies under development, and one (India) does not have a supportive policy in place.
- In Latin America, the largest regional contributor to HIV, Brazil, has a supportive policy in place, and several countries have policies under development, including Venezuela, Suriname, Peru, Bolivia and Paraguay.

Mechanisms that the STAR project has used to help directly influence policy in other countries also include:

- WHO activities by HQ and WHO HIV country focal points have supported country governments by contributing to almost all national HIVST policies (including updates) and policy development in low and middle-income countries (LMICs), supporting countries with submitting Global Fund above-allocation funding requests for HIVST and disseminating the WHO global guidelines to non-STAR countries.
- Country exchanges also took place between STAR project countries and other African countries to share the findings from the STAR project and outline their policies on self-testing. For example, representatives from the Ugandan MoH visited Zimbabwe to learn lessons about the STAR project during the implementation of Phase I.
- Representatives from country governments being invited to the STAR Workshop in Nairobi in 2017, where representatives from 18 African governments were in attendance. This was linked to a WHO regional rollout workshop on HIV testing. The WHO HIVST team that were involved in the STAR project also helped disseminate the findings from the guidelines at regional rollout sessions for other regions at a smaller scale, including in their East Mediterranean (EMRO), American (AMRO/PAHO) and European (EURO) regions.
- General dissemination of STAR findings at international conferences which are attended by other country governments, including the five conferences mentioned previously.

Summary findings:

The project has made an important contribution to developing the policy situation for HIVST in Zimbabwe and Zambia, although lags behind for Malawi. However, key policy questions remain (e.g. on feasibility of alternate distribution models, cost effectiveness, linkage to care) and more work is needed to translate high-level policy into operational plans to guide scale-up.

The flagship achievement of Phase I of the project has been its contribution to the release of the WHO guidelines on HIVST. This has contributed to policy updates for 41 countries globally on HIVST, encompassing all WHO regions and countries with highest PLHIV.

3.4. Improvements in HIVST market and regulatory conditions

5. How has the project contributed to improved market and regulatory conditions for HIVST?

A healthy HIVST market, as articulated in the PSI (2016) *HIVST Market Report*, is characterised by growing demand, multiple buyers and sellers, a diverse range of high quality products, affordable prices and an enabling policy and regulatory environment.[47] An effective regulatory system for HIVST requires clear and efficient pathways for national validation and registration of HIVST kits, enforcement of regulatory standards, appropriate external quality assurance systems, and adequate post-market surveillance.[48] We consider the extent to which these have been achieved, and in particular, facilitated through the project. Specifically:

- Section 3.4.1 compares the state of the HIVST market in LMICs today with the situation prior to the start of the project, and evaluates the extent to which the project has contributed to the development of the market.
- Section 3.4.2 discusses progress with regards to improving regulatory conditions for HIVST.

3.4.1. HIVST market

Market situation prior to the project

At the project outset, the HIVST market was effectively absent in LMICs, outside of relatively small-scale formative research studies. There were two HIVST products on the market with SRA approval namely: (i) the OraQuick In-Home HIV test, an OFT; and (ii) the BioSure HIV Self-Test, a blood-based RDT. In both cases, the target markets were high-income retail consumers. Knowledge among manufacturers on the protocol for acquiring WHO PQ or Global Fund Expert Review Panel for Diagnostics (ERPD) approval was relatively limited.

[47] PSI (2016) Expanding Access to HIV Self-Testing: A Market Development Approach.
[48] WHO (2016) Guidelines on HIV Self-Testing and Partner Notification: Supplement to Consolidated Guidelines on HIV Testing Services, Geneva: Word Health Organization, pp.38-39.

With regard to prices, the OFTs that were being used in HIVST research ranged from US$3.50 to US$4, while the prices of professional-use RDTs ranged from US$0.80 to US$4.[49,50] As mentioned in Section 3.4.2, individuals in project countries have also been able to obtain RDTs in private pharmacies that have not been designed for or registered as self-testing products in the countries, and are seen as being of low quality. In Zimbabwe, PSI have suggested that the price of such products is around US$5 per unit but may very between pharmacies.

Project activities

In addition to the demand generation activities described previously, a number of supply-specific activities have been undertaken through the project in a bid to catalyse the HIVST market, as follows:

- **Procurement** of over 1m kits during Phase I;[51][52]
- **Facilitation of the WHO PQ process**, through collaboration between the WHO HIV and PQ team as part of the WHO HIVST TWG (setting a clinical utility threshold, technical specifications and guidance to manufacturers, which included compiling a sample HIV RDT dossier, which included HIVST), and through technical advice submitted to the WHO PQ team by members of the STAR consortium, helping to define the PQ pathway for HIVST;
- Support for the **clarification of regulatory pathways** for product registration through capacity development of regulators, laboratory technicians and policymakers, and work towards the development of appropriate and harmonised regulatory frameworks in STAR countries (further details regarding this are provided in Section 3.4.2);
- Routine **engagement with manufacturers** to exchange data and information on the STAR project, understand emerging technologies and identify priority areas for market support;
- The **development and dissemination of market landscaping reports** outlining HIVST supply, including pipeline products, demand estimates, pricing and an assessment of the policy and regulatory environment; and
- **Price negotiations** with OraSure, which lowered the price for the OraQuick product to US$3.15 by the end of Phase I (and before the Gates buy-down).

[49] PSI (2015) Unitaid/PSI HIV Self-Testing Africa (STAR) Procurement Strategy, p.7.
[50] PSI (2015) Unitaid/PSI HIV Self-Testing Africa (STAR) Project Plan, p.7.
[51] PSI (2017), STAR project data.
[52] Please note that more kits were procured than distributed to ensure that the project had sufficient buffer stock. Such kits would then be used for the project going into Phase II.

Progress on HIVST supply and project contribution

There has been a considerable increase in the number of HIVST kits with SRA approval over the course of the project. For example, at the time of project close:

- **Four HIVST products had obtained WHO PQ or ERPD approval:** There is one WHO PQ oral fluid HIVST product, the OraQuick HIV Self-Test, (which previously obtained ERPD approval during the implementation of the project); and three blood-based HIVST products approved by the ERPD as Category-3 which permits their use for Unitaid, PEPFAR, USAID and Global Fund procurement (at a limited scale).
- **Five HIVST products had obtained approval by founding member countries of the Global Harmonisation Task Force (GHTF)**. These products are predominantly marketed in Europe or the USA and have either European Conformité Européenne (CE) or US Federal Drug Administration (FDA) approval. Products include the OraQuick product (FDA), while products from Atomo, BioSURE, AAZ and BioLytical have CE approval.
- **Six HIVST products had obtained national regulatory approval in four LMIC countries.** This includes the products provided by the OraSure (Kenya and South Africa), Atomo (Kenya and South Africa), BioSURE (South Africa), BioLytical (Kenya), Orangelife Comércio e Indústria LTDA (Brazil) and MYSP Ltd (Nigeria).

In addition to the HIVST products already on the market, the pipeline for HIVST products is relatively large, with ten HIV RDTs for self-testing currently under development – some of which are already available in certain markets. At the time of writing, three blood-based HIVST products plan on submitting an application for WHO PQ. This suggests that the project was able to obtain key logframe targets, including having one product with WHO PQ, three in WHO PQ pipeline and four with ERPD or WHO LOA, although the target of having 11 products with approval from founding members of GHTF has not been met.

As such, the supply base has progressed substantially from the start of the project. Our consultations with select manufacturers and other stakeholders indicates that the main contribution of the project has been in terms of the momentum created in the market. Further, the project has also supported WHO in the PQ process through the HIVST TWG for PQ noted above.[53]

Beyond this, a *direct role* in supporting manufacturers and their investment decisions has been more limited. In particular:

- Early research on IFUs conducted under the project informed the development of IFUs for the OraSure product as well as other key manufacturers.

[53] More generally, WHO PQ is a lengthy process, lasting four years in the case of OraSure's professional-use RDT, and one additional year for the approval of the self-test product. Given the experience of the OraSure PQ process, there is a view that the process for future applications to WHO PQ for self-test kits will be shorter.

- However, given the timelines for WHO PQ in relation to the research being conducted under STAR, project data was not available in time for use by OraSure as part of their PQ submission. OraSure also noted that data from the project was not forthcoming until formally published which impeded its timely use for the PQ process. The blood-based manufacturers are also currently conducting their own studies (reflecting no work on blood-based products under the STAR Phase I).
- With regard to the market estimate provided through PSI in their 2016 Expanding Access to HIV Self-Testing report (which was funded by the Gates Foundation, therefore was not part of Unitaid STAR funding per se), manufacturers stated that this had been useful in helping to calibrate their own market estimates for the HIVST market, but that the market estimates were based on making assumptions of HIVST uptake in countries as opposed to expected orders for self-test kits, and as a result demand from countries could vary significantly from these forecasts. No manufacturers stated that the market report had significantly impacted on their commercial decision-making. Instead, they need to see concrete orders from governments or procurement agencies such as Unitaid, Global Fund and PEPFAR.

Progress on HIVST procurement and project contribution

With regard to market demand in LMICs, there is widespread policymaker and donor interest, although a significant amount of this is attributable to Unitaid funding for Phase II of the project. For example, of an estimated market size of 4m kits to December 2018 across 39 countries, c.2.2m kits will be procured by Unitaid in the six Phase II project countries, while only Uganda (c.104k), India (c.330k) and Kenya (c.535k) currently have larger expected orders than the procurement levels of the smaller STAR countries.

PSI also note that through Global Fund above allocations, plus the reduction in prices as a result of the Gates buy-down, the market could be as large as 6m. Further, in project countries, MoH-led demand for self-testing has led to the inclusion of HIVST procurement in Global Fund and PEPFAR requests for this year in all three project countries as detailed in Section 4.2.1 below.

Progress on HIVST prices and project contribution

Through the STAR project, the price per test obtained for the OraQuick HIV Self-Test was negotiated down to US$3.15 per test.[54] One stakeholder explained that this negotiated price reduction may have led other HIVST providers to also reduce their prices over the course of the project period. For certain products with ERPD approval, the price has fallen to US$3 per test at current volumes.

[54] Our understanding is that this is price is specific to the STAR project, as opposed to being prices charged to other purchasers of OraSure kits.

Future public-sector and donor procurement of the OraQuick HIV Self-Test will benefit from the four-year agreement between BMGF and OraSure for a US$2 price ex-works, including those purchased for Phase II of the STAR project. OraSure plans to increase manufacturing capacity and anticipates that associated scale economies may enable it to eventually market the OraQuick at US$2 per test after the expiry of the BMGF subsidy, although this is only likely to be possible if it is able to sell 20m kits per year.

Although the STAR consortium was not directly involved in reaching the agreement, it was noted by OraSure and other stakeholders that the decision by BMGF to subsidise the OraQuick was influenced by the evidence generated on HIVST through the STAR project. This suggests that STAR Phase I has played an indirect role in driving down the OraQuick price.

The Gates buy-down agreement has made market entry more difficult for manufacturers, who are not able to compete with a US$2 price at current volumes. Several noted that a number of negotiations had ended following the announcement of the Gates agreement. One manufacturer noted that annual orders would have to amount to 2m units in order to reach a unit price of US$2. While the potential market distorting impact of the Gates agreement is noted, the market-leading blood-based manufacturers consulted as part of this evaluation continue to be interested in entering LMIC markets. In addition, the Gates buy-down is likely to help drive volumes in the market and encourage manufacturers to identify innovative solutions to deliver lower prices.

Manufacturers note that in order to improve on price, they need volumes and more predictability in terms of advance information or forecasting on procurements so they can commit the investment required. Manufacturers generally have capacity for meeting market needs, but predictability and demand are the key challenges. In this regard, successful HIVST take-up in South Africa through planned Phase II activities will be critical to building HIVST demand.

3.4.2. HIVST regulatory barriers in project countries

At the start of Phase I, countries were at varying stages with regards to regulation of in vitro diagnostics:[55]

- In **Malawi** there were no legal obstacles or explicit mechanisms for medical device registration, while importation of medical kits needed to be approved by the Malawi Bureau of Standards.
- In **Zimbabwe**, while the Medicines Control Authority of Zimbabwe (MCAZ) was legally empowered, self-testing kits were not within their scope, given that at the time of Phase I launch were not specified as medical devices.

[55] PSI (2015), *STAR Project Plan.*

- **Zambian** authorities had a more well-established regulatory mandate than the other countries at the start of Phase I, although no specific guidelines on how to do this were in place.

Across all three countries, a number of capacity constraints were in place with regards to exactly what regulation of in vitro diagnostics entailed, specific knowledge of what was required for HIVST and how to assess and prioritise evidence to inform validation. There was also limited linkage between policymakers, regulatory and laboratories, with the latter two stakeholders generally be more cautious about HIVST scale up.

Led by LSTM, STAR has supported regulatory progress in the project countries through the following activities:[56]

- **Desk review** of the policy and regulatory environment for HIVST in STAR countries, as well as **key informant interviews** conducted through the Qualitative Research Network.
- A series of **three technical workshops** comprising regulators, laboratory technicians, and policymakers from all three project countries, held in 2016 and 2017. The workshops have worked towards plans for harmonised regulatory systems in project countries and enabled participants to share lessons learned across the three countries. LSTM also co-hosted a symposium at the African Society for Laboratory Medicines meeting on regulation in HIVST in Africa held in December 2016.
- A **draft toolkit** which aims to facilitate new HIVST product entry by suggesting a clear process for supporting accurate use of HIVST kits among targeted populations.
- LSTM has conducted **visual stability research on late readings of the OraQuick test**, which will support the development of appropriate post-market surveillance systems.

Since STAR implementation, the following progress has been achieved with regard to HIVST regulation:

- In **Malawi,** a medical devices committee has been established and a listing of relevant medical devices has been developed.[57] There is also a bill currently going through Parliament which will establish a regulatory framework for IVDs.[58] Discussion with PSI in Malawi indicate that the ongoing regulatory challenge in the country is that the Pharmacy Poisons Board does not have a mandate for HIVST, inhibiting manufacturers from registering their product in the country. With the help of the STAR project, we understand that an interim committee has been formed but this is an ongoing process and not expected to be concluded during the lifetime of

[56] PSI (2017), *STAR End of Project Report.*
[57] LSTM (2017), *STAR All Partners Meeting Johannesburg Regulatory Update.*
[58] PSI (2017), *STAR Phase II Project Plan.*

the STAR project. Some progress is however being made to facilitate procurement by for example securing a letter of support from the Pharmacy Poisons Board.

- In **Zimbabwe,** MCAZ and the Medical Laboratory and Clinical Scientists Council of Zimbabwe are in the process of clarifying IVD regulation mandates so that responsibilities can become clearer.[59]
- In **Zambia,** the National Reference Laboratory (NRL) is currently taking steps to put in place post-market surveillance (PMS) for IVDs. In addition, registration of the OraQuick product is currently underway.[60]

While this suggests some progress is being made, regulation of HIVST is one of the areas where a considerable amount of work is needed going forward. For example, manufacturers remain concerned that capacity in all countries remains limited and that regulation and registration of HIVST products is still unclear. They also noted that even with WHO PQ, in-country validation and registration is needed, and regulatory processes between countries are yet to be harmonised. Consultations indicated that IVDs that have not been registered, validated or adapted for self-testing purposes are still available from pharmacies in project countries, and anecdotal evidence suggests that some people are accessing tests this way. While these remain issues for HIVST, it should be noted that these are problems that go beyond HIVST, and are also not unique to the project countries.

We understand that STAR Phase II will seek to address these existing regulatory barriers through national and regional workshops for regulators, laboratory technicians and policymakers to further encourage coordination and inter-country learning in support of regional regulatory harmonisation, and support for national action plans to develop appropriate regulatory systems. Manufacturers suggested during our consultations that the STAR consortium can support product registration through: (i) financial support for in-country pilots, and (ii) direct support for registration for products procured and distributed through STAR.

Summary findings:

The market situation in terms of supply base and prices has improved considerably over the project period, with the main project contribution being generating evidence, encouraging demand and supporting WHO with the PQ process (although direct support to manufacturers was more limited). Regulatory challenges in countries continue to serve as a key obstacle to effective product access.

[59] LSTM (2017), *STAR All Partners Meeting Johannesburg Regulatory Update.*
[60] Ibid.

4. RESULTS AND IMPACT

The final dimension of the evaluation assesses the project's public health and wider impact. In the first question under this dimension, presented in Section 4.1, we assess the impact in terms of (i) how the project has supported linkage to treatment and prevention interventions; (ii) a review of social impacts (e.g. HIVST having a positive impact on everyday life); and (iii) efficiency gains on the health system. In the second question of this dimension, presented in Section 4.2, we consider prospects for sustainability and scalability of project activities.

4.1. Public health and wider impact

6. Does evidence suggest that the project achieved its intended public health impact, including ensuring linkage to care? Are there examples of social impacts and health system efficiencies being achieved through use of HIVST?

In order to assess the public health and wider impact (including social impact and health system efficiencies), we have reviewed progress made towards the project logframe outcome of "increased effective use of rapid diagnostic tests (RDT) for HIV self-testing among the target populations in intervention areas" and the associated indicators. We have also reviewed the evidence obtained in select operational research studies, and obtained qualitative feedback from stakeholders through our global and country-level interviews.

As noted in Section 3.2.4 above, HIVST has led to an increase in HIV testing across all population groups, including key target groups such as males, adolescents, key populations and first-time testers. For individuals to know their status has benefits in itself, however, the primary public health benefits lie in: (i) linking those who test positive to treatment and (ii) linking those who test negative to prevention interventions. Progress made towards these aims are discussed below, as well as the wider impact (social impact of HIVST and efficiencies obtained within the health system through use/uptake of HIVST).

4.1.1. Public health impact: linkage to treatment and prevention

Linkage to treatment

Implementers report that respondents are willing to receive confirmatory tests if tested positive. This is due to (i) willingness to confirm a positive status and (ii) willingness to receive treatment which is immediately available under the 'treat all' guidelines.

As one of the main indicators for this project, indicator P2 measures, "% of the target population using HIVST who test positive following HIVST who are appropriately linked to care, disaggregated by country and sex". The midterm results are shown in Table 4.1 below, with Annex E providing more information on the available evidence.

Table 4.1: Uptake of care and treatment services among HIV positive self-testers[61]

	Malawi	Zambia	Zimbabwe
Male	50% (3/6)	8% (697/8,389)	80% (20/25)
Female	67% (4/6)		50% (15/30)

Source: STAR project data.

At the outset, we note the limited strength of evidence in terms of absolute numbers who are positive for Malawi and Zimbabwe, as can be seen in Table 4.1. Also, these are based on self-reported responses in the midline surveys, and as such could also be subject to positive bias (given that those who have not linked to care may not be willing to declare this). Such figures may also change once the results of the endline survey are finalised.

Figures from studies prior to the STAR project found similar rates of linkage to those outlined for Malawi and Zimbabwe above, with one study citing 56.4% of individuals were linked to care and other citing a 59% linkage rate prior to eligibility assessments (see Section E.3 of Annex E for further details). In general, stakeholder consultations indicate that there is still insufficient evidence on the number of people who self-tested and then linked into care in all countries, especially in Malawi and Zambia.

With regards to public sector facility-based distribution, project data from Zimbabwe suggests that of 285 self-testers with positive HIV results, 96% were tested positive following confirmatory testing and all of these were initiated onto ARTs. For fixed-site FSWs HIVST, project data from Zimbabwe also shows high linkage rates, with almost all of the 98 individuals who had tested positive being linked to post-test services (based on data obtained from surveys). Data from a Zimbabwean PSI New Start facility also indicates a 90% linkage to care where there is less scope for loss to follow up after testing in a facility. Linkage through outreach activities conducted from PSI New Start facilities is lower at 60%, but this has increased from previous estimates at 20%.

Additional benefits that have been cited for linkage to treatment through HIVST is the **earlier linkage** to treatment. Given that HIVST has had uptake from first-time testers, and population groups who historically have had lower testing rates, this indicates that clients are linking to care earlier than they otherwise would have done. Health facility personnel from the PSI New Start and public sector facilities in Zimbabwe noted that there has been an increase in men linking to treatment.

For PLHIV, knowing one's status is the first step to accessing treatment which will ultimately lead to **reduced morbidity and mortality**. In addition, once viral suppression is achieved, it will also reduce HIV transmission and **avert new infections**.

[61] Data for Malawi and Zimbabwe based on PSI (2017), End of Project Report. Data for Zambia based on SFH Zambia (2017), STAR Phase I Implementation Lessons Learned, presentation at STAR All Partners Meeting, October 2017, Johannesburg.

However, ongoing challenges remain including the following:

- **There is difficulty in monitoring linkage using the community based model.** It may be that testers who are reactive access confirmatory tests in facilities in which they are anonymous, further complicating the monitoring.
- Thus far, any data has been based on data collection approaches specifically employed under the project, however the endeavour in Phase II especially would be to support an **update of HMIS** to also capture this data. This will require integration with existing national systems.
- Not just linked to HIVST, but testing in the community generally, poses **challenges to ensure linkage to care**. Protocols go some way in addressing this but generally there are still fall outs between testing in the community and linkage to treatment. Some of the barriers include distances to testing facilities as a barrier to confirmatory testing and lack of empowerment (e.g. for female testers) due to travel costs, fear of disclosing status etc. [62]

We note therefore that while linkage to confirmatory testing and treatment appears to have worked reasonably well (i.e. > 50% linking to treatment) under the project, given the general challenges in linking testing to treatment (i.e. not HIVST-related specifically), there is a need to obtain further evidence to prove linkage, and integrate with country monitoring systems in the scale up phase.

Linkage to prevention interventions

For clients who tested negative, consultations in Zimbabwe with clients and health care workers indicated that there is an increased motivation to remain negative and undertake prevention activities. Specific examples are noted below regarding VMMC as well as other preventative/health interventions.

Link to VMMC

Increasing linkage to VMMC is an important HIV prevention measure which has been recommended by WHO and UNAIDS since 2007. Recent estimates suggest that despite high HIV prevalence, the proportion of males circumcised in the Phase I project countries is low at 21.6% in Malawi, 12.8% in Zambia and 9.2% in Zimbabwe, demonstrating the importance of strategies to increase uptake.[63]

The link to VMMC interventions has been performed in a number of ways. The four models in Zimbabwe include: (i) general community based testing in which males with negative

[62] CeSHHAR process evaluation
[63] Morris et al. (2016), *Estimation of country-specific and global prevalence of male circumcision, Population Health Metrics 14(4).*

results are encouraged to get VMMC at their local facilities; (ii) VMMC community mobilization; (iii) HIVST at PSI VMMC clinics and (iv) HIVST at public sector facilities.

Based on consultations with clients and implementers in Zimbabwe, one of the main reported barriers to uptake of VMMC is that a negative HIV test (or positive HIV test with a high enough CD4 count, which incurs delays to obtain results) is required before undertaking VMMC. Therefore the associated barriers around HIV facility-based testing have been prohibitive factors affecting VMMC uptake. These include the following reasons: (i) fear of testing positive at a facility and not being able to receive VMMC, and other men who attended the clinic knowing their status; (ii) long wait times at health facilities; (iii) fear of stigma; and (iv) lack of privacy.

Whilst further discussed in Section 4.1.2 below on social impact, with the introduction of HIVST, beneficiaries and implementers at a VMMC clinic in Zimbabwe noted that strong positives of HIVST included (i) anonymity when testing and (ii) either no waiting time at a facility for a test result (CBDA) or reduced waiting time (at PSI VMMC clinic). Through our consultations with beneficiaries in Zimbabwe, they reported that they had either already undertaken VMMC post a negative test result, or were planning to go in the immediate future. One beneficiary in Zimbabwe noted that receiving a negative result from a HIVST has encouraged him to take up VMMC as previously the barrier of HIV testing was prohibitive. He was aware of the preventive benefits of VMMC and was spurred on by a negative result to undertake a further preventive intervention.

According to Zimbabwe VMMC HIVST implementers, there has been an increase in testing, and request of VMMC services, through the VMMC programme community distribution model and the PSI VMMC clinics. When comparing VMMC programmes with and without HIVST, the uptake of VMMC was 57% (of c.500 individuals reached) compared to 42% (of c.16,000 individuals reached, and thus a much larger sample). In the PSI VMMC clinics, 82% of beneficiaries undertake VMMC after HIVST. In addition, nurses in Zimbabwe public health facilities reported an increase in demand for VMMC post community based HIVST.

Whilst this evidence above indicates positive linkage rates, Table 4.2 shows that the overall VMMC linkage rates of males who test negative are still low (indicator P3 in the logframe). At the same time, evidence from the mid-line survey for Malawi suggests that while only 7.9% of negative self-testers had linked to VMMC, only 4% of those who had tested negative through standard testing had linked to VMMC.

Table 4.2: % of the uncircumcised male target population using HIV self-testing who test negative and who are linked to VMMC

	Malawi	Zambia	Zimbabwe
Male target population	7.9%	5.3%	1.9%

According to consultations in Zimbabwe, one of the reported ongoing challenges with linkage to VMMC with the CBD model is that interest among males is still much higher in HIVST rather than HIVST leading to VMMC uptake. However, we note that consultations

indicated that linkages to VMMC are generally low, especially in Zimbabwe and therefore the fact that uptake has increased since the introduction of HIVST shows a positive trajectory. Overall, stakeholders noted the seemingly positive trends but noted that there is a need for further evidence.

Link for other preventative/health interventions

We note that there is limited data on the linkage to broader prevention programmes but that notwithstanding, the evidence that we obtained is discussed below.

Under the CBD, and facility based models, CBDAs and providers have promoted clients to link to other more broad preventative health interventions such as cervical cancer screening, blood pressure monitoring, TB Screening, family planning etc. Based on facility data, there has been evidence of clients linking to these interventions through the CBD model such as in Chinyika Clinic, Zimbabwe where 54 clients with negative results have presented for follow up for preventive interventions. In facilities, clients are also encouraged to undertake preventative interventions such as in the PSI New Start facilities where cervical cancer screening, blood pressure monitoring, TB Screening, family planning and other interventions are offered.

These are positive steps towards integration of care, however a number of respondents noted that one of the missed opportunities in Phase I is that the HIVST was not integrated with other health assessments/interventions during the CBDA visit (for example, family planning support). Linkage to these interventions was only possible at facilities and had this linkage been introduced as part of the CBD model, it could have possibly also made it more cost-effective.

Indirect public health impact

It may be deduced that the indirect public health impact of this project is indeed greater than what is outlined in the above section regarding the direct impact of the grant given the indication that additional countries will adopt HIVST.

4.1.2. Social impact

The risks of social harms were a key concern of many country governments and these included intimate partner violence, suicide and others. However, there have been no significant social harms identified in the project, as noted in Section 3.2.2 on social harms research, and this evidence has helped to influence policy and regulation barriers.

There has been high uptake among clients with the variety of models with positive feedback obtained from consultations with project implementing partners and health facility/CBDA interviews. The following positive aspects regarding **empowerment, ownership and choice** were noted:

- **Empowerment and ownership**: HIVST, even when conducted at a health facility brings in ownership for HIV status. This has additional positives of ownership extending to follow up care and prevention activities.
- **Privacy, confidentiality and convenience** are some of the most frequently sited positives.
- Intrigue regarding a **new experience**, therefore encouraging testing. Clients reported, "it's innovative" and "it's awesome".
- **Wider options of HIV testing**: Reporting from Mahusekwa District Hospital is that beneficiaries appreciate having wider options of HIV testing, including oral testing. Based on the PSI New Start facility data, when offered a self-test opt out option at a facility, 98% accepted.

Positive aspects regarding **reducing access barriers, and acceptability** were also highlighted**:**

- Regarding the CBD model, this reportedly **reduced access barriers** to testing for individuals in remote areas, as well as those who are not able to travel to the clinic (e.g. elderly, disabled) who were not able to access services at clinic. CBDAs noted that clients reported, "the service has been brought to us". For certain hard to reach populations e.g. religious objectors, males, adolescents, they were able to access testing through the CBDA in the community. This was possible as either the test was brought directly to their home, or they knew where to find the CBDA to receive a test away from family members, which helped to overcome the fear of stigma and discrimination.
- **Males reported an increase in willingness to test** in comparison to other testing methods due to a higher social acceptability. Males reportedly encouraged other males to test through (i) word-of-mouth (particularly from other males), (ii) community sensitisation; and (iii) direct contact through VMMC HIVST programs.
- **Secondary/index testing**. Clients have reportedly been able to reach partners due to the reported ease with which they can distribute a ST kit to a partner.

Finally, clients reported **time efficiencies** with HIVST. In the CBD model, this was due to time saving through not having to travel to and wait at the clinic. For the facility based models (public sector, VMMC, PSI New Start), clients reported satisfaction due to the decrease in waiting time for testing in comparison to the PDHTS.

4.1.3. Health system efficiencies

Based on our consultations with health care workers, other implementers and direct observation during the field visit to Zimbabwe, there are a number of ways in which HIVST has had an impact on health system efficiencies. These are noted below:

- **HIVST in the community can act as a screening tool to triage** those with negative results out of HIV testing in the health system. Furthermore, **HIVST within facilities is much quicker than PDHTS**. Counsellors report being able to test a number of people simultaneously at a facility (in Mahusekwa Hospital this was approximately five people at a time, and in a PSI New Start facility it was more). Reports on the facility based model is that because clients are sensitized in the community, there have been some instances in which beneficiaries attended facilities in groups (especially males) which further enabled group testing. The primary reported efficiency benefit of HIVST is in terms of time saving.
- Used as a triage test, **HIVST frees up counsellor time** previously spent on testing HIV-negative individuals to focus on those with reactive results in need of further testing and initiation of ART. Health care workers can increase the amount of time spent with those who receive positive results, thus theoretically enabling more in-depth counselling and better linkage to treatment, and improved adherence.
- There is a **higher yield** for facility based testing among those who are testing post self-testing in the community. Self-testers at PSI New Start facilities had a yield of 4.3% whilst those opting for provider delivered testing was 12.8%, indicating a self-selection.[64] After the community HIVST distribution, there was a larger number of clients testing positive, indicating that this was due to confirmatory testing and provides a higher yield for PDHTS at facilities.
- **Additional testing services can be offered**. For example, both the PSI VMMC clinic and PSI New Start facility in Harare have been able to reduce the number of staff they have on at one time (for the PSI VMMC clinic staffing was reduced from 2-3 counsellors at a time to one at a time and in the PSI New Start facility, a minimum of 9 counsellors were previously needed and now 5-6 are needed). These facilities are therefore now able to have additional shifts and offer testing for longer periods throughout the day. Counsellors can also redeploy staff to other facilities, or conduct outreach activities. The longer hours enable clients who worker later hours to be tested (e.g. those in employment; high risk men; FSW) and the outreach activities have been able to focus on index testing; FSW; truckers; vendors and high risk men.
- Those who test positive **access treatment earlier**, if linked to treatment. Therefore this (i) reduces the burden on the health system from opportunistic infections and (ii) once viral load suppression is achieved, reduces new infections, and the requirements on the health system associated with this.
- Having HIVST at facilities has enabled **health care professionals to receive HIVST** who previously did not test due to stigma. In Mahusekwa District Hospital, it is estimated that approximately three quarters of the staff have tested using HIVST.

[64] PSI STAR programmatic data

This has benefits of (i) health care professionals being able to know their status; and (ii) health care professional's reduction in morbidity and mortality, and a healthier health sector workforce.

With the introduction of HIVST at public health facilities, there have been some initial 'teething' challenges including recording of results and integration with existing monitoring systems. The integration into monitoring systems has been resolved with clients testing at facilities. However, it is still unclear how results will be recorded for those who have tested at home, for example a partner receiving a HIVST kit and testing at home.

In addition, there were initially fears from facility based counsellors that their role would no longer be required due to the high number of testing being conducted in the community, or due to efficiencies in testing at a facility. However, counsellors have now realised that although efficiencies have been achieved, they are able to prioritise time with clients who are positive.

Summary findings:

The public health impact can be evaluated through linkage to treatment and prevention activities. Initial findings from the project show that linkage to treatment has been at least 50% across population groups. For linkage to prevention programmes, there is some evidence that HIVST has increased uptake in VMMC but these rates are still low. There is limited strength of evidence regarding linkage to other prevention activities. Although the linkage to treatment and VMMC has been described as 'high' in the PSI End of Project report, given limited data and consultation feedback, we conclude there is a need for further evidence in this area.

In terms of social impact, there are very positive results reported by clients including empowerment, ownership, choice of testing, reduction in access barriers, increase in acceptability, and time efficiencies associated with HIVST.

There have been a number of health system efficiencies noted with HIVST, particularly due to the triage nature of HIVST in the communities and time efficiencies with HIVST in facilities.

4.2. Sustainability and scalability

7. What are the prospects for project sustainability as well as scalability?

In this section we consider whether Phase I of the project has laid an adequate foundation for (i) sustainability of the project activities in the three project countries and (ii) whether proof of concept has been achieved for scale up within project countries and beyond.

We define sustainability to refer to a continuation of activities and scalability to refer to an increase in pilot activities to a national scale. As this is primarily an implementation research project, the focus is more on scalability at this stage which will ultimately lead to sustainability. A number of key successes contributing towards scale up and sustainability

have been discussed above in the Section 3.3 regarding policy and Section 3.4 regarding market conditions.

4.2.1. Potential in project countries

As noted in Section 3.3.2, there is an improving policy situation and commitment in the project countries, particularly Zimbabwe and Zambia. The current status of donor funding for these countries is as follows:

- **Zimbabwe**: The plan as per the PEPFAR country operational plans for funding for HIVST for the country is US$2.9m with PEPFAR supporting 13%; Global Fund 13% and a gap remaining.[65] PEPFAR has committed 100,000 tests, and this is likely to be increased. In addition, we learned from consultations that CDC will be providing support for HIVST through partners the International Training and Education Center for Health and the Zimbabwe Association of Church Related Hospitals. USAID plan to invest into PSI and HIVST for community based, and index tracing.
- **Zambia**: HIVST has now moved from a small project to a government programme – but it is unlikely to reach scale in the next 1-2 years. PEPFAR Zambia will pilot the use of HIVST to contribute to reaching first-time testers, people with undiagnosed HIV and those at ongoing risk who are in need of frequent retesting.[66] There is a provision for US$2m of funding for HIVST in the Global Fund application to be approved in early 2018. There have been informal agreements with the US government on procurement for HIVST, but no confirmations to date.
- **Malawi**: Self-testing is being piloted in key population sites in collaboration with Unitaid and Gates funding and PEPFAR is eager to expand this option for select populations.[67] In the Global Fund application for 2018-20, 800,000 HIVST kits from OraSure have been included. While self-testing is under discussion, pilots will be focused in scale-up districts.

As such, the stage for scale-up is being set up, although the countries are not there yet.

In addition, some of our consultations have flagged the issue of sustainability risks with the CBD model, which is being delivered and funded through an international NGO in countries with limited linkages/coordination with domestic NGOs (as also noted in Section 3.2.1). Whilst STAR Phase II is looking into the feasibility of community-led distribution models, the importance of engaging with local NGOs/CSOs cannot be over emphasised.

[65] PEPFAR (2017), *Zimbabwe Country Operational Plan 2017 Strategic Direction Summary*.
[66] Zambia Country Operational Plan 2017 Strategic Direction Summary, March 2017
[67] Malawi Country Operational Plan 2017 Strategic Direction Summary, April 2017

4.2.2. Potential in other countries

More broadly, there has been a large increase in public sector and donor interest in HIVST over the course of the grant. For example,

- The Global Fund (with input from STAR project partners and staff from Unitaid) published a briefing note in 2016 guiding countries on how they could include self-testing in their applications of reprogramming requests, and our consultations have noted that without the STAR project there would have been much less interest for scaling up self-testing from the Global Fund.
- PEPFAR Technical Considerations for Country Operational Plans (COP)/Regional Operational Plans (ROP) for 2017 recommends including HIVST as part of testing coverage services, with many consultees noting that without STAR the emphasis of self-testing in the guidance would have been limited.

The scale of planned implementation varies significantly between countries, from those with plans to procure kits on a relatively large scale to those who are not planning procurement outside of pilot studies, and further development guidance is needed. Examples of non-STAR countries with a relatively large scale HIVST programme includes Kenya, where the self-testing market is relatively well established compared to other countries in the region. India is also another example of a country that is procuring a high number of self-test kits, although based on consultations with WHO this will still initially be done on a pilot basis with wider scale up planned after this. As discussed in Section 3.4.1, 39 countries have planned HIVST procurement between July 2017 and December 2018, predominantly in sub-Saharan Africa and Asia, with at least 4m test kits expected to be procured during this period, although 2.2m of these will be attributable to by procurement through the STAR project.

The expansion in the number of countries that have included HIVST in national policies, strategies, guidelines and procurement plans offers potential that demand will continue to increase. As noted above, a number of countries have included self-testing in their Global Fund Concept Notes and their PEPFAR Country Operational Plans.[68] Apart from support from the Global Fund and PEPFAR, there has been increasing support from other donors such as CIFF (funding exploration of the private sector model in Kenya, and additional scale up innovations). Based on our consultations, we understand that the work conducted under Phase I of STAR gave a lot of confidence to CIFF that the findings could be drawn upon and leveraged for the private sector.

As such, there is broader momentum in funding being generated, with the large global funders in particular (PEPFAR, Global Fund) being well-appraised of the emerging project results.

[68] The specific numbers to be confirmed once we receive this data from WHO.

One of the main risks to scale up of HIVST is the **funding within a resource constrained** environment. With HIV funding plateauing globally, donors and country governments require evidence of the costing and efficiency analysis before committing resources, demonstrating that importance of understanding the cost-effectiveness of different HIVST distribution models for reaching different populations.

Summary findings:

The STAR project is starting to lay a foundation to support the sustainability and scalability in the three countries. Initial commitments for support are being made by donors (especially PEPFAR and the Global Fund) although these are yet to be confirmed.

5. CONCLUSIONS AND LESSONS LEARNED

The final section of the report presents the evaluation conclusions and lessons learned (Section 5.1). We also provide a summary of progress against Unitaid's 2017-21 Strategy Key Performance Indicators (KPIs), including the healthy market dimensions included within the Strategy (Section 5.2).

5.1. Summary of mid-term review findings

The Unitaid-funded PSI-led STAR project is a **highly relevant intervention** that has been **very well-delivered and extremely well-received** by global and country-level stakeholders. Whilst the project is still in relatively early stages in terms of measuring results and success, stakeholder feedback strongly suggests the "game-changing" value add of the project, indicating that a number of achievements under the project would not have happened in the absence of the project, or at least as quickly. The project has served as the necessary push to create momentum for HIVST, in a context where testing gaps are large, HIVST evidence base limited, and policy and market conditions unfavourable.

The key contributions of STAR Phase I have been as follows:

- **The project has demonstrated that HIVST can be acceptable and feasible.** Our consultations in Zimbabwe plus project research and surveys have indicated that self-testing has widely been accepted by beneficiaries, distributors, health professionals and policymakers alike. There has been an increase in use of HIVST in project countries, with a growing interest amongst policymakers both in project and additional countries.
- **The project has also shown encouraging access and uptake in testing, especially amongst population groups not reached through other testing means,** such as men (increase averaged 26 percentage points from baseline to midline) and adolescents (on average a 27-point increase in HIV testing from baseline to midline). While project evidence regarding yield needs to be interpreted with caution, the added value of reaching males and younger people should not be underemphasised.
- **The project has had a significant impact on developing global and country-level HIVST policy.** The flagship contribution of STAR Phase I has been in terms of the development of the WHO Guidelines on HIVST. STAR has also been pivotal in generating policy momentum on HIVST in the project countries (as confirmed by MoH, WHO and other project partners), particularly in Zambia and Zimbabwe, although there has been less progress in Malawi. However, though policy updates have been made, these have not yet been translated into operational frameworks, which we note some countries are on the cusp of developing. The release of the WHO Guidelines as well as ongoing evidence-dissemination and South-South collaboration from the project has also contributed to policy uptake of HIVST

globally, with 41 countries (of which 23 are LMICs) having national HIVST policies to date. All of these developments have initiated funding applications/discussions with the Global Fund and PEPFAR, although in the immediate future the majority of funded commitments are through a continuation of this Unitaid funding.

- **The project has impacted market supply by providing credibility to HIVST that did not exist before.** In particular, the project contributed to stimulating demand for HIVST and added credibility to the market, in order for it to be taken to the next level. The market for HIVST from a supply base is maturing (e.g. four HIVST products have obtained WHO PQ or ERPD approval). While the project has supported WHO with the PQ process, the direct support to manufacturers has been more limited mainly due to mistiming between availability of project data and PQ submission by OraSure.
- **Strong information sharing and dissemination through the project has created a global interest in HIVST.** One of the key strengths of the STAR project has been raising awareness of HIVST at the global level, based on the extensive marketing and dissemination activities of the project. Many stakeholders have noted that PSI has done an excellent job in disseminating the findings from the project as well as generally raising awareness of HIVST.

These are all significant achievements, particularly given the short project timespan, and are reflective of the strong consortium partners, effective management by PSI, and good coordination within the consortium and with the range of HIVST stakeholders (global and country). Key areas for further work, a number of which are being picked up in Phase II, are as follows:

- **Establishing the public health impact in terms of linkage to care and prevention services.** In many instances under the project, individuals have been linked to HIV prevention interventions such as VMMC, as well as broader prevention interventions. A number of individuals who tested positive have been linked to treatment, with cited earlier linkage to treatment than PDHTS. Through linkage to treatment and prevention, and an inferred reduction in HIV transmission, the project has had a positive public health impact, although available data is at best tenuous/limited and further evidence is much needed in this area.
- **Additional areas of evidence gaps for policy makers and funders.** These primarily include cost and cost effectiveness studies to further establish feasibility, evidence on blood-based tests, and further evidence on implementation of non-CBD models (including community-led models). Cost-effectiveness analyses were noted to be particularly relevant, given the resource-limited settings and “flat-lining” of funding from key donors. While some project research has been undertaken on cost-effectiveness as part of informing the WHO HIVST guidelines, this analysis was conducted specifically for the Zimbabwean context. This has also been noted as

being a relatively technical piece of research focusing on aspects such as disability-adjusted life years (DALYs) saved, whereas it can be argued cost-benefit analyses may be more appropriate for convincing policymakers of the benefits associated with introducing HIVST. Issues related to social harms are also an ongoing topics that are critical to policymaker decisions on HIVST (especially outside the project countries). From a Unitaid funding perspective, we note that an appropriate balance would need to be struck between prioritisation of funding for direct market catalytic functions and further research.

- **Limited evidence on HIVST distribution models beyond CBD.** The project to date has mainly been about piloting CBD models, with limited implementation of other models and exclusion of certain key models, such as through private sector pharmacy delivery. Going forward, there is merit in testing additional models, although balancing this appropriately with the project objective and Unitaid mandate of catalysing the market.
- **There has been less progress made in addressing regulatory barriers,** with manufacturers citing an ongoing lack of clarity and consistency in regulatory processes and standards, and a relatively weak enforcement of the standards, as key constraints. Regulatory challenges are common across a number of developing countries and not just in STAR countries, and it is not surprising given the short timeframe for Phase I of the project that challenges remain.
- **Ongoing barriers to policy and health systems implementation.** As noted, going forward, stakeholders have noted that it will be important to complement policy adoption of HIVST with national operational plans specifying how HIVST will be integrated into HTS nationally, as well as ensuring appropriate M&E and surveillance mechanisms are in place. This latter point is particularly important for self-testing, with the anonymity afforded by self-testing presenting a significant challenge.
- **Need for further political engagement, advocacy, and working with domestic NGOs/CSOs to ensure scale up.** An area for further work is in terms of political engagement and advocacy across countries, beyond policymaker engagement – for example, further engagement with advocates such as those who work with young people, CSOs for demand creation, etc.

5.2. Progress made against Unitaid KPIs and healthy market dimensions

Table 5.1 presents a mapping of the progress made by the STAR project against Unitaid 2017-2021 KPIs, and Table 5.2 is a presentation of progress made towards the effective market component under Strategic Objective 2 (Access). With regards to the effective market components, we note that the project has particularly impacted “demand and adoption” and also “supply and delivery”, with the latter mainly on a research/ pilot scale.

Some of the assessments made in this section relate to the HIVST market more broadly, and are not only linked to the outcomes from the project.

Table 5.1: Assessment of progress in terms of Unitaid 2017-2021 KPIs[69]

KPI	KPI description	Progress
1.1	Increasing public health impact (Number of lives saved - Number of infections or cases averted)	643,276 HIVST kits distributed, and people tested for HIV, with varying numbers being linked to treatment across project countries (as well as challenges with data robustness). Through earlier linkage to treatment and prevention, and an inferred reduction in HIV transmission, the project has had a public health impact.
1.2	Generating efficiencies & savings (Financial savings ($) + Health System Efficiencies ($))	Financial savings: a lower price of US$3.15 (subsequently reduced to US$2 with the Gates buy-down) was obtained for the OraSure HIVST kit. Health System Efficiencies: (i) HIVST in the community can act as a screening tool to triage those with negative results out of HIV testing in the health system. (ii) HIVST within facilities is much quicker than PDHTS. Efficiencies: Beneficiaries have reported (i) time and cost savings through testing at home; (ii) time savings through testing in facilities.
1.3	Delivering positive returns (Return on Investment = $ Benefits /$ Costs)	Cost effectiveness analyses results are still preliminary. As the project is only half-way through implementation, it is too early to conclusively comment on return on investment.
2.1	Investing for the poorest (Total number (or $) of active grants designed to benefit people living in LICs and LMICs /Total number of active grants (or $))	This project fits within Unitaid's portfolio through reaching populations in LMICs.
2.2	Investing for the underserved (Total number (or $) of active grants designed to benefit the underserved /Total number of active grants (or $))	This project has benefited population groups that have been underserved, including adolescents, males, first-time testers, and key populations. It has improved access for populations, particularly through the CBD model.
3	Catalysing innovation	Four HIVST products have obtained WHO PQ or ERPD approval.

[69] Unitaid (2017), Strategy 2017 – 2021.

KPI	KPI description	Progress
	(Total number of Unitaid-supported products for which product development activities have been successfully completed)	Five HIVST products have obtained approval by founding member countries of the GHTF. Six HIVST products have obtained national regulatory approval. Ten HIV RDTs for self-testing currently under development.
4	Overcoming market barriers (Total number of critical access barriers overcome during the strategic period)	Elaborated upon in Table 5.2.
5.1	Securing funding (Proportion (%) of project countries where future funding has been secured at grant closure through partners and countries)	Some funding has been obtained for the project countries from donors. Some support from donors for other countries, although this is mostly limited to pilots. An area in which the project has not yet made significant progress (and will be more of a focus in Phase II).
5.2	Scaling-up coverage (Additional number of people who benefit from a better health product or approach)	The STAR project has started to lay a foundation to support scalability, and programmatic and financial sustainability. 39 countries have planned HIVST procurement between July 2017 and December 2018, predominantly in sub-Saharan Africa and Asia, with at least 4m test kits expected to be procured during this period.

Table 5.2: Progress made towards the effective market component under Strategic Objective 2 (Access)

Effective market component	Progress
Innovation and availability: There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers. It means that new and/or superior, evidence-supported, adapted products are commercially available and ready for rapid introduction in low income countries and lower-middle income countries.	Four HIVST products have obtained WHO PQ or ERPD approval. Five HIVST products have obtained approval by founding member countries of the Global Harmonisation Task Force (GHTF). Six HIVST products have obtained national regulatory approval. Ten HIV RDTs for self-testing currently under development.

Effective market component	Progress
Quality: The medicine or technology is quality-assured, and there is reliable information on the quality of the product.	PQ process ongoing Regulatory barriers in countries is an ongoing challenge.
Affordability: The medicine or technology is offered at the lowest sustainable price and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers, with a view to increasing access for the underserved.	A price reduction for the OraSure test kit of US$3.15 (subsequently reduced to US$2 with the Gates buy-down) was obtained for the OraSure HIVST kit.
Demand and adoption: Countries, programs, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products within their local context.	The project has demonstrated that HIVST can be feasible and acceptable. The project has also shown encouraging access and uptake in testing, especially amongst population groups not reached through other testing means, such as men (increase averaged 26 percentage points from baseline to midline), adolescents (on average a 39-point increase in HIV testing from baseline to midline), and first-time testers (approximately 24% of all the tests). WHO guidelines now recommend that HIV self-testing should be offered as an additional approach to HIV testing services. STAR has also been pivotal in generating policy momentum on HIVST in the project countries, particularly in Zambia and Zimbabwe, although there has been less progress in Malawi, on account of leadership changes. Policy uptake of HIVST globally with 41 countries having national HIVST policies to date, of which 23 are LMICs. These developments have initiated funding applications/discussions with the Global Fund and PEPFAR, although in the immediate future, the majority of funded commitments are through a continuation of this Unitaid funding.
Supply and delivery: Supply chain systems, including quantification, procurement, storage, and distribution, function effectively to ensure that products reach end users in a reliable and timely way. Adequate and sustainable supply exists to meet global needs.	The project has demonstrated how HIVST can be effectively distributed across various models, particularly for CBD, although implementation outside of research settings will need to be demonstrated going forward.

UNITAID

MID-TERM EVALUATION OF THE PSI HIV SELF-TESTING AFRICA (STAR) PROJECT

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FINAL REPORT - ANNEXES

Submitted by:

Cambridge Economic Policy Associates Ltd

CEPA

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ANNEX B LIST OF CONSULTATIONS AND INTERVIEW GUIDES

This annex provides the list of consultees interviewed and the corresponding interview guides.

B.1. Consultee lists

Table B.1: Global consultee list

Stakeholder	Organisation	Name	Position
Funder	Unitaid	Robert Matiru	Operations Director
		Heather Ingold	Programme Manager
		Sina Zintzmeyer	Programme Officer
		Ademola Osigbesan	Supply Advisor
		Wale Ajose	Technical Officer
		Vincent Bretin	M&E Team Lead
		Ombeni Mwerinde	M&E Manager
Project grantee/ implementing partners	STAR core team	Karin Hatzold	Project Director
		Petra Stankard	Senior Technical Advisor
		Hussein Ahmed	Head of Market Research/Project Communications
		Chanda Maleku	Financial Analyst, STAR Project
		Shayla Durrett	Technical Support, STAR Phase II
	PSI Washington	Patrick Aylward	Market barriers lead
		Nina Hasen	Director, HIV and TB Programs
		Judith Heichelheim	Vice President, Southern Africa
	WHO	Cheryl Johnson	Technical Officer - Policy Lead
		Rachel Baggaley	Coordinator of HIV Testing and Prevention
	LSHTM/MLW	Liz Corbett	Research Director
	LSTM	Miriam Taegtmeyer	Deputy Research Director
		Russell Dacombe	Regulatory Lead
	UCL/LSTM/CeSHHAR	Frances Cowan	Deputy Research Director
Technical Advisory Group	UNAIDS	Peter Godfrey-Faussett	Chair, TAG
Global partners	BMGF	Tanya Shewchuk	Senior Programme Officer
	Global Fund	Obinna Onyekwena	Disease Advisor, HIV, Technical Advice and Partnerships Department
	PEPFAR	Michael Grillo	HIV Adviser, Office of the Global AIDS Coordinator

Stakeholder	Organisation	Name	Position
	CIFF	Miles Kemplay	Director Adolescent Health
	USAID	Vincent Wong	TWG HIV testing USAID, Senior Technical advisor
Manufacturers	OraSure Technologies	Brian Reid	Vice President, International Sales
	bioLytical	Ryan Bennett	Senior Director, International Sales
	BioSURE	Brigette Bard	Executive Director
	Atomo Diagnostics	Anna Wang	Director, Global Health

Table B.2: Country level consultee list

Stakeholder group	Organisation	Name	Position
Zimbabwe			
Implementing partner	PSI Zimbabwe	Ngonidzashe Madidi	Deputy Director
		Stephano Gudukeya	Director Social Franchising
		Miriam Mutseka	HIVST Coordinator
		Emily Gwavava	HIV Care & Treatment Programme Manager
		Brian Maponga	Director VMMC
		Taurai Kambeu	Regional Director M&E
		Aleck Dhliwayo	Information Systems Manager M&E
	LSHTM	Rashida Ferrand	HIV Clinical Epidemiologist
	CeSHHAR	Tendayi Mharadze	Key Populations Director
		Euphemia Sibanda	STAR Zimbabwe Research Project Lead
		Mary Tumushime	STAR Zimbabwe Research Coordinator
		Collin Mangenah	Health Economist
Government	MOHCC	Owen Mugurungi	Director AIDS and TB Unit
Other donors	Global Fund CCM	Oscar Mundida	CCM Executive Secretary
	WHO	Simbarashe Mabaya	WHO HIVST Focal Point
	USAID	Natalie Kruse-Levy	Senior Health Program Adviser
TWG members	UNICEF	Beula Senzanje	HIV Specialist
CSO/NGO	ZNNP+	Rumbidzai Matewe	Programmes and Training Manager
	AFRICAID	Nicola Willis	Country Representative
	OPHID	Sara Page	Senior Technical Adviser

Stakeholder group	Organisation	Name	Position
Healthcare workers	Goromonzi District	Interviews with community-based distribution agents (CBDAs), community leaders and beneficiaries	
Health facilities	Goromonzi District	Interviews with healthcare facility team and beneficiaries	
	Mahusekwa Hospital, Marondera District	Interview with DHE Interacting with health staff at HIVST entry points and Linkages to Treatment and Care Services	
	Harare, VMMC Clinic	Interviews with providers and beneficiaries	
	Harare, VMMC Interpersonal Communication (IPC) programme	Interviews with IPC agents and beneficiaries	
	Harare, New Start Centre	Interviews with providers and beneficiaries	
Zambia			
Implementing partner	ZAMBART	Helen Ayles	STAR Research Lead
	SFH Zambia	Mutinta Nalubamba	STAR Zambia Project Director
		Namwinga Chintu	Country Representative
		Namuunda Mutombo	Research, Monitoring and Evaluation Director
		Gina Smith	Deputy Country Representative
		Hambweka Munkombwe	STAR Zambia Programme Manager
Government	Ministry of Health	Dr Tina Chisenga	TB/HIV Program Manager
Other partners	WHO	Lastone Chitembo	HIV, TB and Hepatitis Adviser
	African Community Advisory Board (AfroCAB)/Unitaid Board	Kenly Sikwese	Interim Coordinator/Alternate Board Member for Communities
Malawi			
Implementing partner	PSI Malawi	Richard Chilongosi	Programme Manager
		Ricky Nyaleye	Communications Manager
Government	Ministry of Health	James Kandulu	Assistant Director - Diagnostics
Other partners	Malawi Network of AIDS Service Organisations (MANASO)	Abigail Dzimadzi	Executive Director

B.2. Interview guides

B.2.1. PSI

1. Please describe the origins of the project in terms of the initial discussions between Unitaid and PSI and how the grant was shaped to its current design? Were any key issues raised by Unitaid during the design and approval phase?
2. Were there any major delays between the project being approved by Unitaid and rolling out project implementation? If so, what were the causes of these delays and how did they affect project delivery?
3. What have been the main reasons for project underspend to date? For example, was this due to cost-efficiencies or some activities not being conducted/conducted at the scale initially envisaged?
4. How effective has project coordination worked between different partners, countries and different project workstreams? Were there any aspects of coordination you feel could have been done more effectively?
5. What do you see as the key results and achievements of this project to date? What areas would you like to have seen more results?
6. Do you believe the project's distribution models have been effective in targeting individuals that were not previously tested? What models were most effective and identifying positive individuals and for targeting previously untested individuals?
7. Would you liked to have seen additional models tested during this phase? To what extent do you think linkage to treatment and prevention could have been improved? How has the experience of kit distribution varied by country?
8. To what extent have activities related to raising consumer demand resulted in improved awareness and knowledge of HIVST? Is there evidence of this being linked to higher levels of testing?
9. What evidence and areas of research do you feel have been most important for i) mobilising greater political commitment for HIVST; and ii) informing manufacturers about key pieces of information to convince them to enter the market? Do you think there are any key pieces of evidence that are still missing?
10. To what extent has this project contributed to removing policy and regulatory barriers, both within the project countries and more widely? To what extent has this project contributed to policymakers committing to adopting or scaling up HIVST activities? Are there any additional requirements governments have needed in place that have not been addressed by the project?
11. To what extent have activities contributed to removing or reducing market barriers? What aspects of the project do you believe manufacturers have found most useful?

12. What is the emerging evidence on the public health impact (including linkage to care) and is this aligned with expectations? What evidence is there of the project having social impacts (such as positive employment effects or people having greater control over their health)?
13. How has Phase I informed the design and activities of Phase II? Were there any areas of the project where you would have liked to have seen more evidence or focus in Phase I?
14. To what extent to believe that project activities will be sustained and scaled up following the conclusion of Phase II?

B.2.2. Research partners

1. What was your involvement in HIVST before the project and how did you become involved in the STAR project?
2. How were research-related activities determined and selected during the design phase? Who was responsible for identifying these? Were there any delays in project start-up that had knock-on effects for the project's research activities?
3. How effective has PSI management of this project been? Has Unitaid involvement in the project been sufficient? Were there any aspects of project management and implementation you would like to have seen done differently?
4. How have research activities linked to i) country distribution activities; and ii) global activities for increasing consumer demand and reducing policy, regulatory and market barriers?
5. What do you see as being the key research outputs of this project? To what extent do you feel that these outputs have helped close previous knowledge gaps regarding HIVST?
6. What evidence and areas of research do you feel have been most important for i) mobilising greater political commitment for HIVST; and ii) informing manufacturers about key pieces of information to convince them to enter the market? Do you think there are any key pieces of evidence that are still missing?
7. To what extent has research been able to identify and highlight the public health impact of HIVST in terms of i) increased levels of HIV testing; ii) reducing health system burden; and iii) effective models for linking HIVST to treatment and prevention?

B.2.3. WHO

1. What HIVST work was WHO involved in at the global, regional and country level before the STAR project?
2. What was WHO's involvement during the initial project stages in terms of designing specific activities and areas of focus and liaising with Unitaid, PSI and other project partners?

3. How have WHO activities been coordinated with that of other project partners, both at the global and country level? Do you believe this has worked efficiently and effectively?
4. To what extent did the project's research and activities inform WHO guidance for HIVST? How would this evidence have been obtained in the absence of this grant? How important was this project to guidelines being developed?
5. How did this project support the WHO PQ process for HIVST? To what extent is its establishment attributable to the support from this project, accounting for other funding provided by Unitaid and others to support WHO PQ-related work?
6. To what extent has this project supported WHO activities over and above what it would have been doing as part of its core focus of providing normative guidance and technical assistance for HIV prevention and diagnosis?
7. What evidence and areas of research do you feel have been most important for i) mobilising greater political commitment for HIVST; and ii) informing manufacturers about key pieces of information to convince them to enter the market? Do you think there are any key pieces of evidence that are still missing?
8. How do you think this project has contributed to HIVST policies and rollout in other countries? Were countries considering and adopting these policies because of this project being implemented, or were these activities being pursued anyway?
9. How has this project contributed to reducing market barriers? Has any evidence or work from this project directly contributed to more products and manufacturers entering the market? What level of activity do you think would have occurred without this project?
10. We understand that WHO is leading the development of an HIVST framework, including assessment of impacts of HIVST. What is the current thinking regarding estimating HIVST impacts? What key factors do you believe need to be measured in order to measure impact?
11. What have been the key public health impacts of this project? Has the project resulted in increased testing and linkage to care? What do you believe have been the most effective distribution models for achieving this? Do you think any additional distribution models should have been tested?
12. What activities would you like to have seen undertaken that were not implemented during Phase I? Are these being implemented as part of Phase II?

B.2.4. Global Partners (BMGF, Global Fund, PEPFAR, CIFF, USAID)

1. Please describe the experience that your organisation has had of supporting or introducing HIVST, and what have been some of the driving forces in introducing this in different countries?

2. Did the STAR project impact on your organisation's work in the HIVST space? To the extent that you're aware, what has worked well and what has worked not work so well in implementation of the project in the 3 STAR countries (Malawi, Zambia, Zimbabwe)?
3. What has your organisation's procurement experience been? Can you provide some data on your organisation's procurement volumes and prices achieved (including STAR countries and non-STAR countries)?
4. What evidence and areas of research do you feel have been most important for i) mobilising greater political commitment for HIVST; and ii) informing manufacturers about key pieces of information to convince them to enter the market? Do you think there are any key pieces of evidence that are still missing?
5. How important has the STAR been for raising awareness of and demand for HIVST? What evidence is there that the STAR project influenced activities in other countries?
6. How has the STAR project contributed to reduced policy, regulatory and market barriers? Do you think results in this respect are a direct result of the project? What other factors contributed to attaining these results?
7. What do you see as the current challenges to HIVST uptake? What activities is your organisation planning in future to address these? To what extent are these being met by the activities planned under STAR Phase II?
8. Do you believe that HIVST uptake will be sustained following the conclusion of the STAR Initiative? To what extent do you think national governments will rely on the Global Fund, PEPFAR and other organisations to support them with sustaining HIVST?

B.2.5. Manufacturers

1. We understand that the STAR project has supported manufacturers through facilitating progress of HIV testing products towards Global Fund ERP-D or WHO PQ submission. What support did this entail, and what worked well and less well?
2. What challenges have you experienced in your efforts towards achieving Global Fund ERP-D or WHO PQ? What difference did the STAR project make to achieving this? If not already introduced, what is the anticipated introduction date for your HIVST product following (i) ERP-D approval and (ii) WHO PQ?
3. What will be the likely maximum production capacity? At what price do you anticipate being able to sell HIVST?
4. To the extent that you're aware, has the STAR project been successful in increasing demand and facilitating uptake for HIVST in countries?
5. If any, what additional research and evidence would you like to have seen from the STAR project to support market entry? To what extent was market size estimations important for convincing manufacturers to enter the market?

6. How do you believe the HIVST market will change over the next 3-4 years? What do you believe will be your key markets? Who do you believe will be the key players?

B.2.6. Government/Policymaker

1. What was the situation regarding HIV testing and self-testing prior to the STAR project? Was there a need for HIVST and what are key challenges to adoption/ uptake?
2. What has been your interaction with the STAR project to date? How has the activities of this project linked to other HIV initiatives in the country, including other prevention, diagnosis and treatment activities?
3. What do you view as the main value add and contribution of the STAR project in country? What key gaps remain with regards to rolling out and scaling up HIVST in the country?
4. What is your view on the emerging evidence and experiences from the different distribution models employed under the project in terms of i) reaching previously untested individuals; ii) identifying HIV positive individuals; iii) linking HIV positive patients to treatment and negative patients to prevention activities (including re-testing)? Do you think any additional models could have been explored during Phase I?
5. What have been key policy and regulatory barriers to HIVST in the country? To what extent has this project contributed to addressing these policy and regulatory barriers? To what extent has this project contributed to policymakers committing to adopting or scaling up HIVST activities? Has HIVST been incorporated into national guidelines and country operations? What activities and key pieces of evidence do you believe have helped to increase political commitment?
6. What do you see as being the key pieces of evidence and research coming out of this project? To what extent do you feel that these outputs have helped close previous knowledge gaps regarding HIVST? What areas of research do you feel have been most important for i) mobilising greater political commitment for HIVST; and ii) informing manufacturers about key pieces of information to convince them to enter the market? Do you think there are any key pieces of evidence that are still missing?
7. What do you believe has been the impact of this project in terms of i) increased levels of HIV testing; ii) reducing health system burden; and iii) effective models for linking HIVST to treatment and prevention?
8. What are the country's plans for adopting and scaling up HIVST in the coming years? Will this be funded through government or donor (e.g. Global Fund, PEPFAR) resources?

ANNEX C SUMMARY OF RISKS IDENTIFIED BY THE PROJECT DURING PHASE I

Table C.1 below summarises the key risks identified throughout Phase I of the STAR project.

Table C.1: Risks highlighted during STAR Phase I

Report(s)	Risk	Description	Mitigation measure
Multiple annual reports	Delay in ethical and regulatory approval	Ethical approval was needed in order to begin kit distribution in all the countries, meaning that delays to this would have knock-on effects for obtaining findings by the end of Phase I.	Regular meetings held between ministry officials and ethic approval committee at LSHTM.
Multiple annual reports	No RDTs for self-testing are submitted and/or approved for WHO PQ/EPRD	WHO PQ can be a lengthy process which is largely beyond the control of project partners. Delays in WHO PQ for the OraSure product would have meant that South Africa could not have been included in Phase II, while for other countries ERPD approval was also important to obtain.	Updating the market with landscape reports, facilitating the development of WHO guidelines to increase political interest, engage with ERPD and WHO PQ teams to ensure that progress is being made and support can be provided.
Project Plan/ 2016 Annual Report	Uncertain/ lack of demand for HIVST	The novel nature and nascent market for HIVST meant that it was difficult to anticipate the level of demand for kits among communities and beneficiaries.	Conducting formative work at the start of the project to better understand attitudes and preferences towards HIVST.
Project Plan/ 2016 Annual Report	Loss of complementary funding	PEPFAR funds several PSI programmes and projects across the three countries, while DFID has been an important funder of activities in Zimbabwe. Gates is also a key funder of several areas of PSI focused on self-testing, including the VMMC programme. Without this funding support, the project would not be able to leverage existing platforms to test the various distribution models.	PSI saw this as a low risk given their strong programme performance making funding losses unlikely. In the event that this did occur, it would look to leverage other existing projects that have a strong interest in advancing HIVST.

Report(s)	Risk	Description	Mitigation measure
Project Plan/ 2016 Annual Report	Potential for unintended consequences (including social harm)	There were concerns that unsupported HIVST in a private setting may be less likely to trigger behavioural change and health-seeking behaviour, and more likely to be associated with social harms than provider-delivered HIV testing services (PDHTS). As a result, uptake from PLHIV, discordant couples and VMMC could be lower. Issues were also raised of the increased possibility of severe psychological reactions with HIVST.	CBDAs would be trained to address potential issues of social harm. In addition, regular monitoring and surveys were incorporated into the project to assess whether unintended consequences were being realised. n
Project Plan	Health worker and laboratory resistance	Risks that some health professionals may feel threatened or less values with the introduction of self-testing, creating tension between promoters of HIVST and these individuals.	Stakeholder engagement incorporated into the project aimed to make health professionals aware about the project objectives and minimise resistance.
Project Plan	Data confidentiality and data ownership	Confidentiality of HIV patients is an important aspect in all forms of testing and counselling, but given the nature of some distribution models being used and the way in which data was being processed it was perceived that there could be risks to personal data from individuals being accessed.	Confidentiality and data ownership in the project were to be in line with established guiding principles, including the UK Data Protection Act 1998, plus necessary encryption was used on project software and management ensured all confidential information was not openly available.
2015 Annual Report; 2016 Semi-Annual Report	Negative results from validation studies in other countries	Negative results from external studies could undermine the results coming from the STAR project, or implementation issues found on other projects may not be identified appropriately and incorporated into the STAR programme.	PSI and WHO regularly engaged with other researchers to ensure problems were identified and learnings are incorporated into STAR programming.
2015 Annual Report; 2016 Semi-Annual Report	Loss of backing from ministries due to changes in government/staffing	Ministries in countries can experience staff turnover due to changes in government, in addition to issues faced with staff retention. This in turn can result in having to make additional efforts to win buy-in for the project. This was a specific issue that was found in Malawi.	Project partners (particularly WHO) to engage with the government and highlight the benefits and importance of the project in the country.

Report(s)	Risk	Description	Mitigation measure
2015 Annual Report; 2016 Semi-Annual Report	Lack of external quality assurance of OraSure self-test kit	No external quality assurance laboratories were trained on quality testing of the HIVST kits from OraSure, therefore PSI had to rely only on the manufacturer's internal quality assurance procedures instead of the standard process of using external sampling and testing agents.	PSI worked with OraSure to ensure that they trained external WHO PQ Quality Control Laboratories on the quality standards of HIVOFT so that this could be in place by the time the kits receive WHO PQ.
2016 Semi-Annual Report	Draught in Malawi limiting ability to implement Community-based Distribution (CBD) model	A draught in Malawi resulted in a famine crisis in rural Malawi that slowed down the pace that the CBD model could be implemented.	PSI engaging additional CBDAs and support those who are facing challenges associated with the famine.
2016 Annual Report	No implementation evidence being available for blood-based tests	Phase I of the project focused significantly on generating evidence for the OraQuick OFT, while blood-based kits were not included in implementation due to the products being less established during Phase I, plus blood-based distributors remaining sceptical on the potential of the market in resource limited settings until well into Phase I implementation.	PSI has been collaborating with CeSHHAR and MLW to undertake accuracy, feasibility and acceptability studies for four blood-based products in Zimbabwe and Malawi. This will support governments choosing the appropriate mix of HIVST and not limit the market to one product.
2016 Annual Report	CBDs failing to implement protocol-required procedures	CBDs were trained specifically for distributing kits, however, it was noted that without ongoing training certain procedures may not be followed.	Re-training of staff to ensure quality control processes were in place.

ANNEX D CONSULTATION FEEDBACK ON DISTRIBUTION MODELS

This annex provides further details regarding experiences with the implementation of the various distribution models.

As part of Output 1 of the STAR project, a number of distribution models were tested across the three project countries. These included:

- **Community-based distribution (CBD):** This involved the distribution of kits in communities through community-based distribution agents (CBDAs). CBDAs would distribute kits largely via door-to-door distribution in villages as well as via key community sites such as youth and recreational centres. This model required PSI to approach community leaders to get approval and facilitate implementation. CBDAs would then be recruited and trained both through intensive training at the start of implementation as well as ongoing follow-up training. These individuals would be identified through a recruitment process, and often would be involved in providing health services in the community prior to the project. Given the staffing requirements, this model has been highly resource-intensive. The actual implementation varied between the countries, with Zambia and Malawi distributing kits in the same communities over the duration of Phase I implementation while Zimbabwe opted more for a campaign-style approach, whereby kits were distributed intensively within a six week period in one area, after which PSI would move to a different area and distribute kits (which would involve re-training new CBDAs). As part of Phase II, countries will be adopting this latter approach when using CBD models.
- **Facility-based distribution:** This model involves distribution of kits via health facilities whereby patients are tested on the sites or (less commonly) collect kits from the sites and test themselves at home. The specific nature of this model varies both within and between countries. For example, in Zimbabwe facility-based distribution was conducted largely via PSI New Start Facilities. These are integrated health facilities that offer a range of services beyond HIV testing, and include both static facilities as well as outreach facilities whereby "pop-up" facilities can be provided in communities or rural areas that are not reached by traditional facilities. In Malawi, some limited testing towards the close of Phase I of the project was conducted in social franchise clinics, targeting the urban general population. Facility-based distribution was also conducted via public health facilities in each of the countries, whereby HIVST was integrated into testing in hospitals and health clinics. This was the principle method of facility-based distribution in Zambia, while in the other countries facility-based distribution was primarily undertaken via PSI New Start/TUNZA facilities.
- **Voluntary medical male circumcision (VMMC):** PSI provides VMMC services across a number of countries and was able to use its existing infrastructure to include HIVST. The rationale for integrate HIVST into this model is that males are generally harder to

reach via traditional means for testing. In addition, HIV testing can be a barrier to undertaking VMMC and self-testing can act as an entry point for VMMC interpersonal communication (IPC) agents to increase the extent to which males opt for circumcision, as males will be more willing to use HIVST due to the convenience and anonymity it provides, and once they know their status will be more willing to opt for circumcision if tested negative. As part of Phase I, kits were distributed both via VMMC static clinics as well as IPC agents conducting their outreach activities.

- **FSW distribution:** This built on the existing activities of project partners in the countries. For example, in Zimbabwe CeSHHAR has been running clinics as part of the National Sex Workers Program since 2009, while in Malawi existing relationships with SW and the National Female Sex Worker Alliance were utilised to incorporate HIVST into existing social marketing activities.
- **Secondary distribution:** This refers to distribution of HIVST kits through individuals who have been tested positive for HIV. This model was tested in Zimbabwe.
- **Workplace distribution:** These models were tested during the later stages of Phase I in Malawi and Zambia, and mostly involved targeting working men.

The selection and focus of distribution models was determined by a range of factors, including: i) extent to which models were perceived to be feasible in reaching untested populations; ii) the nature of research activities to be undertaken in each country; and iii) the extent to which existing activities and infrastructure could be utilised in each country.

Table D.1 below summarises findings regarding the implementation of models, highlighting key aspects that have worked well across the three countries as well as some of the challenges that have arisen. This was informed by qualitative research and process evaluations taken as part of the project as well as partner implementation experience.

Table D.1: Implementation of distribution models

Model	Positive findings	Challenges
CBD	• *Acceptability*: Model widely accepted in different communities, given the convenience it provides to patients, especially those less willing or able to visit facilities. • *Feasibility*: Model most applicable for distributing kits at large scale. • *Acceptability*: Acceptance and buy-in from community leaders was obtained. Community members were also important in helping to identify CBDAs and areas within districts to target. • *Feasibility*: CBDAs seen as effective in marketing product in communities and reaching different households. • *Feasibility*: Research and implementation of model was well coordinated between partners.	• *Feasibility*: Is an expensive model to implement - - while it ensures large coverage, yield may not be high in this model, especially when HIV is not prevalent in general populations. • *Feasibility*: Linkage to care remained an issue that many have been noted with this model, plus there have been some difficulties in monitoring linkage. • *Feasibility*: Some stakeholders noted that campaign-style CBD in Zimbabwe meant that some people did not receive kits if they were not at home, particularly if CBDAs came to houses at the end of the period. • *Feasibility*: Some CSOs felt that existing community support structures were not fully utilised during implementation, and that existing community support networks could have been more engaged and better informed of project activities. • *Feasibility*: Initial issues were found with implementation design. For example, in Zimbabwe one kit was initially distributed per household, even if some adults eligible for testing were out. In addition, follow-up activities were initially taking place two weeks after distribution, but this was later seen to be too long as people were linking to care earlier than this if tested positive. • *Acceptability*: Some concerns from religious groups with regards to distribution of such kits. • *Acceptability*: Some evidence from research suggests there was subtle pressure from CBDAs for clients to take the test, as well as families feeling subtle peer pressure to take tests if given kits with other members present. • *Acceptability*: Anecdotal evidence suggests that youths found it hard to accept kits from CBDAs in presence of parents, and would often obtain kit secretly. Also some evidence of women and people from particular religious faiths (apostolic) only accepting kits in secret.
Facility-based	• *Feasibility*: Self-testing was well integrated into facility-based models ran by PSI.	• *Feasibility*: Relatively limited experience of distribution through public facilities outside of Zambia, given limited implementation periods.

Model	Positive findings	Challenges
	• *Feasibility*: Welcomed by a number of staff in facilities for its impact on ensuring more people could be tested and limiting staff time. • *Linkage*: Immediate linkage to treatment and prevention services possible in static facilities.	• *Acceptability*: Some concerns from healthcare workers in Zimbabwe of introducing self-testing due to fears of staff reductions following introduction.
VMMC	• *Acceptability*: IPC agents saw self-testing as a useful entry point for linking men to circumcision. • *Feasibility*: Self-testing able to integrate relatively easily into existing PSI implementation infrastructure. • *Linkage*: Referral of positive patients to health facilities seen as working well. • *Acceptability*: Self-testing viewed positively by males who are often less willing to be tested in clinics.	• *Feasibility*: Some issues highlighted with being unable to offer self-testing to some younger people, who were eligible for circumcision.
FSW	• *Targeting*: Self-testing through outreach services useful for reaching individuals who may not come to sex clinics to be tested. • *Targeting*: Positively tested individuals offered kits to provide to partners (indexing). • *Acceptability*: Well-received by FSW clinics for ease of use and ability to free up time elsewhere.	• *Acceptability*: Around half of FSW opting for PDHTS in Zimbabwe when given the choice, largely due to greater confidence in results compared to self-testing. • *Acceptability*: FSW can sometimes feel uncomfortable about taking kits home to their partners if tested positive. • *Acceptability*: Evidence that many FSWs were uneasy about using self-testing at first, although this was mitigated through information provided by nurses at facilities. • *Acceptability*: Sex workers sometimes felt unclear at facilities whether they could take kits home and test themselves, or if they had to take tests at the static clinics.

Source: CEPA analysis.

ANNEX E ASSESSMENT OF EVIDENCE ON DISTRIBUTION MODELS FROM STAR PHASE I

This annex provides a summary of the emerging evidence on the acceptability, feasibility, targeting and linkage to care/prevention of key distribution models implemented during Phase I and the overall strength of the evidence generated. The section is structures as follows:

- Section E.1 summarises our findings from our review of the research across the dimensions.
- Section E.2 assesses the strength of the evidence that has been reviewed across the dimensions, based on the DFID framework for assessing the strength of evidence. [1]
- Section E.3 summarises the findings from the individual pieces of research reviewed.

E.1. Summary of findings

This sub-section includes a summary of the findings that have emerged from various studies on the acceptability, feasibility, targeting and linkage of different distribution models in the Phase I project countries. Based on our review of the evidence, we have defined these as:

- **Acceptability** refers to the extent to which individuals support HIVST being delivered through a particular distribution model. This is assessed through revealed preferences whereby individuals actively opt for self-testing over other forms of testing, as well as the extent to which participants surveyed that they would either be interested in undertaking self-testing or recommending self-testing to friends or family.
- **Feasibility** refers assessments of how distribution models could be scaled up and implemented. This includes reviews of the cost of HIVST relative to standard of care (SOC) testing, as well as studies on cost effectiveness. It also refers to any qualitative research that has assessed ways that certain distribution models could be implemented.
- **Targeting** includes analyses of yields observed following the implementation of distribution models.
- **Linkage** includes the extent to which individuals that have been identified as positive have i) had confirmatory tests; and ii) have been initiated onto treatment. Linkage also includes the extent to which individuals that have been tested negative are linked to prevention strategies. This is particularly relevant for VMMC.

We have included a summary of findings from 24 sources (including STAR project data, research studies and non-STAR studies) on the following models: i) CBD; ii) Facility-based distribution; iii) VMMC; iv) FSW; and v) Secondary distribution (primarily to male partners of

[1] DFID (2014), *Assessing the Strength of Evidence.* See here for further details.

pregnant mothers and FSWs).[2] For each model and dimension outlined above, we have categorised findings from evidence as high, medium or low, based on the evidence on the potential of the model. These categorisations are defined relative to the different distribution models, for example linkage to care under the CBD model relative to the facility-based model, as opposed to being absolute categorisations. We note that these assessments are subjective assessments based on CEPA's review of the evidence, and therefore should be interpreted in this manner.

Our review only includes studies and research from the three project countries, and it should be noted that a substantial amount of evidence has been generated in high income countries as well as some research conducted in resource-limited settings (with South Africa, Kenya and Uganda being notable examples). It should also be noted that our review includes studies undertaken both under the STAR project as well as relevant studies from the countries that include STAR consortium members and non-STAR authors that are funded from other sources.[3] Details of the findings from individual studies is summarised in Section E.3.

Our assessment is presented in Table E.1, which summarises findings for the various distribution models.

Table E.1: Summary of key dimension findings for different distribution models

Model	Acceptability	Feasibility	Targeting	Linkage
CBD	High	Medium	Medium	Low
Facility-based	Medium	Medium	Medium	High
VMMC	High	Medium	Low	Medium[4]
FSW	High	High	High	High[5]
Secondary distribution	High	High	No evidence	No evidence

Source: CEPA analysis of Phase I country research.

As the table suggests:

- Evidence suggests that **self-testing overall has been highly accepted across each of the countries.** This is supported by evidence of people directly choosing self-testing over conventional testing methods, as well as surveys suggesting that individuals would recommend HIVST to family members or friends. With regards to specific models, focus group discussions (FGDs) and discrete choice experiments (DCEs) have suggested that people would prefer to test at home as opposed to testing in facilities or mobile clinics. This partly explains facility-based distribution being categorised as

[2] We have not included details on workplace models, given the limited evidence generated.
[3] The sources of the studies are based on reviewing research posted on hivst.org (accessed here), plus the list of research outputs provided as part of the STAR End of Project report.
[4] Note that linkage for the VMMC model refers to linkage to circumcision.
[5] It should be noted that this only applies to FSW models where individuals are tested at sites, as opposed to models where FSW can test away from health facilities.

'medium', given that many studies suggested while individuals have been open to using self-testing at facilities, this was rarely preferred except in the case of FSWs testing at specialised clinics. There has also been some evidence that HCWs in the Zimbabwean public sector have initially been uneasy about self-testing due to the risks it places on their job security.[6]

- The evidence generated on feasibility suggests that **from a practical implementation perspective, most models have been shown through the initial stages of the STAR project to be feasible (especially for the CBD model).** In terms of **costs and cost-effectiveness, evidence on the feasibility of different models has been mixed.** For example, bottom-up costings of CBD models in Malawi and Zimbabwe have suggested that the cost of HIVST can be comparable to provider-delivered HIV testing services (PDHTS), and could be even lower with recent reductions in the cost of the OraQuick self-test.[7][8] However, identifying positive patients through the CBD model has shown to be higher than PDHTS models in Malawi.[9] In addition, Annex 23 of the WHO Guidelines on HIVST suggested that CBD models require substantially high cost-effectiveness thresholds in order to be seen as cost-effective in Zimbabwe. For other models, we note that evidence from the FSW and secondary distribution models is high, which primarily reflects the findings on practical implementation through the STAR project for FSW, as well as evidence on cost-effectiveness generated from Annex 23 of the WHO HIVST guidelines, which suggested these models could be highly cost-effective relative to other models. Our scoring of facility-based and VMMC models notes that while the STAR project has showed some evidence that they can be integrated into existing activities and programmes, no evidence has been generated on their costs or cost-effectiveness.
- With regards to targeting or yield, unsurprisingly **models targeted at key populations have demonstrated higher yields than more general models**, while VMMC yields have been relatively low. Reasons for this can be found in Section 3.2.4.
- As regards linkage, **facility-based models have shown far higher linkage rates than community-based models**, given the proximity individuals have to post-test services once they have obtained their results. For the CBD model, evidence on linkage rates have varied substantially from single digit proportions to linkage rates nearing 60%, although it should be noted that the time in which these rates are reported vary between studies. For VMMC, while preliminary evidence from the STAR project

[6] Madanhire et. al. (2016), *"Not without us…": Views on the introduction of HIV self-testing among health care workers providing integrated HIV and sexual and reproductive health services.*
[7] Maheswaran et al. (2016), *Cost and quality of life analysis of HIV self-testing and facility-based HIV testing and counselling in Blantyre, Malawi;*
[8] Mangenah et al. (2017), *The costs of community based HIV self-test (HIVST) kit distribution: Results from 3 districts in Zimbabwe.*
[9] Maheswaran et al. (2016), *Cost and quality of life analysis of HIV self-testing and facility-based HIV testing and counselling in Blantyre, Malawi;*

suggests that self-testing can help increase the rate of males opting for circumcision, evidence from the project overall suggest that rates of male circumcision still remain low.

E.2. Strength of evidence

We have also undertaken an assessment of the strength of evidence that has informed these findings. This assessment has used the DFID methodology for assessing evidence, which specifically looks at the overall technical quality, the size of the evidence (in terms of studies undertaken and where relevant sample sizes of particular studies), the context of findings (in terms of applicability to other countries outside of the Phase I countries) and the consistency of findings between countries for the different distribution models.

E.2.1. Summary

Table E.2 summarises our assessment of the strength of evidence with regards to the findings outlined above. Our general observations include:

- **The evidence base to date is strongest regarding the acceptability of different models,** particularly for CBD and FSW, while evidence on the acceptability of other models is relatively strong but further work to understand acceptability of other models is needed, yet this should come as part of the STAR Initiative.
- **Evidence on the feasibility of scale up is more limited across all models**, particularly for feasibility of scale-up from a cost and cost-effectiveness perspective, with no evidence found in our review of the cost and cost-effectiveness of facility-based and VMMC models.
- In terms of targeting, **while a lot of data is available for the CBD model, questions regarding the validity of figures sourced from late-read kits and self-reporting** mean that it has not be possible to provide a higher score, which is also the case for the FSW model. For both facility and VMMC, yield data is limited to findings from the STAR project, and therefore also is subject to similar limitations as well as no comparator data being available in the project countries.
- **The evidence on linkage to care also remains a key issue for most models**. For CBD, while more evidence has been generated for this model the inconsistency of findings means that it is not possible to give it a higher score.

It is important to note that our assessment has not revealed any shortcomings in the quality of research implementation, which given the calibre of research institutions conducting the activities is not surprising. Instead, most of the current shortcomings in evidence are simply related to research not being conducted (for example, cost-effectiveness of all models) or difficulties in obtaining findings for results (for example, on yield and linkage).

Table E.2: Summary of strength of evidence for different distribution models

Model	Acceptability	Feasibility	Targeting	Linkage
CBD	Strong	Medium	Medium	Medium
Facility-based	Medium	Limited	Limited	Limited
VMMC	Medium	Limited	Limited	Limited
FSW	Strong	Medium	Medium	Limited
Secondary distribution	Medium	Limited	No evidence	No evidence

Source: CEPA analysis based on review of literature

Further discussion on the strength of evidence against different dimensions is provided below.

E.2.2. Technical quality

Technical quality of STAR research is high, being delivered by leading academics.

Key areas of concern regarding the quality of findings (which the STAR consortium are aware of) include the extent to which findings from self-reported data collected in surveys can be truly relied upon (for example, the extent to which individuals report they are positive, or whether people admit that they have not linked to care), as well as the validity of late-read kits (see Section 3.2.4 for further details). Such limitations mean that findings coming from such sources should be viewed with some degree of caution.

E.2.3. Size of evidence

In terms of the size of the evidence base, we have reviewed both the number of studies conducted in different areas as well as the sample size of specific studies. The following is observed:

- For **acceptability,** a number of studies have been conducted across the three countries accessing the extent to which models would be accepted, particularly for CBD models and models targeting FSW (although the latter studies had relatively limited sample size). Less research has been conducted to date on the acceptability of facility-based models, with only one FGD study conducted in Zimbabwe with a limited sample size informing findings.
- For **feasibility,** the overall size of the evidence base is limited, especially regarding their costs and cost-effectiveness and for non-CBD models. For example, findings on FSW and secondary distribution in these countries currently rely on research undertaken to inform the WHO HIVST guidelines. For CBD, while some cost and cost-effectiveness analyses have been undertaken, four studies have been completed and rely on data from only certain regions with Malawi and Zimbabwe, with no costing studies for HIVST having been completed for Zambia. For facility-based models, we

note that the project has undertaken a considerable amount of research to understanding the costs associated with HTC in general. However, specific costs and cost-effectiveness of facility-based models for HIVST have not been completed to date, primarily because these models have only been implemented on a limited scale (especially outside of social franchise facilities).

- For **targeting**, the majority of data that has been generated for the project countries is based on implementation of the STAR project, with a handful of other studies also reporting yield data. While there is relatively more data on FSW and CBD, further analysis is still likely to be needed in order to get a better understanding of what actual yields are likely to be, especially for other models.
- As regards **linkage,** other than the CBD model relatively little research has been undertaken to greater understand linkage in other models where self-testing is used. However, given that linkage is more of an issue associated with community-based models this is understandable. For VMMC, while less research has specifically looked at the role of self-testing on linkage, it should be noted that issues associated with lower levels of uptake of male circumcision are well-known and not specifically related to self-testing.

E.2.4. Context of findings

As noted in the main report, many of the overall findings from the STAR project are likely to be specific to the countries and regions within countries. For example, while a CBD model may be acceptable and appropriate for increasing uptake in populations with more generalised HIV, countries in which HIV is more concentrated in key populations are likely to see findings from models for FSW more appropriate. In relation to this, the yields found as part of the STAR project may only be specific to the countries and regions where kits were distributed, given the wide variation in prevalence both within and between general populations in countries. Findings regarding linkage may also be specific to the contexts of the countries included in the STAR project, as the major constraints to linkage discussed in the report may only be specific to countries where stigma and relatively limited health facilities are present.

E.2.5. Consistency of findings

As regards the consistency of findings, the following was observed from our review:

- For **acceptability**, **findings tended to be consistent across the three project countries,** particularly for the CBD model where most individuals were supportive of this model. It should also be noted that some studies were undertaken on a multi-country basis, including those assessing the acceptability of self-testing among young people and FSWs, and findings tended not to vary substantially across countries.

- For **feasibility,** findings on **costings for Malawi and Zimbabwe from different authors were generally consistent** with one another, notably that CBD costs were relatively in line with SOC, as well as findings that CBD models may not be cost-effective.
- For **targeting**, the **FSW model consistently showed the highest yields across countries, while VMMC models were generally lower than others**. However, within the **CBD model, the yields found among study participants have often varied substantially** between studies and countries. For example, in Malawi the STAR project data suggested a yield of 4%, while earlier work by Choko in Blantyre, which was one of the key areas of distribution during STAR Phase I, showed a yield of 12%, while yields in Zimbabwe have been even higher, as noted in Section 3.2.4.
- As is the case with targeting, **evidence regarding linkage for the CBD model has been mixed.** For example, for the STAR project in Zambia, linkage rates for CBD were reported to be only 8% of project participants, while in other countries linkage rates for CBD have been as high as 56%. For other models, while less studies and sources of evidence are available these appear to be more consistent.

E.3. Summary of evidence findings from STAR project countries

Table E.3 below summarises the research studies and key pieces of evidence from the STAR project that have informed the analyses carried out in Sections E.1 and E.2.

Table E.3: Summary of research findings in project countries

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
CBD	**Malawi** *1. Neuman et al. (2016)* Baseline data collected from 5,682 respondents in Malawi prior to self-testing suggested that 21% of respondents would prefer self-testing as the method of testing for their next test. *2. STAR Project data* Midline survey data from project suggests that 98% of females and 99% of males would recommend HIVST to a friend/family member. *3. Indravudh et al. (2017a)* DCE (n=245) of 16-24 year olds in Malawi suggested that accessing HIVST at home was favoured to mobile clinics and health facilities. *4. Indravudh et al. (2017b)* DCE with 771 participants suggested that respondents preferred home-based delivery of HIVST by lay providers as opposed to delivery through health facilities or mobile clinics. Local lay providers were also	**Malawi** *1. Maheswaran et al. (2016a, non-STAR)* 1,241 participants either underwent HIVST (n=775) or facility-based HTC (n=446). The mean societal cost for those tested through HIVST (US$9.23) was lower than through facility-based HTC (US$11.84). Although mean health provider cost per participant (US$8.78) per participant was comparable to facility-based HTC (range: US$7.53-US$10.57), the associated mean direct non-medical and indirect cost was lower (US$2.93). The mean health provider cost per HIV positive participant identified through HIVST was higher (US$97.50) than for health facilities (range US$25.18-US$76.14), as was the mean cost per HIV positive individual assessed for ART eligibility and the mean cost per HIV positive individual initiated onto ART. This led the authors to conclude that while HIVST reduces the economic burden on clients, it is a costlier strategy for the health provider aiming to identify HIV positive individuals and initiate them onto treatment. The provider cost of HIVST could be substantially reduced with	**Malawi** *1. Choko et al. (2015, non-STAR)* Of 14,004 participants who undertook HIVST in 12 months, 76% (10,614) reported their result to a volunteer counsellor, with 1,257 (12%), reporting a positive result. *2. Maheswaran et al. (2016b, non-STAR)* Of 775 people tested for HIV using self-testing, 104 (13%) were identified as positive. *3. STAR project data* STAR project data suggested that of 81,232 late-read kits c.4% (3,379) for the CBD model. **Zambia** *4. STAR project data* Project data of 68,943 late-read kits suggests	**Malawi** *1. STAR Project data* Project presentations suggest that based on the midline household survey, 27% of those tested positive in the CBD model had linked treatment following HIVST. *2. Choko et al. (2015, non-STAR)* Of 930 newly diagnosed HIV positive individuals, 524 (56.4%) were linked to care. *3. Maheswaran et al. (2016b, non-STAR)* Of 104 individuals identified as HIV positive through HIVST 36 (31%) met national ART eligibility criteria and 20 (19%) were initiated on treatment. Additional individuals were also linked to care and treatment through home-based provision, bringing each of the above figures to 59% and 30% respectively. *4. D'Elbee et al. (2017)* DCE for Malawi (n=555) found that optimal linkage programmes should prioritise waiting times and incurred

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
	preferred to intimate partners and health workers. **Zambia** *5. Neuman et al. (2017)* Baseline data collected from 5,878 respondents in Zambia prior to self-testing suggested that 33.3% of respondents would prefer self-testing as the method of testing for their next test. 6. *STAR project data* Midline survey data suggests that 99% of females and 100% of males would recommend HIVST to a friend/family member. *7. Zanolini et al. (2017, non-STAR)* Among 1,617 participants, 1,392 (86%) reported that HIVST would make them more likely to test. 35% reported some concerns, but only 2% had serious concerns. Main concerns were around suicide and lack of post-test counselling support. 91% of participants reported they would be comfortable using HIVST, 76% felt friends would be comfortable and 86% felt family would be comfortable. **Zimbabwe** *8. Mavedzenge et al. (2016)* Based on a study of 1,000 participants, 695 (c.70%) opted for a	reductions in the cost of self-test kits, as well as more targeted distribution models. *2. Maheswaran et al. (2016b, non-STAR)* Of 325 participants attending HIV clinics for assessment for ART, 265 were identified through PDHTS and 60 through HIVST (via CBD), and 168/265 and 36/60 met national ART eligibility criteria. The mean total health provider assessment cost for ART initiation was US$22.79 for PDHTS and US$19.92 for HIVST, and the difference was seen as statistically significant. The mean total health provider cost for the first year of ART was US$168.65 for PDHTS and US$164.66 for HIVST, making costs comparable. The total societal cost was US$181.91 for PDHTS and US$179.38 for HIVST, which were also not statistically significant from one another. *3. Maheswaran et al. (2017, non-STAR)* From this study, authors found that: Over a 20 year time horizon, introducing HIVST alongside introducing the 2015 WHO Guidelines costed US$253.90 per quality-adjusted life year (QALY) gained (2014 US$), which was slightly higher than introducing guidelines alone at US$226.85 per QALY gained. If a cost-effectiveness threshold of US$270/QALY were adopted, introducing HIVST alongside the WHO 2015 guidelines was considered optimal.	that 8% (5,292) of those tested via CBD in Zambia were tested as positive. **Zimbabwe** *5. STAR project data* STAR project data from late-read of 71,198 kits suggested that 16% (11,115) individuals tested positive. *6.. Mavedzenge et al. (2016)* Based on 590 self-testers, 47 (8%) were tested positive. *7. Sibanda et al. (2016)* Of 5,479 late-read kits, 1,153 (21%) were positive, representing a minimum yield of 1,152/8,095 (14%).	costs to potential users. Community-based approaches were seen as an alternative to overcome such issues. The need to address high stigma associated with HIV services remains. Traditional views of diseases and cures can also impact health-seeking behaviours. **Zambia** **5.** *STAR project data* Of 8,389 late-read test kits that were identified as positive, 697 (8%) had undergone a confirmatory test. *6. D'Elbee et al. (2017)* DCE for Zambia (n=388) found that optimal linkage programmes should prioritise waiting times and incurred costs to potential users. Community-based approaches were seen as an alternative to overcome such issues. The need to address high stigma associated with HIV services remains. Traditional views of diseases and cures can also impact health-seeking behaviours. **Zimbabwe** *7. Mavedzenge et al. (2016, non-STAR)* Based on 47 self-testers tested positive, 25 (53%) had linked to post-test HIV services 2 weeks after kits were initially distributed. This proportion is similar to linkage rates found in PDHTS for Zimbabwe.

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
	self-test. Those opting for a self-test were more likely to be male, <35 years, more educated and had one or more sexual partners in past three months. They were also less likely to have tested positive for HIV and used condoms when they last had sex. From two-week follow-up questionnaire of self-testers (590), 586 (99%) would recommend test to friends/family, and 540 (92%) were comfortable learning their test result without a provider present. *9. STAR project data* Project survey data collected six weeks after distribution in communities suggests 97% of females and 95% of males would recommend HIVST to a friend/family member. *10. Indravudh et al. (2017a)* Study of DCE (n=96) of 16-24 year olds in Zimbabwe suggested that accessing HIVST at home was favoured to mobile clinics and health facilities. *11. Sibanda et al. (2017)* FGDs (n=81) and DCEs (n=168) suggested that CBD via community volunteers was the preferred method of testing.	In conclusion, given that the 2015 WHO Guidelines opt for early HIV treatment compared to previous guidelines, introducing HIVST can complement the introduction of these guidelines given that it enables individuals to be found positive earlier than if we rely on facility-based testing alone. Note this study does not consider how this could impact transmission, and therefore may be a conservative estimate. **Zimbabwe** *4. WHO (2016) Annex 23 of Guidelines* Implementing CBD model for young people (16-24), men 25-49 and FSW would avert 4,400 DALYs, but would cost an additional US$41m, corresponding to an incremental cost-effectiveness ratio (ICER) of US$9,300 per DALY averted. This led authors to conclude that given the relatively low prevalence of undiagnosed HIV in Zimbabwe, any substantial increase in untargeted HIV testing is unlikely to be cost-effective. However, this is not specific to HIVST, as the authors show that any large increase in HIV testing is not likely to be cost-effective due to the high incremental cost in reaching every individual who is HIV positive. However, the authors assume a cost per kit distributed is US$4.84 (regardless of distribution mode), US$3.50 of which is due to the cost of kits (this also includes shipping, insurance, clearing and domestic		*8. Sibanda et al. (2016)* Of 5,479 late-read kits, 824 of participants accessed post-test services, while 4% (48) were initiated onto treatment.

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
		distribution). Therefore, if these costs were reduced substantially the cost-effectiveness of CBD would be substantially higher. *5. Mangenah et al. (2017)* The unit cost of distributing kits through CBD in Zimbabwe was US$6.86, which was slightly lower than the cost per mobile health facility (US$8.18) and for fixed site facilities (US$8.79). In terms of cost drivers, the 62% of the total unit cost was attributable to purchasing of kits, which equates to US$4.25 in the sample used in the project cost analysis. This is now significantly lower, meaning that the cost of HIVST is likely to be even more comparable.		
Facility-based distribution	**Malawi** *1. Indravudh et al. (2017a)* Study of DCE (n=245) of 16-24 year olds in Malawi suggested that accessing HIVST at home was favoured to mobile clinics and health facilities. **Zambia** *2. Chanda et al (2017)* Study found that differences between uptake between direct and facility-based distribution of self-test kits to FSWs was not significantly different. **Zimbabwe**	Implementation experience of STAR project suggests that facility-based distribution can be implemented, although experience with this model is relatively limited (especially for public sector models). No evidence of regarding cost or cost-effectiveness could be found from the review.	***Malawi*** *1. STAR Project data* Project data of late-read kits in Malawi suggests that from late reading of 968 test kits, c.7% of those tested through facility-based models were positive. ***Zambia*** *2. STAR Project data* Project data for Zambia suggests that from late reading of 11,724 test kits, c.8% of those tested	**Zimbabwe** *1. Hatzold et al (2017)* All 285 self-testers with reactive results were linked to care, and 95.5% were tested HIV positive following confirmatory testing and initiated on ART. *2. STAR project data* Distribution of 9,803 kits by end of February 2017 showed that 40% opted for self-testing when given the choice. 99% of reactive tests were confirmed positive and 100% of confirmed positive tests were on ART.

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
	3. Indravudh et al. (2017a) Study of DCE (n=96) of 16-24 year olds in Zimbabwe suggested that accessing HIVST at home was favoured to mobile clinics and health facilities. *4. Madanhire et al. (2016)* Four FGDs with HCWs (n=43) found that while they generally believed that HIVST can increase testing uptake among men, wealthier individuals and those living in remote areas, a recurrent theme was that HCWs felt that HIVST could threaten HCW jobs, with jobs of HCW who provided primary counselling being seen as the most threatened. HCWs had mixed views on whether self-testing would lead to optimised linkage to post-test services. A good HIVST programme was viewed as one which worked with existing health delivery structures and centred on continued HCWs involvement, including counselling before and after testing, and storage of kits by HCWs. *5. Hatzold et al. (2017)* Of 21,260 individuals looking to be self-tested, 31.2% (6,636) opted for a self-test over PDHTS. Study also found that positivity rates among those tested under PDHTS		through facility-based models were positive. **Zimbabwe** *3. STAR Project data* Project data for Zimbabwe suggests that from late reading of 24,375 test kits, 9% of those tested through facility-based models were positive. *4. Hatzold et al (2017)* 4.3% of self-testers (285) had a positive result, compared to 12.8% of PDHTS testers.	

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
	were higher than self-testing, suggesting that those who believe that they might be HIV positive are more likely to opt for PDHTS, therefore self-testing could be used as a method of triage negative individuals out of the health system. *6. STAR project data* Distribution of 9,803 kits by end of February 2017 showed that 40% opted for self-testing when given the choice.			
VMMC	**Zimbabwe** *1. STAR project data* At VMMC fixed sites, 54% (161/299) self-testers took up VMMC).	Implementation experience of STAR project suggests that VMMC distribution can be implemented, although experience with this model is relatively limited. No evidence of regarding cost or cost-effectiveness could be found from the review.	**Malawi** *1. STAR project data* Project data suggests positivity rate of 4% for VMMC in Malawi, based on late-reads. **Zambia** *2. STAR project data* Project data suggests positivity rate of 7% for VMMC in Zambia, based on late-reads. **Zambia** *2. STAR project data* Project data suggests positivity rate of 7% for VMMC in Zimbabwe, based on late-reads.	**Malawi** *1. STAR project data* Based on mid-line survey data, of those who had undertaken HIVST and received a negative result, 7-9% opted for VMMC, compared to 4% of those who had obtained a negative result from standard testing. **Zimbabwe** *2. STAR Project data* When comparing VMMC programmes without HIVST and with HIVST, the uptake of VMMC was 42% (of c.16,000 individuals reached) for individuals who did not use self-testing while the proportion of those that did was 57% (of c.500 individuals reached). In the PSI VMMC clinics, 82% of beneficiaries undertake VMMC after HIVST.
FSW	**Malawi**	**Malawi**	**Malawi**	**Zambia**

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
	1. Lora et al. (2017) Rapid ethnographic assessment (REA) of 34 FSWs and 101 venue owners suggested that HIVST could provide convenience and increase the opportunity for regular testing. **Zambia** *2. Chanda et al. (2017, non-STAR)* Three separate arms of FSWs monitored: i) Directly given HIVST kit (n=316); ii) Given a coupon to obtain HIVST kit from health facility (n=329); and iii) standard-of-care (SOC) HIV testing (n=320). Delivery via peer educators. In the HIVST arms, 92% and 90% of participants reported using HIVST kits after one and four months respectively. **Zimbabwe** *3. Mavedzenge et al. (2017)* When offered the choice between HIVST and conventional testing, 54% (325) FSWs opted for self-testing. Of 227 respondents, 100% stated they would test again. 98% of FSW self-testing felt comfortable learning their result without a provider present. FSWs felt that distribution should be done via FSW clinics (62%),	1. *Lora et al. (2017)* Venue owners suggested that lack of immediate support after HIV-positive diagnosis was identified as a potential social harm due to HIVST. A peer-led delivery model was perceived as an option for delivering HIVST to hard-to-reach FSWs, but mistrust and storage of HIVST kits were barriers to implementation. **Zimbabwe** *2. WHO (2016) Annex 23 of Guidelines* Distribution to FSWs via CBD in Zimbabwe was estimated to cost c.US$600k and would save c. 1,200 DALYs, resulting in an ICER of US$467 per DALY averted and US$202 if costs of kits and international distribution/shipping reduced from US$4.84 to US$1.50. This suggests that FSW distribution of HIVST could be highly cost-effective, primarily driven by the high prevalence of HIV in this population, which subsequently would result in increase in identification, treatment, viral suppression and lower transmission.	*1. STAR project data* Project data for Malawi suggests yield of 35% for FSW, based on late reads. **Zambia** *2. Chanda et al. (2017, non-STAR)* Three separate arms of FSWs monitored: i) Directly given HIVST kit (n=316); ii) Given a coupon to obtain HIVST kit from health facility (n=329); and iii) SOC HIV testing (n=320). Of 573 FSWs who tested in previous four months, 158 (28%) tested positive. **Zimbabwe** *3. STAR project data* Project data for Zimbabwe suggests yield of 30% for FSW, based on late reads.	*1. Chanda et. al. (2017, non-STAR)* Of 144 participants reporting a positive after one month, 51% (19) of individuals who were directly given a self-test kit and 53% (25) of those who were given a coupon to obtain a kit linked to care after one month, while in the SOC arm 77% (44) of those tested positive were linked to care. At month 4, of the 235 participants reporting a positive HIV test, 72%, 77% and 86% of the direct, coupon and SOC arm reported linking to care. Suggests self-testing is less effective at linking individuals to care (although differences were not statistically significant). Of those tested positive, after 1 month 23% (11) of the direct, 25% of the coupon (9) and 47% (27) of the SOC arm were on ARTs, with differences being significant between the direct and SOC arms. At month 4, these proportions increased to 48% (35), 57% (44) and 64% (54) for each of the models respectively, with differences not being statistically significant. **Zimbabwe** *2. Mavedzenge et al. (2017)* Of 325 FSWs who opted for self-testing 30% (98) had a positive result, and of those 99% had attended post-test

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
	pharmacies (18%), peers (14%) and/or workplace (13%). *4. Tumushime et. al. (2017)* FGDs with FSWs (n=54), peer educators (55), condom-promoting hairdressers (16) and female condom distributors (7) suggested that FSWs preferred HCWs from dedicated FSW clinics to distribute and provide information, with preference for on-site testing. FSWs and other stakeholders expressed interest and willingness to distribute HIVST kits.			services by the two-week post-test questionnaire.
Secondary distribution	**Malawi** *1. Choko et al. (2017)* FGDs with 42 men and women found that HIVST secondary distribution via ANC was supported by participants over facility-based HIV testing, given that it fits into men's lifestyles. **Zimbabwe** *2. Tumushime et. al. (2017)* FSWs supported secondary distribution to friends and clients.	**Malawi** *1. Choko et al. (2017)* Study estimated that partner-delivered HIVST in Malawi costs US$25.85 per person tested. **Zimbabwe** *2. WHO (2016) Annex 23 of Guidelines* Introduction of secondary distribution via ANC in Zimbabwe was expected to cost c.US$800k and would save c.1,700 DALYs resulting in an ICER of US$462 per DALY, reducing to US$364 if base costs are assumed to be US$1.50 rather than US$4.84. This was primarily driven by low levels of testing among sexually active men, relatively high assumed HIV prevalence in this population (4%) compared to the general population as	No studies/evidence available.	No studies/evidence available.

Model	Acceptability	Feasibility of scale-up	Targeting (yield)	Linkage to care and prevention
		they are more sexually active and comparatively lower additional cost associated with this model (US$0.16 additional cost per kit distributed).		

ANNEX F DISTRIBUTION MODELS NOT TESTED UNDER STAR PHASE I

Table F.1 summarises key models, some of which are being tested under Phase II while others are being tested through other projects being undertaken by PSI and others.

Table F.1: Key distribution models not tested in STAR Phase I

Model	Description
Models to be tested under the STAR Initiative	
Community-led distribution	HIVST kits are provided to communities, who determine the best way to distribute the tests and manage all distribution activities.
Pre-exposure Prophylaxis (PrEP) demand creation	Community HCWs distribute HIVST to high risk adolescent girls and young women (and men) interested in PrEP.
Secondary distribution via FSWs	FSWs distribute HIVST to male clients.
Key population distribution (men who have sex with men (MSM), injecting drug users (IDUs))	HIVST is distributed among key populations through peer educators, health clinics, support groups and other applicable distribution channels.
ANC secondary distribution	HIVST is distributed by pregnant and breastfeeding women attending ANC clinics to their husband.
Reproductive health/contraceptive services	HIVST is delivered alongside other reproductive health services.
Additional workplace programmes	HIVST is distributed through work programmes of occupations traditionally taken up by men and other key or high risk populations (lorry drivers, miners and fisherfolk). This model could also apply to HCWs and their partners.
Models not tested under STAR Initiative	
Pharmacy-based distribution	HIVST kits that have been approved for sale and distribution are sold via pharmacies. Currently method of distribution in many high income markets. PSI are currently implementing a study testing pharmacy-based distribution in Kenya (funded by the Children's Investment Fund Foundation (CIFF)).
Vending machines/kiosks	HIVST available for sale through specified vending machines/kiosks in
Internet-based distribution	Clients purchase HIVST kits online. Noted as a particularly useful distribution channel for key populations.

ANNEX G STAR RESEARCH OUTPUTS INCLUDED IN WHO GUIDELINES

A total of ten research outputs or presentations from the STAR project, and publications by STAR researchers, contributed to the development of the WHO Guidelines on HIV Self-Testing, which were published in December 2016. These research outputs addressed a number of key HIVST policy concerns, including accuracy, acceptability, user preferences, social harms, community-based distribution and feasibility.

Table G.1: STAR research outputs, STAR presentations and STAR author publications contributing to WHO Guidelines on HIV Self-Testing.

No	Title	Lead Author	Publication Status
1	HIV Self-Testing Technology Landscape, 2nd Edition.	Unitaid	Published
2	Systematic review on HIV self-testing (HIVST) performance and accuracy of results.	Figueroa, C.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.
3	"Not without us…" – views on the introduction of HIV self-testing among health care workers providing integrated HIV and sexual and reproductive health services.	Madanhire, C.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.
4	Understanding coercion in the context of semi-supervised HIV self-testing in urban Blantyre, Malawi.	Lora, W.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.
5	Community-based distribution of HIV self-test kits: results from a pilot of door-to-door distribution of HIV self-test kits in one rural Zimbabwean community.	Sibanda, E.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.
6	Getting HIVST right: results from the STAR project clinical performance study in Zambia	Neuman, M.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.
7	Designing safe, acceptable and appropriate HIVST interventions for female sex workers	Cowan, F.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.
8	HIV Self-Testing Africa (STAR) Project Launch	Hatzold, K.	Presented at 19th International Conference on AIDS and STIs in Africa, Zimbabwe 2015
9	Acceptability of woman-delivered HIV self-testing to the male partner: a qualitative study of antenatal clinic-linked participants in Blantyre, Malawi.	Choko, A.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.

No	Title	Lead Author	Publication Status
10	Acceptability, feasibility, and preference for HIV self-testing in Zimbabwe.	Mavedzenge, S.	Abstract, presented at 21st International AIDS Conference, 18-22 July, Durban, South Africa, 2016.