UNITAID STAR (SELF-TESTING AFRICA) INITIATIVE: PHASE 2 END OF PROJECT EVALUATION

EVALUATION REPORT

May 2021

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Executive Summary

In 2015, an estimated 30% of all people living with HIV (PLHIV) did not know their status and had no access to lifesaving HIV treatment, putting them at risk of premature death and onward HIV transmission (UNAIDS, 2016). To find the undiagnosed, the HIV Self-Testing AfRica (STAR) initiative was funded by Unitaid to address common barriers to testing, such as stigma, discrimination, and a lack of access to diagnostic services. STAR Phase 2 aimed to bring HIV self-testing (HIVST) to scale by optimizing distribution models, evaluating the public health benefits at the national level, and generating evidence for cost-effectiveness. To achieve these ambitious objectives, Unitaid invested US$48.7 million for Phase 2 implementation through a consortium led by Population Services International (PSI): the *HIV STAR project to catalyze the self-testing market in six countries in Southern Africa: Malawi, South Africa, Zambia, Zimbabwe, Lesotho and eSwatini* (Unitaid, 2018).

Methodology

This evaluation took place from December 2020-April 2021 and aimed to inform Unitaid's current and future investments by providing an assessment of the overall successes and challenges of STAR Phase 2. The objectives were to consolidate knowledge on best practices for catalyzing innovation and to provide Unitaid with an assessment of the overall success of the project. Using mixed methods, including secondary data analysis, modeling analysis, and primary qualitative data collection (key informant interviews and focus group discussions), the evaluation team explored the impact of STAR Phase 2 according to the Organization for Economic Co-operation and Development (OECD) Development Assistance Committee (DAC) framework criteria, including: Relevance, Coherence, Efficiency, Effectiveness, Impact, and Sustainability, as well as Unitaid's Key Performance Indicators 2-5 to provide analysis of findings, a summary of lessons learned, and recommendations.

Findings

The evaluation team found that STAR Phase 2 was overall a highly successful project that met its objective to catalyze the HIV self-testing (HIVST) market. Prior to the STAR Project in 2015, three years after the Food and Drug Administration (FDA) approved the first kit, sales within the United States were far below expected and only a few countries were actively implementing HIVST services as part of their HIV response (Ingold et at, 2019; Corbett, 2021). The STAR project achieved a catalytic effect by generating evidence to attract other scale-up partners, resulting in the total demand for HIVST in low- and middle-income countries (LMIC) is now projected to reach 29 million tests by 2025 (Unitaid & WHO, 2019).

STAR has also provided a strong foundation for introducing HIVST in low- and middle-income countries (LMICs). The collection and rapid knowledge translation of robust evidence from multiple countries that STAR pioneered allowed for rapid scale-up of HIVST. The information generated is now being used to inform policy and practice through national Technical Working Groups (TWG), scientific conferences and international workshops for donors, governments, regulators, and manufacturers. From 2015-2025 an estimated 15,551 lives will be saved, 97,762 HIV infections averted, and 46,500 Disability Adjusted Life Years (DALYs) averted because of STAR Phase 2 investments (Unitaid, 2021a). As of 2020, thanks to a variety of testing interventions including STAR, the percentage of people with HIV estimated to be unaware of their HIV infection has decreased from 30% in 2015 to 19% (UNAIDS, 2020).

STAR largely succeeded in creating an enabling environment for HIVST scale-up. Prior to the STAR initiative, only three high-income countries had implemented self-testing and WHO had no formal position and no mechanism to pre-qualify self-test products. As of July 2020, 88 countries had policies allowing for HIVST, of which 41 countries were implementing HIVST, and an additional 31 countries

had HIVST policy in development[1] (Unitaid & WHO, 2020). The WHO has now issued multiple normative guides including HIVST, largely based on data from the STAR project, as well as research from other partners and regions. The WHO prequalification program, a certification of quality, was supported by Unitaid and other partners to approve the first HIV self-test in July 2017 and has since approved three additional blood-based products. The cost-effectiveness and affordability of HIVST has dramatically improved largely due to optimization of the delivery model and price reduction. Manufacturers now offer Emerging Markets Small (EXW) prices in the US$2 range, with at least one product sold at US$1.50 (PSI, 2020) (compared to approximately US$40 in the United States and up to US$15 in the private sector in South Africa in 2015). STAR and partners initiated volume pricing and supported other manufactures to enter the market, resulting in three new blood-based products during Phase 2, and a fourth product in Phase 3. Kits were free at the point of care for all participants in STAR Phase two countries, improving access for the poorest and underserved (PSI, 2020).

Recommendations

#	Recommendation
HIV Self-Testing	
1	Advocate for the sustainability of high-impact community-based HIVST models and clearly communicate the equity imperative to scale up to funders and national governments**.** Expand partnerships with a wide range of potential scale-up partners, including the private sector, to expand reach and sustainability.
Funding & Grant Management	
2	Streamline funding approval processes and limit layers of approval to improve timely replies to grantees. Ensure grantees have adequate autonomy for adjusting plans with limited bureaucracy in keeping with a catalytic, innovative granting agency.
Monitoring & Evaluation	
3	Scale up novel approaches to monitoring impact (such as forecasting and community level monitoring) to ensure metrics don't stifle innovation and that they promote access to HIVST, rather than obstructing it. Develop evaluation frameworks that allow for increased experimentation and risk taking.
4	Leverage equity lessons from STAR and improve agency-wide health equity key performance indicators (KPIs) to better reflect strategic objectives, including clear expectations for grants to report on disaggregated results and differentiation of unique subgroup needs (age, gender, ethnicity, rurality, etc.)
5	Develop more transparent quantitative metrics related to supply chain and procurement (e.g., stock-outs, expired products, % of consignments delivered on time in full (OTIF)).
Catalytic Models	
6	Identify and share lessons from HIVST that could be applied to other self-testing technologies for other diseases: • digital health tools to support patient testing and navigation; • frameworks for identifying the right mix of self-testing and provider testing; • focus on regulatory barriers and rigorous research with direct links to WHO guideline process and national policy-makers; • Research consortium approach with frequent in-person meetings to build trust among a large network of stakeholders
7	Clearly scope and define Unitaid's role in the development ecosystem and review best practices and innovations in catalytic funding models.
8	When selecting countries in the future consider both disease burden but also qualities of regional leadership and expertise. Fund a mix of different countries in various regions with diverse needs that could catalyze a new technology. Develop guidance for choosing countries for new funders.
9	Continue to fund operational research but develop agency guidelines and training to minimize perceived conflict of interest.
10	Continue to partner closely with scale-up partners, in addition to improving partnerships with national governments, local innovation partners, and the private sector to ensure sustainability.

In summary, STAR Phase 2 was a highly effective and ambitious project that catalyzed the HIVST market while laying the groundwork for STAR Phase 3 and future self-testing technologies in other areas. Its improved access to HIV testing, resulting in improved access to HIV treatment and saving lives, particularly for those unreached by traditional testing.

[1] Out of a total of 194 WHO reporting countries.

Introduction

At the inception of Unitaid's HIV Self-Testing AfRica (STAR) initiative in 2015, an estimated 30% of all people living with HIV (PLHIV) did not know their status and had no access to HIV treatment, putting them at risk of premature death and onward HIV transmission (UNAIDS, 2016). To find the undiagnosed—most often men, adolescents, and other high-risk groups across Africa— the STAR initiative was funded by Unitaid to address common barriers to HIV testing, such as stigma, discrimination, and a lack of access to diagnostic services. It was envisioned that HIV self-test (HIVST) kits, using an oral swab or finger pinprick, could offer a means to inform millions of people of their HIV status. The project aimed to identify different delivery models to enable people to learn their HIV status in private while exploring if the technology could help link more people living with HIV to treatment. Project advocates argued that self-testing could also contribute to HIV prevention goals by linking those who test negative to voluntary medical male circumcision, preventive therapy (e.g., pre-exposure prophylaxis [PrEP]), and other preventive services and counseling.

STAR Phase 1 implemented the world's largest evaluation of HIVST and established that this mechanism can be used accurately by lay users, is widely accepted when offered at the community level and in health facilities and can reach high-risk populations that do not use conventional testing services. STAR Phase 2 aimed to bring HIV self-testing to scale, optimizing distribution models, evaluating the public health benefits at the national level, and generate evidence for a cost-effective way of using HIVST to help contribute to finding the undiagnosed 11 million PLHIV.

To achieve the objectives, Unitaid invested over US$48.7 million through the HIV Self-Testing Africa (STAR) Phase 2 project to catalyze the self-testing market in six Southern African countries and beyond. STAR Phase 2 implementation was led by Population Services International (PSI) (self-test kit distribution, including all marketing and demand creation activities in Malawi, Zambia, Zimbabwe, Lesotho, and Swaziland) and Society for Family Health South Africa (SFH) (in South Africa), in close collaboration with the World Health Organization (WHO) and consortium partners. Research activities were led by the London School of Hygiene and Tropical Medicine (LSHTM), Liverpool School of Tropical Medicine (LSTM), and University College London (UCL). In-country HIVST research activities were led by local research institutions: Malawi-Liverpool-Wellcome Trust Clinical Research Programme, Zambart, the Centre for Sexual Health and HIV/AIDS Research Zimbabwe, and the Wits Reproductive Health and HIV Institute (WRHI). Support to the South African National Department of Health (NDOH) and integration into the program was also provided by the Clinton Health Access Initiative (CHAI).

APMG Health, Inc. (APMG) was contracted to conduct a final independent evaluation of Phase 2 of the STAR Initiative. Phase 2 was implemented from August 2017 to July 2020 in six countries in Southern Africa: Malawi, South Africa, Zambia, Zimbabwe, Lesotho, and eSwatini, and aimed to build upon and amplify the findings of Phase 1, solidify the evidence base to inform broad scale-up of HIVST and shape the market, making HIVST more affordable in the public sector.

The evaluation aimed to inform Unitaid's current and future investments by providing an assessment of the overall successes and challenges of STAR Phase 2. The objectives of the evaluation were to:

1. To consolidate knowledge on best practices for catalyzing innovation; and
2. To provide Unitaid with an assessment of the overall success of the project, including relevance, coherence, efficiency, effectiveness, impact, sustainability, and lessons learned with focus on what the contribution of HIVST has been on closing the testing gap.

Ongoing Phase 3 is being implemented from January 2020 to June 2021 in seven countries: Cameroon, India, Indonesia, Mozambique, Nigeria, Tanzania, and Uganda as outlined in Figure 1. Phase 3 is focusing on discrete activities to increase access to HIVST in additional key priority countries; this

includes reducing regulatory barriers, addressing demand generation needs, supply chain barriers and bottlenecks, and enabling the environment for scaled delivery approaches.

Figure 1. STAR Initiative Countries Phase 1-3 (PSI, 2021)

Methodology

Between December 2020 and April 2021, the APMG evaluation team conducted a mixed-methods evaluation including desk review and secondary data analysis of a mathematical model, program reports, peer-reviewed publications, and grey literature in addition to primary qualitative data collection. From January 10 to March 20, 2021, the evaluation team conducted semi-structured interviews and focus group discussions in Malawi, South Africa, Zambia, Zimbabwe, Lesotho, and eSwatini and with global stakeholders based in India, Switzerland, the United States, and the United Kingdom to understand their perceptions of the STAR project and gather lessons learned. The evaluation team sampled and interviewed 75 national-level key stakeholders from Ministries of Health (MoH) and the national regulatory, laboratory, logistical, academic, donor, non-governmental and civil society sectors, and 38 stakeholders from global headquarters or academia. The evaluation team used a thematic approach to analysis with an inductively developed common coding framework to allow for inter-country comparison of emerging themes.

The Organization for Economic Co-operation and Development (OECD) Development Assistance Committee (DAC) evaluation framework was adapted as the guiding framework for the evaluation. The DAC evaluation criteria is a prominent and widely adopted development evaluation framework in use since 1991. The framework includes six criteria which serve as the core reference for evaluating international development and humanitarian projects, programs, and policies (OECD, 2019). A summary of criteria and overarching questions is provided below, in Table 1.

Table 1. OECD DAC Framework Criteria & Summary Questions (OECD, 2019)

Relevance	Is the intervention doing the right things?
Coherence	How well does the intervention fit?
Efficiency	How well are resources being used?
Effectiveness	Is the intervention achieving its objectives?
Impact	What difference does the intervention make?
Sustainability	Will the benefits last?

Notably, other frameworks and indicators also informed the evaluation questions under each OECD DAC criteria. Overcoming three out of the five access barriers as per Unitaid's dimensions of effective market, were part of the objectives of STAR Phase 2: affordability, demand & adoption, and supply & delivery (Unitaid, 2017). Additionally, STAR Phase 2 performance was measured against Unitaid's Key Performance Indicators (KPI) 2, 3.1, 3.2, 4.1, 4.2, 5.1, and 5.2. Refer to Annex 1 for an outline of the combined framework used by the evaluation team throughout this evaluation.

Sampling Strategy

The sampling strategy consisted primarily of a purposive sampling framework, including snowball sampling, intending to obtain data saturation among key informants involved in the STAR project or the broader HIV response or self-test manufacturing arena. Sampling was conducted to ensure the inclusion of key informants within several sectors including community, as described in Table 2. Recruitment was conducted via email with an introduction by PSI or Unitaid and recruitment for further interviews was stopped after data saturation was reached. Data saturation was defined as the point where further interviews with key informants did not generate significant new findings (Moser, 2018). Key informants were defined as individuals with direct experience of the STAR project or expertise in HIV/AIDS or self-testing with an emphasis on external stakeholders to balance the large amount of available internal project data. Informants included the lead grantees; consortium partners, STAR Implementing partners; manufacturers; donors; in-country partners such as key decision-makers at the country level, officials (high and mid-level) at relevant ministries, in-country donor representatives, civil society organizations and community groups, clinicians, and UN agencies. Focus group discussions included wider stakeholder groups that were indirectly involved with the respective grants such as the World Health Organization, Technical Working Groups (TWG), and relevant staff at the Unitaid Secretariat.

Data Collection

Qualitative and secondary quantitative data were collected by the evaluation team from January 10 to March 25, 2021. Quantitative data was collected from sources such as UNAIDS Global AIDS Monitoring (GAM) data, internal project reports, PSI and WHO project modelling, as well as external publicly available data sources including demographic and health surveys (DHS) and the Global Fund. For the document review, evaluators undertook a review of the grants using grant documents including the project plan, log frame, annual and semi-annual reports, evaluation reports, publications, presentations and abstracts from conferences, manuscripts currently under review, tools and guidelines developed by the project, and other grant-related material. The evaluation team also assessed the validity of the existing PSI Health Impact Modelling to make recommendations to strengthen the methods (see Appendix 7 for more details).

Overall, a total number of 113 stakeholders (global and country-level) were interviewed via key informant interviews and focus group discussions held virtually. Stakeholders were purposely sampled from an initial list provided by Unitaid and PSI to identify organizations involved in the implementation of STAR Phase 2 and external stakeholders working more broadly in HIV or self-test manufacturing. Additional stakeholders were selected via snowball sampling to obtain a wide range of experiences and opinions about STAR Phase 2. A summary of qualitative data collection by participant constituency can be found in Table 2. For more details on key informant interviews and focus group discussions conducted as part of this evaluation, please refer to Annex 2. Names have been removed to protect confidentiality.

Table 2. Summary of Qualitative Data Collection

	Total Number of Respondents (key informant interview & focus group discussions)							
Participant constituency	**Global**	**Malawi**	**South Africa**	**Zambia**	**Zimbabwe**	**Lesotho**	**Eswatini**	**Total**
MoH/Policy Makers	-	1	5	1	1	5	9	**22**
NGOs	5	1	3	1	1	-	1	**12**
WHO	2	-	-	1	-	-	-	**3**
Research Institutions	3	1	1	2	2	-	-	**9**
Manufacturer/Pharma	4	-	-	-	-	-	-	**4**
Community	-	6	1	10	-	-	8	**25**
Donors	24	-		-	-	-	1	**25**
Other consortium partner	-	-	3	-	-	4	6	13
Total	**38**	**9**	**13**	**15**	**4**	**9**	**25**	**113**

The evaluation team developed key informant interview and focus group topic guides, which were informed by a desk review and the literature on catalyzing innovation, impact, and the creation of an enabling environment for scale-up. The topic guides focused on questions considered to be important by Unitaid as identified in the request for proposal (RFP) and outlined in the OECD DAC evaluation framework and Unitaid KPIs. Additional questions were added iteratively after interim analysis of emerging themes and invitation from the Unitaid senior leadership to provide input into their upcoming strategic planning process. Participants gave verbal consent to be interviewed. Interviews were conducted in English between January and April 2021, by Prof. Meaghan Thumath, Dr. Tracey Konstant, Nkandu Chikonde, and Haley Falkenberry. Focus groups related to the mathematical model and modelling activities were conducted by Dr. Steve Kanters and Dr. Eve Limbrick-Oldfield from RainCity Analytics. Interviews were digitally recorded, and emerging themes were discussed within the evaluation team to triangulate finding in regular team meetings. For key informant interviews and focus group discussion guides, please see Annexes 3-5.

A thematic approach for data analysis was used which generated themes inductively based on what emerged from the data. To ensure trustworthiness, initial analysis was discussed and refined by all the interviewers. Findings were then presented to a wider audience of Unitaid staff, PSI staff and funders to check for inaccuracies that could be validated and to further refine the themes. The evaluation team also aimed to triangulate findings via both STAR and non-STAR affiliated peer-reviewed literature, program reports, and other grey literature sources.

Additionally, the evaluation team worked with a biostatistician and mathematical modeler (RainCity Analytics) to do an in-depth analysis of the prospective mathematical impact models that PSI created in 2017 and 2019 to demonstrate the public health and economic impact of HIVST in the STAR countries. This included a review of the modelling assumptions, an analysis of the raw modelling data and write up, and a focus group with the model development team at PSI. Further details on the modelling methods are available in Annex 6.

Ethics approval

Research ethics board review was not required, as this study informed quality improvement and routine program evaluation activities (CDC, 1999; World Medical Association, 2013). Potential harms

were identified and reviewed, and ethical guidelines were developed for the interviewers in accordance with the Ethical Principles for Medical Research involving Human Subjects, Declaration of Helsinki, World Medical Association (2013). Key informants and focus group participants provided verbal consent to be interviewed and included in the study. Confidentiality was ensured by avoiding the use of names and roles in the final report and avoiding the collection of informant identifiers, other than their general sector. The operational evaluation guide and all tools were reviewed by Unitaid staff prior to commencing the evaluation. Further information on the ethics approvals for the original STAR research is available in the relevant papers in the reference and at https://hivstar.lshtm.ac.uk/.

Evaluation Limitations

Due to the COVID-19 pandemic, all key informant interviews and focus group discussions were held via virtual platforms, limiting opportunities for site observations, beneficiary focus groups, and in-person rapport building. Similarly, some stakeholders were unable to be reached, possibly because of their involvement in the COVID-19 response. Additionally, implementation of the project had ended several months prior to data collection, further limiting our ability to independently monitor project implementation. These limitations were overcome by attempting to triangulate reports with multiple sources, including program data, peer-reviewed papers, and reports from other organizations external to STAR.

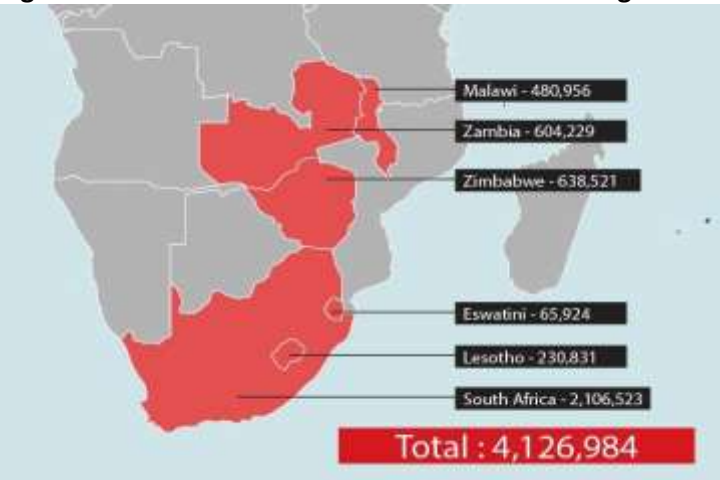
The qualitative data collected during this evaluation may not be generalizable, but where possible, the evaluation team has attempted to triangulate findings and point out alignment between quantitative and qualitative data. The qualitative interviews and focus groups allowed the evaluation team to explore successes and challenges in further depth at multiple levels of implementation of STAR Phase 2 in a way that quantitative data cannot. The evaluation team attempted to capture a wide range of stakeholders from different countries and sectors. This was variable between countries, with some being far more responsive than others. Time and resource constraints placed limits on the number of respondents and the total calendar time for follow-up, although the sample was sufficient to establish consistency and triangulation. The sample was not, however, sufficient to provide an analysis per constituency group. Some areas related to usability, feasibility, and acceptability were not explored in depth during the interviews as they related more to Phase One and we aimed to focus more on the lessons for future Unitaid grants. Finally, given the large breadth of peer-reviewed literature on the STAR project, we did not have the mandate or scope to conduct a systematic review of the literature; particularly since this is currently being conducted by the research partners and would have been a duplication of effort.

Finally, because of the phased approach of the STAR Initiative, at times it was also difficult to distinguish between phases, particularly between Phases 2 and 3, as Phase 3 is ongoing. The evaluation team worked to highlight aspects of Phase 2 throughout the findings but acknowledges this evaluation can also be seen more holistically across Phase 1-3. However, this is in keeping with Unitaid's catalytic model where they view gains made up to five years post project as relevant to the grant (Unitaid, 2021b).

Evaluation Findings

According to project data accessed in the annual project reports 2017-2020, Phase 2 of the STAR project distributed 432,266 HIVST kits in 2017 in the six project countries; 1.9 million HIVST kits in 2018; 1.4 million HIVST kits in 2019; and 286,301 HIVST kits in 2020 (PSI, 2017; PSI, 2018; PSI, 2019; PSI, 2020). The total numbers of HIVST kits distributed by country are displayed below in Figure 2.

Figure 2. Total Numbers of HIVST Distributed during Phase 2 (PSI, 2020)



The STAR Initiative, implemented in six countries in Southern Africa since 2015, has provided proof-of-principle for the effectiveness of a multi-faceted approach to HIVST scale-up in low-and-middle-income countries (LMIC) that systematically identifies – and then resolves – country-specific barriers to implementation at legislative, policy, strategic, financial, and operational levels. Innovatively, STAR also set out to establish a robust multi-country evidence base to facilitate informed decision-making by governments, funders, and implementers in non-STAR countries on which of the many distribution models for HIVST match country conditions and epidemic profiles. This legacy of STAR is seen as a valuable resource to help new countries define their HIVST Roadmaps, address barriers to scale-up, and put them in the best position to leverage HIVST funding from scale-up partners.

Relevance

This evaluation determined that STAR Phase 2 **fully achieved** relevance, and the intervention was ultimately successful in doing the right thing. STAR Phase 2 achieved its goal to reach populations that were not otherwise being reached, including key populations (namely female sex workers (FSW) and men who have sex with men (MSM)), adolescent girls and young women (AGYW), men and young people. The project dove into issues of implementation such as HIVST test kit usability, different models of distribution (community-based and facility-based, full outline of 13 models provided in Annex 7) and provided a basis for scale up to other partners by contributing to the development of guidance documents and tools. Throughout implementation, STAR Phase 2 had the ability to course-correct and respond to safety concerns about HIVST among vulnerable populations. Table 3 below presents quotes from key informant interviews and focus group discussions from national and global level stakeholders.

Table 3. Key Informant Quotes Related to Relevance for STAR Phase 2 Evaluation (2021)

Country	Theme	Quote	Source
Malawi	Reaching key population	*"Self-testing has challenged the traditional way of doing things...self-testing is helping us reach people who were not coming to facilities to test."*	KII19
eSwatini	Reaching adolescents, men and key population	"*STAR helped us target adolescents and men. It is not easy to reach those people, as well as key populations who had issues going to facilities...We reached those populations and extended HIVST to businesses and workplaces for people who could not go to facilities"*	eS KII3
Zimbabwe	Course corrected	*"STAR contributed to adopting HIV self-testing, influenced the components of medical devices, the push that came with self-testing was not existing in our framework. This made us amend our pharmacy and medicine framework."*	KII16
South Africa	Reaching key populations	*"The online technology for key populations was innovative and very impressive. They typically might feel ostracized. They want confidentiality and to get kits in their own time and place and have privacy...but it needs more investment. We did not have enough time to let it grow so that government can work with it."*	SA KII6

This evaluation found that the STAR project was a crucial intervention to decrease the testing gap, particularly in helping to reach those not reachable by conventional testing. Stakeholders felt it was useful that STAR implementation was backed by a good supply of HIVST kits; support on policy and systems; and innovative distribution models. Many argued it was an important additive technology that did not replace but instead enhanced traditional testing, helping to make the case for increased empowerment and self-management approaches to HIV and other chronic health conditions. The intervention also became increasingly relevant during the COVID-19 pandemic when many health care services were closed.

Target Populations: Key Populations, AGYW, Men & Young People

STAR Phase 2 aimed to support national governments in establishing an enabling environment for HIVST scale-up that would strengthen supply and delivery by ensuring the adoption of cost-effective distribution models that reach vulnerable, underserved, and key populations effectively. The STAR Phase 1 pilot distribution of HIVST kits showed that 60-90% of those offered HIVST at the community level accepted, and HIVST was able to reach populations not typically accessing HIV testing services (HTS) such as men (44-52% self-testers, adolescents (28-44% of self-testers) and first-time testers (21-35% self-testers) (STAR, 2016). STAR Phase 2 built off the Phase 1 pilot to target additional key populations, men, young people, and other vulnerable groups.

Both country and global-level stakeholders overwhelmingly agreed that Phase 2 focused on an equity-oriented framework and improved access to HIVST for key populations, AGYW and men. Further, the groundwork and research done by STAR demonstrated acceptability in a wide array of groups and promoted conversations about how we think about healthcare for men and AGYW particularly. HIVST implemented through STAR Phase 2 reduced inequities in access for AGYW but respondents remained skeptical about cost-effectiveness and suitability compared to community-based peer testing. Interviewers also suggested that the STAR initiative has been successful in reducing stigma and discrimination.

Generally, respondents from the community cohort indicated that their need for access and acceptability to testing in a secure manner was assured through STAR. Evaluators found that there

were some concerns regarding the referral modalities requiring participants to end up at a health facility which they were avoiding altogether; however, the HIVST referral (specifically) provided a linkage to other health care services in a more facilitated and friendly manner. In addition, HIVST in key populations was integrated with other prevention services such as PrEP, PEP, and condom distribution and thereby encouraged demand within the population.

> *"The self-testing worked well because our distributor was someone we trust, and this helped to make our access secure"- FGD11*

Furthermore, STAR Phase 2 helped to destigmatize access to HIV testing among same-sex partners and FSW. Health care systems for most of the countries are not always suited to the needs of privacy and confidentiality for key populations -- STAR enabled improved access to highly marginalized key populations. By working with influential members of key population networks, the project dealt with the barrier to HIV testing in general and self-testing in particular. Although HIV testing was generally a challenge among key populations, self-testing provided a platform for dialogue between the distributors and testers.

To the extent that STAR was able to distribute in workplaces, especially remote and under-serviced workplaces (SA KII5); transport hubs; sporting events; pharmacies, and other non-medical sites which are open beyond health facility hours, there was potential to meet the needs of men and adolescents (eS FGD3). Targeting of people known to need testing was achieved through a selection of strategic approaches, such as index testing (LO FGD1); high risk, underserved workplaces (SA KII5); sex workers in dedicated clinics (SA KII 4); LGBT through peer-based NGOs (LO FGD1); male and youth dominated public events (eS FGD2); and higher education institutions (SA KII1), as a few examples. The distinction between reaching the public, and targeting certain populations was seen as important. Less targeted approaches, such as taxi ranks and supermarkets are still in debate, compared with tightly controlled facility-based testing and secondary testing. In eSwatini, where mass distribution resulted in stock-outs, respondents stated that:

> *"They can't just do distribution of HIVST. They have to do distribution to the target populations. Anyone who asks for a kit can get one regardless of if they are in a target population or not. So, then the facilities end up running out of HIVST kits." – eS FGD1*

The results show that reaching isolated, previously excluded, and vulnerable populations through HIVST cannot be achieved through '*spray and pray distribution'*. In a notable innovation, the workplace partner in South Africa used snowball approaches to find increasingly excluded, remote and underserved workplaces in the mining and construction sectors. They asked managers of remote businesses for contacts in more remote areas and entered rural zones and small businesses which do not generally receive health services of any kind.

> "*We know that we did not over-service people who were already tested because we went and dug and looked. We went to the last mile to find people … We take out a map and ask 'where else are there workplaces' to get into the deepest rural or forest areas. And then we interrogated them to try to see every worker in a company. At one of the sites, we tested 12 people and 10 were positive. Most construction and forestry workers are migrant, low literate, and have no medical aid."* -- SA KII5

While the debate on linkage and targeting has resulted in less innovation by mainstream government and global partners, with insistence on screening interviews, facility-based distribution, and follow-up; the opportunities for effectively reaching underserved populations lie in far more innovation in

search of underserved spaces and sub-populations. Targeted distribution is one of the many nuanced and complex areas which warrant more interrogation and innovation, particularly with regard to cost.

According to respondents in Zambia, the project objectives, design, and implementation addressed key barriers to HIVST and reached the most disadvantaged populations by increasing demand, availability, supply, and delivery. The STAR initiative in Zimbabwe was able to reach rural communities which would have otherwise not been adequately reached through conventional testing. In dealing with the barriers of demand, supply and delivery, STAR also enabled sustained HIVST kits distribution in Zambia. They successfully trained selected employees as workplace champions to provide interpersonal communication messages to fellow employees which increased demand and adoption.

In a study external to STAR, Amsutz, et al. (2020) established a significantly higher uptake of testing among adolescents and young adults, and especially young men, in a randomized control trial in Lesotho. Offered a self-test, compared with a control group encouraged to visit a facility for HTS, 75% of young people used the Orasure self-test received at their homes, compared with 39% following advice to access rapid testing at the nearest local facility. Interview respondents also described how facility based HIVST was used by adolescents who came in groups, bringing their friends (SA KII7).

HIVST was described as the 'the holy grail' for persuading men to test (SA KII2), and interview respondents described how facility based HIVST was being used by more men than HIV testing and counseling (HTC), thanks to accessible private testing booths, without a need for queuing (SA KII7). This was supported in literature external to STAR, in a study showing high uptake and yield for men in South Africa, and 68% linkage to care (Shapiro et al, 2020). While some gains were observed with HIVST at facilities, reaching men at scale has not been achieved by facility based HTS, or by publicly accessible non-clinical test sites (eS FGD1; SA KII5). To effectively reach this group, innovative spaces and allies are needed, such as MSM NGOs, workplaces and discordant couples. The access barriers of privacy, time spent, opening hours, and autonomy need to be acknowledged and supported, despite the strong preference by mainstream services for the restricted hours and waiting times of in-facility testing.

> *"It was a wonderful thing that came to help people know their status. More men… want to take up prevention services and continue testing. [Community distribution] has reached a population that normally would not come forward and test." -- eS FGD3*

In all countries, the STAR initiative used the antenatal care model to reach men through their partners, a group that would otherwise not interact with the health system. In Zambia, the STAR initiative was successful in enabling workplace interest in self-testing. For example, the initiative catalyzed interest among mine employees and employers, an industry dominated by men. It was also reported that the project responded to stigma, which was a critical concern especially among men working in highly populated environments. The project also leveraged informal businesses such as retail shops in Zambia as a way of reaching more men. The initiative enabled governments to course correct and adapt self-testing as an approach in filling the testing gaps.

During qualitative interviews in South Africa, sex worker organizations reported feeling reluctant to accept HIVST except where it has been directly offered by the WRHI sex worker program. Key informants stated that sex workers in South Africa were concerned about mental health and risk of suicide, and equally concerned about not having been consulted or engaged during design, although this has not been substantiated in the peer reviewed literature on STAR which found no increase in suicide rates. As a key population, sex workers experience themselves as being the target of multiple interventions, and find that *'people come with this, and people come with that, just because we are*

sex workers' (SA KII3). Service fatigue, in the absence of more holistic engagement, has become an access barrier in this sector.

HIVST, unintentionally, also reached the needs of PLHIV who wish to re-test their known positive status. (eS FGD1,3; LO FGD1). Despite attempts to exclude people with previously diagnosed HIV infection, 6% of those who enrolled in a study external to STAR by Moore et al. (2019) were later discovered to have known their HIV positive status. Although WHO does not recommend re-testing or re-screening, nearly half of those previously diagnosed PLHIV reported a false negative HIVST result, although there was no evidence of disengagement from care. Far higher ratios of 'known positives' were reported by other informants (SA KII2), and self-testing (as well as traditional HIV lab testing services) for re-testing is widely noted.

This concern is highly relevant to HIVST initiatives, as well as more general HTS. While all national and WHO policy states that HIVST should not be used by people with known positive status, the experience has shown that many PLHIV mistrust the health system and are determined to occasionally confirm their status. Attempting to deny them access can lead to further mistrust, and use of HIVST without disclosure, preventing their access to harm reduction communication. Although re-testing should be discouraged and the risks clearly communicated, a leading health expert observed that unavoidable re-testing could be used as an entry point to self-care and adherence support, and an opportunity for appropriate health promotion (SA KII2).

Assisted testing in facilities

The findings from this evaluation suggest that demonstrating, and sometimes assisting, HIVST is necessary for some populations, even if digitally. Assistance, along with ease of follow-up and rapid linkage lends to the health sector's preference for facility-based testing (SA KII4). These findings are supported by a *Médecins Sans Frontières* (MSF) study external to STAR, which found that given the option of assistance or not, 70% of men opted for unassisted HIVST, compared with 29% of women in a facility based HIVST study in eSwatini (Pasipamire, 2020).

> *"Sometimes facility-based testing is assisted, but if the client wants to do it alone, they are given a space. If the client has lower literacy, then a health care worker can assist the person in doing the HIVST." - SA KII8*

Assisted testing in homes and communities

Studies outside of STAR data suggest that solutions beyond facility-based, clinician-assisted services are critical to achieving access to testing (Pasipamire, 2020). High levels of uptake were achieved in Lesotho through door-to-door household visits by counsellors who trained a household member and left HIVST kits for absent family members, especially adolescents (Amstutz et al., 2020). During qualitative collection, global respondents mentioned new innovations in guided WhatsApp groups or videos developed during COVID-19 to improve usability as a promising new intervention, although access to data and devices by underserved people was raised as a major obstacle to online media.

The peer-led strategy adopted in Zambia involved a network of peers trained on HIVST distribution at KP network meeting places or other places identified by peers which conventional testing was not able to reach. The project also ensured that testers obtained HIVST kits as well as information brochures, envelopes for putting used test kits, and self-referral cards from the distributors. eSwatini STAR also successfully deployed teams of community health workers, nurses, and expert clients into distribution and case finding, although they found that even this could not achieve universal coverage or access by the most marginalized (eS FGD3).

Respondents recommended building cadres of peers, community practitioners, and HIVST supporters who are trained, remunerated, and supplied with kits (eS FGD2,3). Some recommendations for greater innovation included:

a) Discreet packaging using '*neutral spaces where you are not judged*' in remote rural areas without pharmacies (eS FGD3);
b) Sex workers and members of other '*hard-to-reach populations in hard-to-reach areas'* form a trained cadre, embedding task-shifting into systems, and offering incentives for HIVST demonstration, follow up and confirmation (SA KII2);
c) Partnership with traditional healers was recommended by several respondents in eSwatini, since these practitioners are preferred by many of those who do not use the health system (eS FGD3; eS KII2);
d) Further innovation and reach could be achieved by partnership in the private sector with more purposeful access to remote workplaces (eS KII5);
e) Progress has been made by STAR in distribution and promotion of HIVST across churches, including training of church members for assistance (eS KII3); and
f) Continue to expand digital health and AI-assisted tools to improve usability and affordability.

Project Response to Scale-Up Partners

The following key tools and guidelines were developed during the project by technical partners:

- HIV Self-Testing Quick Reference Guide (PEPFAR, USAID, EpiC, March 2020)
- Considerations for HIVST in the Context of the COVID-19 Pandemic and its Response: An Operational Update (Unitaid, HIVST Africa Initiative, Atlas Project, 2020)
- Guidelines on HIV Self-Testing and Partner Notification (WHO, December 2016)
- HIVST Strategic Framework: A Guide for Planning, Introducing and Scaling Up (WHO, 2018)
- Reaching the First 90: HIVST for Key Populations (USAID, PEPFAR, Linkages, FHI360, no date)
- HIVST: Key Questions, Answers and Messages for Community Organizations (WHO, 2019)
- HIV Testing Services: HIV Self-Testing at the Workplace (WHO & ILO, 2018)

Evaluators found that STAR Phase 2 provided the evidence needed to justify the guidelines and inform their development, which ultimately had a huge influence on the global uptake of HIVST. PEPFAR and the Global Fund have accepted primary responsibility for commodities and continuation in eSwatini and Lesotho (LO KII1, eS KII3, eS FGD1), and supplementary commodity support in South Africa (SA KII1). In South Africa, they have accepted responsibility for distribution to KPs, men, and youth where the MoH will lead on primary and secondary distribution from high burden facilities (SA KII1). While distribution, commodities, and facility-based testing are likely to continue, these partners do not offer the MoH capacity building and systems support that STAR has provided:

> "*Unitaid was not like PEPFAR, mainly because they built MoH capacity and in-country policies. That does not happen with other funders unless you are getting funding specifically for HSS."* - LO FGD2.

MSF has taken an active interest in key population HIVST in eSwatini, including distribution through traditional healers (eS KII2), and EGPAF and JHPIEGO are serving different regions in Lesotho for HIVST roll-out (LO KII1).

Adaptation & Course Correction

The most profound context change in STAR Phase 2 was clearly the 2020 COVID-19 epidemic. COVID-19 forced programs to become even more innovative than planned. Phase 2 countries developed alternative and innovative distribution models for HIVST during lockdown or quarantine, such as direct distribution at pharmacies, retail outlines, facilities, and online distribution (PSI 2020a, SA KII1, eS

FGD2). Self-testing was viewed as a solution for maintaining facility-based testing services with minimal physical contact with health care workers in all countries. In South Africa, COVID-19 contact tracing was leveraged to provide information on HIVST, connecting clients to online distribution, with a focus on HIV as a possible comorbidity for COVID-19 (SA KII1,4,6). COVID-19 demonstrated a broader movement and opportunity to move toward self-managed HIV care. Overall, STAR shifted thinking about HIV testing in general - there was a clear link between HIVST and self-care and the movement towards democratization of health and letting people do things on their own and be more in control of their health. The process of taking autonomous control through self-testing was motivating, and people were often more willing to engage with facilities having tested positive with HIVST and more committed to prevention if testing negative (eS FGD3).

While rapid adaptation in distribution was the theme for 2020, just four months before STAR close-out in July 2020, the COVID-19 pandemic profoundly impacted delivery of systems and capacity building in government. All countries requested no-cost extensions to attempt to work with the government to finalize systems and mechanisms, but eSwatini and Lesotho were denied. This has impacted transition and sustainability, discussed in greater detail in the sustainability section of this report.

Safety concerns

All countries grappled with concerns about potential suicide, mental health, and lack of counselling (LO FGD1). STAR Phase 1 and Phase 2 were able to prove that people are willing and able to test themselves without increased risk of harm. In adopting HIVST, the risks of psychological distress and potential suicide are no greater with HIVST than they are with HTS (SA KII1). This was confirmed by a study external to STAR by Pasipamire (2020), where almost 2,000 people received tests for themselves or their partners, with no adverse events. The STAR project, similarly, received no reports of adverse events through its community or facility distribution models. While this does not preclude mental health problems, the results suggest that these are not exacerbated by HIVST (eS KII3). The importance of accessible and clearly communicated steps to take depending on self-testing results was highlighted in all countries, and accessible, effective mental health services are critical, regardless of testing modalities. This is also reflected in the WHO HTS Guidelines (2019).

Coherence

This evaluation determined that STAR Phase 2 **largely achieved** coherency and overall, it fits well with other HIV prevention and treatment interventions. There were some issues in specific project countries at inception with involvement of national government institutions. Significant progress was made in the debate about HIVST and linkage to HIV care.

Table 4. Key Informant Quotes Related to Coherence for STAR Phase 2 Evaluation (2021)

Country	Theme	Quote	Source
Malawi	Linkages	*"One of the things we are trying to do with ST is increasing choice of testing, by increasing choice you are increasing the uptake...its shifted into trying to identify people who have not tested but are positive and can benefit from the treatment or might be negative but benefit from prevention"*	KII18
South Africa	Coordinating mechanisms	*They should have engaged with SANAC at an early stage – that is where the stakeholders are...Everyone sits at the main SANAC table – CSOs, donors, government. We engaged with Unitaid leadership to strengthen that relationship and see the work they are doing and who they are working with.*	SA FGD1

Implementation of STAR Phase 2 had a high level of coherence with other HIV testing initiatives. The respondents revealed that self-testing worked well with other interventions such as ART clinics, ANC, and where possible, PrEP and voluntary male circumcision. The linkage to these interventions was leveraged as an entry point to introduce HIV testing for couples and males with partners that did not know their HIV status. The project made use of these already existing health systems to create demand for self-testing, encourage scale-up and linkages. The project did not create parallel systems but worked to enhance collaboration among health care workers, community health workers, workplaces, and health facilities. Furthermore, there was an indication that the project supported national targets towards improved universal health coverage that encompassed HIV testing which is perceived to be in high alignment with all components of the HIV response in respective countries.

> *"One of the things we are trying to do with HIVST is increasing choice of testing, by increasing choice you are increasing the uptake. The aim was to improve universal coverage of testing but now its shifted into trying to identify people who have not tested but are positive and can benefit from the treatment or might be negative but benefit from prevention"*- KII19

Stakeholders in all six countries reported that the STAR project added value to the HIV testing response by helping to strengthen national HIVST scale-up efforts alongside conventional testing. The high-level engagement with MoH's ensured that self-testing was harmoniously integrated within the existing health system. By working through a consortium, the project enhanced opportunities for collaboration across government, communities, researchers, and civil society organizations. This cooperation catalyzed common efforts towards scaling up self-testing and alignment with the public health system as opposed to the creation of parallel structures.

In Zambia, through working with the HIV Technical Working Group (TWG), STAR Phase 2 enabled the integration of self-testing in the HIV sector (through the national HIV testing implementation toolkit). The national testing implementation toolkit, used widely within the HIV and AIDS response, included HIVST and enhanced coherence and linkages with other national prevention efforts. As a result of this project outcome, HIVST is seen as a critical element of multi-level interventions which respective local partners have continued to scale up in their respective activities.

In Zimbabwe, the STAR initiative was used as a model example by the Ministry of Health and Child Care (MoHCC) to share with others partners such as PEPFAR in their country prevention strategies. Furthermore, the country encouraged training of health cadres in self-testing to bolster gains and linkages in HIV in the country at the sub-national level.

STAR in eSwatini began in a context where HIVST was not permitted or accepted by the MoH and progressed to the MoH taking a strong lead and central ownership of the system. While integration with MoH took some time, during which there was concern about external leadership of a core health function, once fully embedded in MoH systems coordination, partner collaboration and engagement improved.

Proving Linkage

Evaluators found that there are different perspectives on the challenge of follow-up on HIVST to show linkage to prevention services or confirmatory testing and treatment services. HIVST is promoted as anonymous, so if programs implement assisted testing, there is a perceived risk of missing the purpose of an HIVST. Consumers want their HIVST to be less controlled, in that they don't want to share their status and they want the autonomy to seek care themselves.

"There are certain pieces of the HIV response that we are never going to solve unless we give people more space and privacy" - FGD5

Community distribution in public spaces was highly successful (SA KII4), but questions were raised around the opportunities for linkage to follow-up services, in relatively untargeted mass-distribution approaches, such as taxi ranks and shopping malls (SA KII1). While follow-up and linkage were mentioned by many respondents as a clear challenge, rigid control, screening, and identification as being of a target population was not seen as a solution. Denying access to HIVST in absence of linkage data carries implications for confidentiality, trust and scale-up, with loss of privacy likely to repel people who are reluctant to test (SA KII4).

Differing schools of thought were clearly expressed among interviewees (both global and country-level). For some respondents, follow-up, support to people who test positive, and data were seen as critical to a successful HIVST system, and in need of further effort and innovation (eS FGD1). For others, testing for under-tested populations was seen as a valid and reasonable expectation, with the conditionality of follow-up and linkage leading to the continued exclusion of these reluctant populations (SA KII4). Monitoring whether people used the test and used it correctly, while valuable for research purposes, cannot be a permanent and consistent aspect of HIVST. Marketing HIVST for its autonomy and privacy, and then demanding to know the details of the tester and their results, is clearly contradictory. Some felt in the long term the task of promoting HIVST could be undermined if this complexity is not engaged with, even in the face of conservatism and skepticism among the scale-up stakeholders (SA KII2).

Evaluators considered this debate and determined that there is a compromise needed between complete anonymity and controlled linkage to care. Not all HIV-positive self-tests can be linked, and acceptable levels of risk and opportunity need to be discussed and agreed upon. The South African NDOH outlined a well-nuanced rationale for finding this balance. Mass distribution of HIVST in transient public spaces with no linkage options, such as commuter hubs or public malls, was deemed by some as inefficient and wasteful since it gave neither the user nor the distributor a point of contact for follow-up. Instead, community distribution through peer organizations, online contact, pharmacies, workplaces, facility reception areas, and COVID-19 tracing contacts offer a range of highly accessible distribution points, with enough contact detail for mutual follow-up options. This principle had been taken as good practice by the country's MoH (SA KII1). Facility, peer, or community distribution (with the advantages of assistance if needed) provides information points for linkage and follow-up, whether directly with the user, or through partners, contacts, and peer networks (eS FGD3). Although too costly for the MoH to take forward, online distribution in South Africa offered contact information and ongoing communication while distributing kits to more than 1.9 million users on eight targeted social media platforms[2] (PSI 2020a). Other global respondents noted innovations in community-level monitoring as a best practice that could be taken up periodically to monitor the impact of HIVST on linkage to treatment.

STAR coherence with PEPFAR: "The yield mantra"

Although STAR was able to demonstrate an increased yield in targeted health facilities in Zimbabwe, Malawi, Lesotho, and South Africa (d'Elbée et al, 2020), a consensus was not reached among stakeholders between prioritizing HIVST's potential for testing access, and PEPFAR's policy on the yield of HIV positive cases. With PEPFAR as a central scale-up partner, this was viewed as a concerning obstacle (SA KII5). Reaching hard-to-reach populations in the last 5% requires that *'those who do not want to be measured'* have access to testing as the first step in the cascade towards care. A further

[2] Grindr, Gay SA Radio, Instagram, Facebook, Tinder, Bumble, Google Ads and Media24

challenge is that prioritizing yield could result in implementers favoring test sites most used by PLHIV to retest as opposed to identifying new HIV positive cases (SA KII2). Differences in approach were also sometimes seen as a challenge to PEPFAR's goals in defining policy with governments and were a source of mild tension in some countries. This was well managed by all parties, and ultimately all have taken HIVST seriously and offer future commitment, within their own paradigms.

> *"For PEPFAR it was difficult that someone else might take the lead on policies. So when Unitaid/PSI was influencing policy, which suddenly PEPFAR had to follow, they were not used to it. It is difficult to influence PEPFAR."* – Key Informant Interview

Community and Civil Society Organizations (CSO)

The STAR project was highly rated by respondents for having met community and CSO needs in understanding and filling the HIV testing gap. Respondents indicated that the project provided an opportunity to know about the different players in the HIVST field. For example, in Zambia, the project enabled CSOs who had limited knowledge and awareness of activities in self-testing to be exposed to other stakeholders in HIVST such as John Snow Inc. (JSI). The CSOs indicated that through the respective (HIV testing/self-testing) technical working group, they got to know the stakeholders involved in commodity purchase and supply in the country. Furthermore, the project was identified as being key in bringing resources together in the HIV testing/self-testing field. It was pointed out by respondents in Zambia that the project particularly provided an interface with needed expertise in HIVST from the MoH and research.

While select civil society partners were included as service providers and community distributors, engagement with the National AIDS Councils (NACs), the inter-sectoral, public-civil convening and monitoring and structures for country HIV response coordination; as well as civil society networks or key population movements were not perceived to be a STAR priority in some countries (SA KII1, SA FGD1). This has resulted in low acceptance in some groups, and late engagement by the NACs, and their members and sectors.

> *"There was insufficient consultation with SANAC.* (South African National AIDS Council). SANAC *is currently writing a Global Fund grant proposal and could negotiate for funds to get kits – but we need work on usage, unit costs, and advocacy for this commodity. Lack of involvement is a major flaw."* (SA FGD1)

Efficiency

This evaluation found that STAR Phase 2 **largely achieved** its goal to be efficient, regarding how well resources were used. The project (and implementation of HIVST in general) was timely, and while the project was expensive to implement, overall, the evaluation found that it was a good value for money.

Table 5. Key Informant Quotes Related to Efficiency for STAR Phase 2 Evaluation (2021)

Country	Theme	Quote	Source
Zimbabwe	Stock outs	*"We did not experience any stock-outs, and this means the commodities were constantly available to meet the demand of the clients."*	KII14
South Africa	Facility based self-testing, given low rates of PICT	"*Research with facility users revealed that only 10% had been offered HTS during their visit, of those 85% had accepted the test, and 25% had been tested HIV positive. The low offer rate was found to be due to staff and space limitations in the facility. … The STAR system enabled up to 10 times more people to be tested in the facility with the same staffing."*	SA FGD1

Stakeholders indicated that the project was well resourced and balanced between commodities supply, and delivery. Partnerships with organizations already operating in the HTS field were highly efficient entry points for both community and facility distribution in South Africa, Lesotho, and eSwatini, especially for MSM, transgender persons, and FSW, where they were critical to access to these key populations (LO FGD1). By working closely with partners in each country, access was optimized, efficiency increased, and lead time reduced. As part of implementation, HIVST was added onto provider duties, leveraging existing implementation structures in the six countries where STAR Phase 2 was implemented.

There were some challenges to efficiency during implementation of STAR Phase 2 related to the lack of flexibility in terms of time allowed for implementation of the project. Additionally, there were multiple layers in South Africa from Unitaid down to implementing partners which were seen as wasteful with regard to funds, with PSI, SFH, and WRHI (in that order) all combining to be what some described as "unhelpful and expensive layers" between Unitaid and actual service delivery.

Timeliness of Implementation

A few actors made the implementation of STAR Phase 2 very timely. The entire STAR Initiative was reported to have been a long time coming, with preparation for the grant starting as early as 2013 and the grant not being signed until 2015. Stakeholders had already begun to work on HIVST research and preparation for STAR, so key actors were ready. It was overwhelmingly reported that STAR Phase 1 generated sufficient research to prove that HIVST was a strategy that could play an important role in reaching the hardest-to-reach individuals and help countries to achieve their 95/95/95 targets. Implementation of STAR Phase 2 came at a time when stakeholders, including donors, governments, policymakers, healthcare workers, etc. had been convinced that HIVST could have a positive health impact rather than be harmful (which was a fear prior to the STAR Phase 1 research that demonstrated acceptability and feasibility). Thirdly, HIVST implementation became an even more timely technology in March 2020 when the COVID-19 pandemic severely limited peoples' movement and ability to access health services. HIVST created an outlet for people to still access HIV testing and even presented opportunities for other innovative models of distribution such as online ordering.

Cost-Effectiveness & Cost Efficiency

During STAR Phase 2, nine community-based models and four facility-based models of HIVST distribution were implemented, for a total of 13 innovative models developed. Most of the models were either newly implemented (eight models) or optimized from research conducted during Phase 1 of the STAR Initiative (see Unitaid Access Barrier: Demand & Adoption section for more information).

A recent analysis by the research consortium found that the workplace, transport hub or fixed-point models were best for distributing the largest number of kits (Matsimela, et al, 2021). However, the transport hubs and workplace models as well as the sex worker model distributed kits in the most

efficient and least costly way. If future scale-up aims to distribute kits in a way that finds the most HIV positive people at the lowest cost, secondary distribution via index cases at facility as well as sex worker network distribution were found to be highly efficient. STAR Research found that the average costs per kit distributed were comparable to the cost of community based HIVST distribution in Malawi, Zambia, and Zimbabwe ($8.91 to $17.70) (Maheswaran et al., 2016; Mangenah, 2019).

According to the Impact Calculation Maps for STAR Phase 2 developed by Unitaid, from 2015-2025, there were a projected 46,500 DALYs averted[3] (Unitaid, 2021). In addition to this model, studies have been conducted regarding the cost-effectiveness of HIVST. In a 2021 paper Cambiano, et al used mathematical models parameterized with STAR data to evaluate the cost-effectiveness of introducing HIVST. The authors found that HIVST interventions reaching high-risk or underserved populations tend to be highly cost-effective (ranging from cost-saving to US$345/DALY-averted), depending on distribution models and time frames. A 2021 Malawi randomized control trial by Indravudh, P. et al found that community led HIVST was effective, safe, and affordable, with population impact and coverage rapidly realized at low cost (US$5.44 per HIVST kit distributed). Maheswaran, H., et al (2018) found that HIVST may be cost-effective in a Malawian population with high HIV prevalence and is suited to an early HIV diagnosis and treatment strategy. Further, Sande, et al (2021) found that the average cost of integrating HIVST into public facilities ranged from $4.27 to $13.40 per kit distributed between countries.

Value for Money & Project Budget

Overall, this evaluation found that while the project was expensive it represented good value for money and the funds were well spent. PSI reported that their unit costs per HIVST kit distributed were aligned with their initial costing of models in STAR Phase 1. They used the following key assumptions: that the three countries which had been involved in STAR Phase 1 would be able to implement more efficiently than the three countries added for Phase 2; and there would be a relatively low cost per HIVST kit distributed (between US$6 for STAR Phase 1 countries, US$10 for new countries, and US$12 in countries very new to HIVST implementation). The operational budget allocation to the two smaller countries, Lesotho and eSwatini, with lower numbers of test kits allocated was based on the initial quantification and had to be adapted due to insufficient funds. These funds required realignment during STAR Phase 2, which was feasible with a 10% budget line flexibility built in by Unitaid. Overall, respondents noted that while flexibility was eventually granted there were often multiple layers of approval and long delays in budget processes which they viewed as unnecessary.

The budget for STAR Phase 2 was well constructed and used the allocation of unit costs based on Phase 1 evidence. Additionally, the allocation between commodities and activities was effective in meeting targets. Many stakeholders suggested that the budget for convening meetings and doing knowledge translation was vital to the project's success and built trust among diverse stakeholders.

Collaboration with National Authorities

STAR collaboration with national authorities was excellent in most countries and STAR was identified as a best practice in this area compared to other Unitaid grants. Some of the strongest systems for collaboration included: secondment of technical support into the eSwatini MoH; a dedicated consortium partner (CHAI) in South Africa responsible for engagement with and representation of NDoH processes and participation; participation by STAR in multi-sectoral approaches on HIVST and coordinating TWGs – and usually in shorter-term dedicated HIVST TWGs.

Stakeholders reported that perhaps Unitaid could have been more flexible around exit points when it came to integrating HIVST into the six national health systems involved in STAR Phase 2. At the time

[3] For complete model data, please refer to findings under KPI 4.2, under DAC Framework Topic 'Impact'.

of implementation, HIVST was very new to these countries, and national stakeholders needed to be convinced that it worked before making any major changes. It was reported that integration into national Monitoring and Evaluation (M&E) systems varied from country to country throughout the six countries involved in STAR Phase 2 (FGD5). Stakeholders in three selected countries felt it would be helpful for Unitaid to take into consideration short- and medium-term project achievements, for example, all six Phase 2 countries adapted their evaluation tools to capture HIVST data (including flow of commodities to distribution points outside of the health facility), the integration of HIVST indicators into paper-based tools, which was achieved during STAR Phase 2. While the integration of HIVST systems into traditional HTS, and recording of data in HIV registers was achieved, this constituted a relatively low level of integration.

Effectiveness

This evaluation determined that STAR Phase 2 **largely achieved** its goal in effectiveness with regards to achieving its outputs and objectives. The project had major successes in implementation, but implementation did not come without challenges, many of which are being addressed in STAR Phase 3 (ongoing). Of note, the evaluation determined that STAR Phase 2 fully achieved its target to overcome three Unitaid Access Barriers: Affordability, Demand & Adoption, and Supply & Delivery.

Table 6. Key Informant Quotes Related to Effectiveness for STAR Phase 2 Evaluation (2021)

Country	Theme	Quote	Source
Zimbabwe	Innovation (Human-centred approach)	*"It was not just the introduction of HIV self-testing it was human centered from the ground. We used consumer testing to make sure the instructions were clear. Throughout the entire process actual users were involved in the process and then adapted, that way it was innovative and helped the success and uptake of self-testing."*	KII17
South Africa	Innovation	*"The innovation was phenomenal, for example the digital innovation, and testing more than 12 distribution models. The team made a strategic decision not to focus on 'routine distribution', with this having been tested well in Phase 1 countries. Instead, we focused on innovative options, such as taxis, pharmacies, workplaces, and succeeded in very high rates of distribution and acceptance. … I don't think HIVST would have got to where it has without this investment. It really has been catalytic. It kick-started distribution models by providing a lot of money and a lot of tests."*	SA KII4
eSwatini	Integration, and tensions between supply and accessibility	*"We [partner agency] integrate into the MoH system, so we also receive PEFPAR testing kits through Central Medical Stores. There are some supply issues. Facilities don't always have kits. It is not always clear if this is due to enough supply, or supply restriction on to whom you give them out. Will health care workers on the ground have access to those kits? Not if policy restricts it."*	eS FGD2

One of the major factors related to STAR's gains in overcoming barriers to implementation of HIVST was the extraordinary consortium between the implementers, policymakers, and academics, outlined in Annex 1 and the project background section. During STAR Phase 2, 17 publications were published, and 13 presentations were given at conferences. An additional two abstracts and 26 manuscripts were also submitted in quarters 3 and 4 of 2020. In 2020 STAR hosted nine webinars - this platform was identified as crucial for dissemination of data and information during the COVID-19 pandemic (STAR, 2019).

The creation of the Implementation-Research Consortium was viewed as a highly effective strategy, allowing STAR access to accelerated WHO guidelines (2016, 2019), and setting the stage for global scale-up. Outside of the consortium but still on a similar note, the early engagement with scale-up partners like PEPFAR and the Global Fund was described as a key success unique to STAR. A spirit of collaboration and inclusiveness was described throughout the process.

> "*STAR was the most impactful and successful in the sense that it was truly implemented through a partnership approach...They [PSI core project team] really embraced the common goal and perspective, where on other projects, work is siloed*" - FGD1

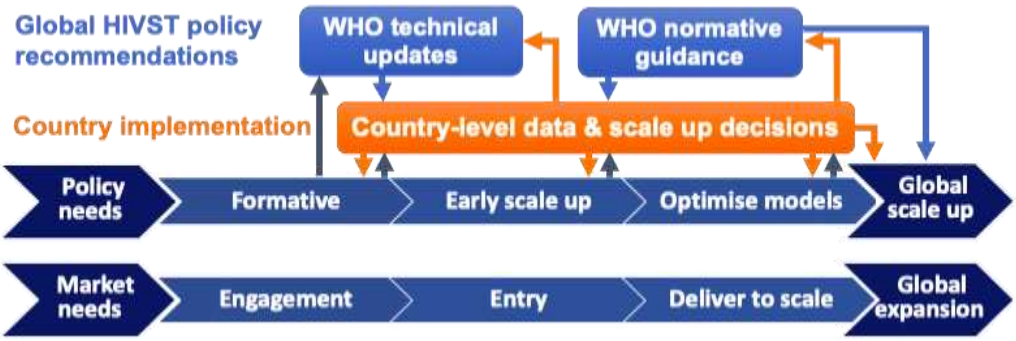
While most countries found a consortium approach helpful, some stakeholders found it to be inefficient in South Africa, where a total of five partners attempted to share (and sometimes compete around) roles, territory, and leadership. Unitaid assigning SFH as the lead grantee for South Africa created multiple layers between Unitaid and delivery on the ground preventing direct communication, resulting in insufficient maneuverability, and creating a sense of gatekeeping of decisions and strategic approaches through the PSI/SFH interfaces.

Layers of management responsibility (each with its own fee deduction) and contested decisions seem to have plagued the process, and fewer agencies in a more efficient and cooperative team would have been preferable (multiple KII).

STAR research was focused on producing multi-country data on key delivery models relating to usability, social harms, costs, and health impacts to inform countries and WHO Guidelines (WHO, 2016; WHO, 2019; UNAIDS, 2020; WHO Press, 2013; Ministry of Health & Population Malawi, 2018). Evaluated models included peer-distribution by female sex workers, facility-based secondary-distribution whereby kits are taken for sexual partners by antenatal and newly diagnosed "index" HIV patients, community-based and community-led models. The evaluation methodology used randomized trials where formative results were promising, dropping unsuccessful models. Including additional partner funding, the STAR project resulted in 26 manuscripts and 76 conference abstracts to date, with eight Ph.D. registrations including four LMIC students (Corbett, 2021, PSI 2021). Seven STAR-funded cluster-randomized trials have investigated outcomes including population-level knowledge of HIV status, demand for ART, and male circumcision. Economic evaluations have defined preferences, and provider, societal, and projected scale-up costs, and informed cost-effectiveness modelling.

The research was an ambitious project with multiple critical goals, tight timelines, and high-volume implementation targets in a very new field. The corresponding research needs were complex, with significant ethical challenges. Academic partners articulated that given the challenges they felt the decentralized model was essential to STAR's success since if one country failed or was delayed it would not hamper the others. While decentralized research networks require more research funding, they ultimately build more national capacity and were viewed as vital to the project's success. Researchers were also very deliberate in building trials that would meet the WHO criteria for "Strong Recommendations" in the GRADE framework and to enable implementation in national policy requirements. The research team also anticipated policy and market needs, as outlined in Figure 3.

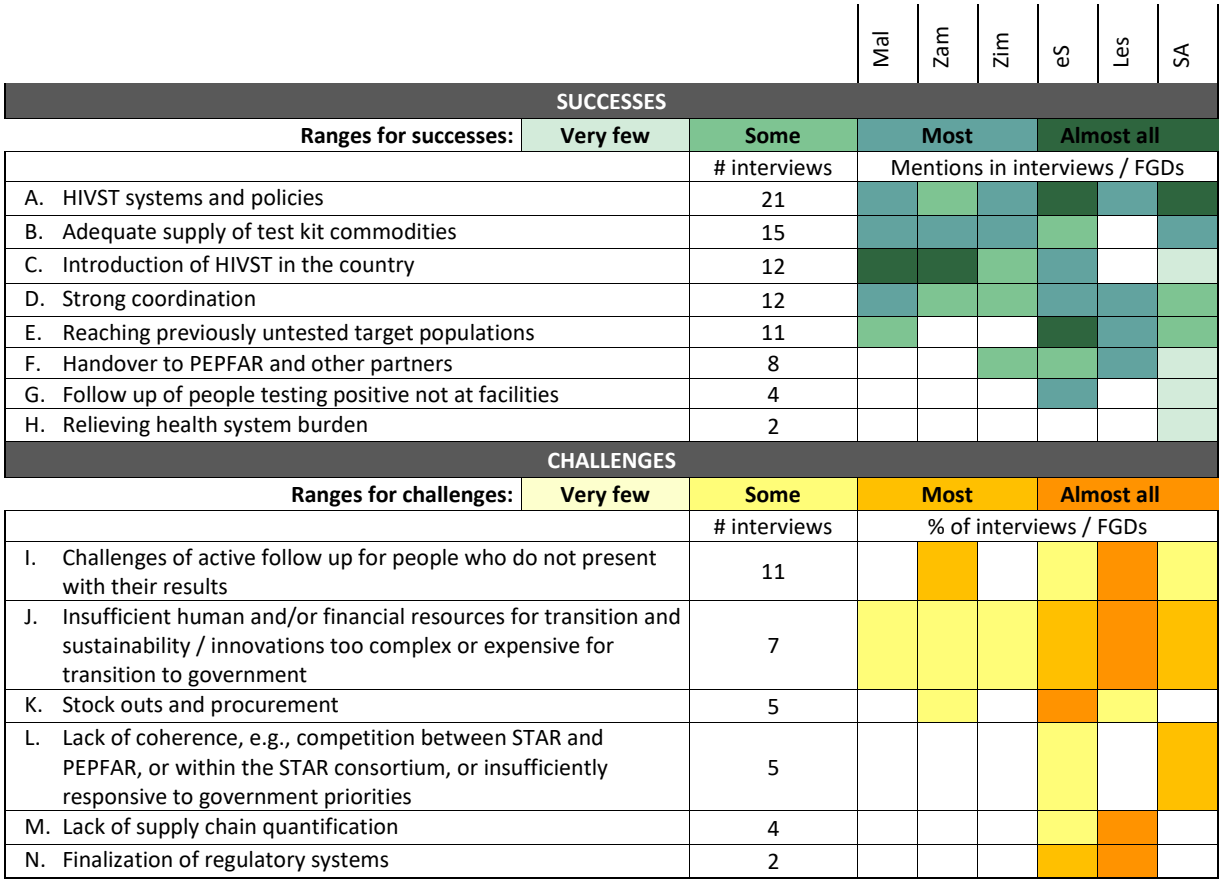
Figure 3. STAR Research Consortium and Regulatory Approach (Corbett, 2020)



While the research consortium was seen as a crucial aspect of STAR's success, some key informants expressed concerns about perceived conflicts of interest related to authorship and publication bias. The research consortium did in fact have a clear authorship and publications policy with clear conflict of interest guidance and actively attempted to publish negative findings, although this was not widely known by some external stakeholders. Other stakeholders felt that limiting authorship only to academics was not in keeping with the collaborative nature of implementation science and suggested a more middle ground with agency training and clear respect for the ICMJE Authorship Guidance Criteria. Unitaid may want to identify clear criteria for decision-making around authorship for implementation research that they fund and more proactively manage perceived conflicts of interest among stakeholders. Ultimately, the research was of very high quality and from the evaluator's perspective; conflicts were well managed and negative findings were proactively reported and published so it is more about addressing perceived rather than real conflicts and building trust in the validity of the research by improving transparency. There is always a degree of conflict of interest in scientific publications and a wider issue beyond the remit of STAR related to publication bias towards significant results. In summary, it our view that the STAR research consortium maintained scientific integrity by publishing widely, using highly rigourous methods including randomized control trials, by aiming to promptly replicate promising data with similar projects and by declaring conflict of interest clearly.

Figure 4, below, displays overarching contributions, successes, limitations, and challenges throughout implementation of STAR Phase 2, and the frequency in which they were reported by stakeholders during qualitative data collection. The Figure is based on interviewees who provided a response on each of the thematic areas listed. Their lack of responses in other themes does not necessarily indicate a lack of agreement. The table is intended to communicate the weight of themes emerging naturally from interviews and FGDs. It provides an overview of the topics most discussed in interviews and focus groups. It is important to note that just because a topic was not discussed (e.g., introduction of test kits in Lesotho as a STAR success (C)), does not suggest that this did not happen in this country (e.g., in Lesotho STAR certainly was responsible for introduction of HIVST). The opposite also applies - e.g., although a few people mentioned STAR as introducing HIVST to South Africa, this was not the case since progress had already been made before STAR's arrival. The assessment is therefore an overview of the conversations and does not offer an objective ranking or a comprehensive account of successes or challenges. It simply offers an impression of the topics highest in respondents' minds and priorities.

Figure 4. Thematic Analysis of Successes & Challenges Raised in National-Level Interviews & Focus Group Discussions for STAR Phase 2 Evaluation



The topics raised in Figure 4 are discussed in detail in their respective sections. Overall, STAR was widely credited with enabling the introduction of HIVST to national program (C), including the value of HIVST in reaching previously untested populations (E). Respondents appreciated the large number of test kits as a valuable contribution and a key success factor (B), although short-term stock-outs were noted by respondents in three countries (K). This is elaborated in the section on supply.

STAR support to HIV systems and policies were almost universally described as a program success (A). Good coordination through government and partners (D) or in handover to other agencies during exit (F) was also mentioned. In some countries, however, inter-agency or government coordination was raised as conflicted or inadequate (I).

Although in general, systems, policies, and public sector health systems strengthening were greatly appreciated (A), the most raised challenges were around insufficient (J), or incomplete systems support (M, N). Although mentioned by fewer respondents, STAR was also noted for finding important and innovative ways of follow-up of community distribution (G), the difficulties of which were frequently mentioned as a major obstacle to effective scale-up of HIVST by government and partners (I).

Table 7, below, summarizes some of the key factors for achievement. It should be noted that some of the challenges have already been conceptualized and are being addressed during ongoing implementation of STAR Phase 3.

Table 7. Summary of Factors for Achievement of STAR Phase 2, summarized from primary qualitative data collection January 5 to March 20, 2021

Outputs	Factors for Achievement
Output 1: Supportive environment for introduction and integration of HIVST is established in national policies, strategies, plans and regulations.	● **Phased Approach:** Research conducted in STAR Phase 1 demonstrating effectiveness set up the STAR Phase 2 implementation. ● **National Technical Working Groups (TWGs):** STAR worked with governments through TWGs to ensure project coordination and that research was continuously informing implementation. ● **Development of toolkits:** to guide research design and HIVST implementation. ● **Regular in-person meetings:** stakeholders from all 6 countries were able to share HIVST implementation experiences and identify research and policy making priorities. Project and non-project countries also attended workshops in Nairobi and in Bangkok linked to WHO regional guidelines. ● **Technical assistance:** identified the steps necessary to establish external quality assurance and post-market surveillance (PMS) systems and brought technical resources together to supplement the needed expertise by MoH. ● **Platform for tools & best practices:** development of commodity forecasting model, national and regional distribution tracker, M&E system, dedicated SOPs, marketing and communication guides, marketing intelligence tools, PSM best practice documents and other HIVST TA support which can be adopted by other LMICs based on HIVST implementation stage (introduction, pilot or scale up), national and regional priority and local context.
Output 2: Selection, adaptation, and scale-up of effective HIVST and linkage models.	● **In-depth research (phased approach):** to understand consumer preferences and provider perceptions of HIVST and used this evidence to inform the design and refinement of 13 distribution models. ● **Focus on sustainability:** distribution models aimed to promote sustainable access to self-test kits for target populations without major external investment in the long-term, through sustainable public-private partnerships and social network and community-led interventions. ● **Development of *health* solutions** (especially during COVID-19 pandemic): to ensure that HIV self-testers are followed-up and referred for prevention, care or treatment, depending on their results. These models can be replicated in other countries and markets and with other diagnostics. ● **Consistent engagement with national and global stakeholders:** MoHs, Global Fund, and PEPFAR communications through the routine dissemination of STAR's findings prompted these key partners to integrate HIVST into their longer-term country-specific plans in the six STAR countries and globally. National governments owned the process and entrusted the consortium partners to galvanize other stakeholders. ● **Focus on global acceptance:** In 2018, HIVST was included as a dedicated testing strategy in PEPFAR country guidance and received a substantial funding increase. ● **Influence at national and international level:** HIVST was added as an option to national and international testing policies,

	allowing distribution of test kits in multiple strategic points. HIVST for index partners and for men whose partners are coming to antenatal clinics have evolved as key cost-effective strategies in many countries.
Output 3: Evidence dissemination and resources to support transition and scale-up identified and mobilized.	● **The Consortium approach** brought in multiple players, researchers, policymakers and implementers working together to drive the research agenda, improve collaboration and generate global evidence. ● **Focus on high impact journals, conference presentations & webinars:** STAR reached a large number of stakeholders, had a presence at key global conference and conducted webinars during COVID-19 for dissemination. ● **Focus on rigorous RCT research:** In South Africa, the importance of the STAR research and evidence production approach was crucial to successful national adoption, with rigorous research and compelling RCT-level evidence having been a clear requirement for financing and inclusion in national programming. Similarly, in Zambia and Zimbabwe, rigorous research was seen as critical in enabling acceptance and uptake of scale-up among MoH. ● **Dissemination beyond health sectors:** dissemination of HIVST into other sectors such as workplaces, taxi ranks, and the South African Department of Mineral Resources (SADMR, 2020).
Challenges to Achievement	
● **Regulatory process:** manufacturers remain concerned that the regulatory process remains confusing, lack of clarity about which authorities are responsible for the registration of HIVST products, lengthy in-country validation, and registration processes for products even after they have achieved WHO PQ status. ● **Perceived cost of HIVST kits:** remains higher than the cost of professional-use HIV rapid test kits (when you exclude labor); there may be additional opportunities for price reductions for the oral and blood-based tests as countries begin to scale volumes. ● **Research objectivity:** While STAR has published extensively on HIVST, respondents raised concerns about the appearance of reporting and publication bias, with a view of demonstrating effectiveness, advocating to skeptics, and promoting the use of HIVST (SA KII2; (Moore et al., 2019). Emphasis in publication has been placed on successes within targeted studies, in supported conditions, which is a problem in the larger global health research infrastructure beyond STAR's control. The extensive use of cluster randomized trials within the consortium does mitigate this concern to a degree – as controlled trials have built-in features (a comparison arm, preset primary outcomes, pre-agreed statistical analysis plans, trial registration) aimed specifically at minimizing reporting and publication bias. ● **Varying priorities among implementers**: Distributors were sometimes MOH staff and if they were unable to do the distribution, there was little control, and this was reflected in the challenges in the workplace intervention. ● **Scale-up strategy unclear to all stakeholders**: Impact could have been greater with a less abrupt handover to government Ministries of Health in some countries. ● **Distribution numbers vs testing vs linkage**: The expectation to be able to measure the direct contribution of self-testing to case identification and ART was identified as an ongoing challenge in all countries. ● **Political and Economic factors**: The STAR research period coincided with a time of political instability and high inflation in Zimbabwe leading to timeline adjustments.	

KPI 2: Overcoming market barriers

There is no question that STAR was successful in overcoming market barriers for which the project aimed to address – affordability; demand and adoption; and supply and delivery. Under STAR, the pipeline for HIVST products has expanded dramatically with four WHO prequalified (PQ) HIVST products: the INSTI HIV Self-Test (Bioanalytical, Canada); the Mylan HIV Self-Test (Mylan, Atomo Diagnostics, Australia); and the OraQuick HIV Self-Test (OraSure Technologies, USA) and the SURE CHECK HIV 1/2 Assay (Chembio, USA). Prior to STAR, only one product existed and only three countries had HIVST. As of July 2020, 88 countries had policies allowing for HIVST, of which 41 countries were implementing HIVST, and an additional 31 countries had HIVST policy in development[4] (Unitaid & WHO, 2020) A total of 4,186,209 HIV self-tests were distributed in Phase Two in the six countries (PSI, 2020) compared to tiny volumes in 3 high-income countries prior to STAR.

A crucial step, supported by Unitaid funding directly to WHO, was the publication of the first global guidelines on HIVST in 2016, in which HIVST was recommended by WHO to be offered as an additional approach to HIV testing services and the subsequent 2019 HIV testing guidelines. The WHO prequalification program, supported by Unitaid and other partners, approved the first HIV self-test in July 2017. Three other HIVST products have also received WHO pre-qualification as a direct result of STAR. STAR widened the scope of HIV testing from traditional testing to self-testing and in turn had an impact on demand for HIVST kits at national levels. Phase 2 increased HIVST kit demand (it was reported that Zambia ran out of kits due to improved demand). There was significant evidence of a multi-level supportive environment through policies, strategies, and actual test kit procurements (i.e., in Zambia HIVST toolkit incorporated in national HIV testing standard operating procedures (SOP)).

Unitaid Access Barriers

As previously stated, STAR Phase 2 aimed to overcome three out of the five total Unitaid Access Barriers: Affordability, Demand & Adoption, and Supply & Delivery which are addressed below.

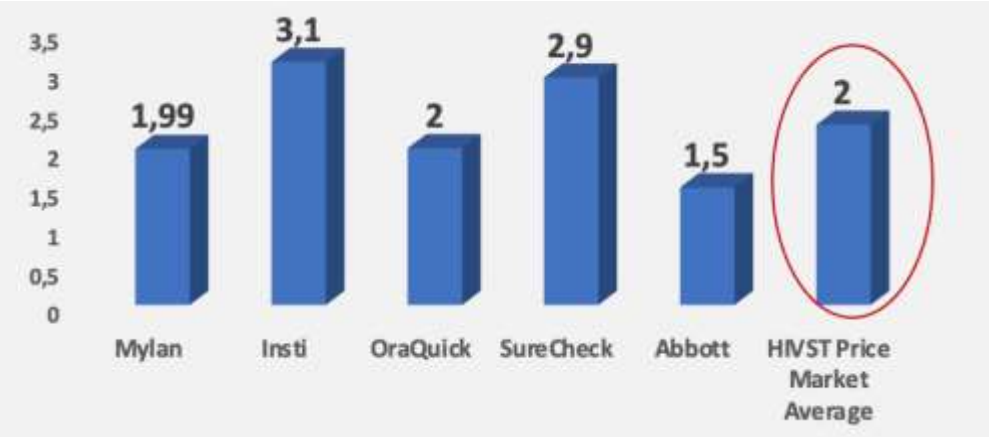
Affordability

Affordability is defined as: "*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 to the underserved*" (Unitaid, 2017). This evaluation of STAR Phase 2's performance against this market barrier was 'fully achieved'.

Cost-effectiveness and affordability of HIVST has dramatically improved as a result of STAR interventions. Self-tests can now be procured for as little as US $1.50 per kit across 135 LIC, LMIC, and UMIC (compared to approximately US$40 in the United States and up to US$15 in South Africa, in the private sector in 2015) (Unitaid, 2018; Unitaid, 2021). This price reduction was achieved thanks to a combination of efforts by multiple partners, including an agreement for one oral self-testing product secured by the Bill & Melinda Gates Foundation. Unitaid and other partners have also secured lower prices using volume pricing and forecasting and by bringing together manufacturers to support an increase in the number of products to improve competition in the marketplace. Figure 5 displays HIVST price by product in 2021 (post-market intervention).

[4] Out of a total of 194 WHO reporting countries.

Figure 5. HIVST Price (US$) by Product, 2021 (PSI, 2021)



Evaluation respondents stated that a modest payment for HIVST was seen as an option, and to some extent, preferable in some contexts. Community respondents in eSwatini, for example, experience people placing greater trust and value in a commodity they have paid for (condoms having demonstrated this clearly). Payments of $0.75 would be acceptable in urban areas, down to under $0.50 in rural areas (eS FGD3). Knight (2017) found that people in South Africa strongly preferred free tests, but most were willing to pay $1.25 - $2.50. In a study external to STAR, Ritchwood et al, 2019 found that HIVST would need to be free or very low cost (as above) for uptake in resource-limited settings. Some global stakeholders felt that Unitaid needed to engage more with private sector partnership models for future technology grants and that a reliance on public or no-cost models limited innovation.

Evaluators were able to delve into both the benefits and the challenges regarding the Gates buy-down of the first oral HIV self-test product: Orasure. Both Gates and STAR have funded research to build the evidence around blood-based tests to expand that market (and today there are three pre-qualified blood-based HIVST) but there was reportedly some resistance from the STAR project in terms of expanding blood-based testing. Since only one manufacturer was involved in the Gates buy-down, manufacturers and donors felt it wasn't a level playing field for other products and may have brought some imbalance to the market. While STAR did not initiate the buy down, stakeholders largely felt that STAR influenced it, and had there been two to three manufacturers involved, additional products could have been in circulation for the past five years. Multiple stakeholders expressed support for STAR's more recent efforts to catalyze the market with volume pricing and forecasting, seen as crucial to building a more robust and healthier competitive marketplace with more sustainability.

In addition to working on improved competition, it was also noted that several unsafe and illegal products continued in the private sector in some countries, and this was noted as an area for further intervention. For instance, some innovative work was conducted in South Africa to remove unsafe products from private pharmacy shelves. Future technology grants could include an audit of unsafe products pre and post-implementation to ensure regulatory systems include an ongoing post-market auditing and enforcement arm. Similarly, several stakeholders noted the lack of engagement with private sector models and co-pay models as a barrier to sustainability. There was a general feeling that Unitaid was unwilling or unable to partner with the private sector and this was a lost opportunity as many other similar testing commodities had achieved scale up only by partnering with the private sector.

Demand & Adoption

Demand & Adoption is defined as: "*Countries, programs, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products within their local*

context" (Unitaid, 2017). The evaluation team's evaluation of STAR Phase 2's performance against this market barrier was 'fully achieved'.

HIVST has been successful in reaching previously under-serviced testing spaces, greatly stimulating the market. Within the short space of time in which STAR has been active, demand for HIVST has increased. Market barriers to access have been overcome by widespread community distribution, counsellor-supported pharmacy and retail distribution, the use of CSOs among key populations, snowball access to workplaces that are outside of the traditional reach of health services, and multiple other highly innovative and targeted methods for reaching those who are not usually reached (and then those who are least-reached within that group).

While continued demand creation can be expected in most countries, handover of marketing has not been achieved in Lesotho (LO KII1), where IEC materials and branding, systems for demand communication strategies have not been transferred to MoH. Demand creation communication has therefore declined in the absence of transition of this aspect. STAR messaging in South Africa is also likely to be replaced or discontinued (SA KII9), mainly due to high-cost alternative platforms for communication, rather than the use of existing NDoH communication platforms. For example, the highly sophisticated, innovative, and interactive online platforms that were developed and tested could have been anticipated to be unaffordable for the public sector to maintain.

There was significant demand created for community models during STAR Phase 2; however, some models were more expensive than facility-based distribution. Advocacy for another partner or support to finding funders for organizations such as MSF, PSI, or WRHI which are committed to community distribution would enable this market opportunity to be realized. For now, there is considerable risk of stimulated demand being disappointed by supply.

In-facility models also offer moderate effectiveness in overcoming market barriers by offering a no-queue, semi-private, optionally assisted testing booth, with the important advantage of fast-tracked access to confirmatory testing and ART on-site (LO FGD1; SA KII7). This has stimulated demand at facilities, including increased uptake by men and adolescents.

STAR has significantly contributed to the research evidence based on the cost-effectiveness of the different models. The main factors influencing the cost-effectiveness of the different models were prevalence of undiagnosed HIV; size and risk of HIV in the sub-population receiving HIVST; linkage to treatment or prevention following HIVST; and cost of HVST distribution (Cambiano et al, 2021). STAR-supported mathematical modeling suggests that HIVST can also be cost-effective with appropriate targeting of men in southern Africa among priority groups (Johnson et. al., 2020). The next step remains for STAR Phase 3 and partners to further disseminate the framework that has been developed for countries to choose the right mix of testing modalities for their local context.

Although quality and usability were not a focus of the Phase 2 project, they were raised as significant ongoing concerns among global stakeholders and as an ongoing barrier to scale up by multiple large funders and policymakers in all countries. Preliminary data from quality assurance programs in selected countries during Phase 1 have returned proficiency error rates for HIVST between 5% and 10% (Johnson, C. et al, 2017). However, the magnitude of misdiagnosis is unknown since some are not reported and many countries do not have comprehensive Quality Assurance (QA) procedures or post-market surveillance in place (PEPFAR, 2021). Although the existing WHO prequalified HIV rapid diagnostic tests all have sensitivities of >99% and specificity >98%, given the large volume of tests conducted worldwide, it is inevitable that a not insubstantial number of tests will be false negative or false positive, a concern that was raised by multiple global stakeholders. Based on data from a systematic review of 64 studies, an estimated 93,000 people could be misdiagnosed per year (Johnson

et al, 2017), which may not be fully accounted for in the STAR Impact Modelling or future phases of the project.

A study external to STAR by Figueroa et al, 2018 found that finger-prick tests will require more instruction than what is currently included in the package insert. However, a systematic review noted that individuals' performance of unassisted HIVST is highly comparable to the performance by health care workers, indicating that HIVST can be utilized accurately (Figueroa et al, 2018). While a portion of blood-based tests is included in commodity supply, respondents felt that, for example, *'as a country [Lesotho] we were not yet ready'* for blood-based self-testing. Users express an aversion to the finger prick (LO FGD2, SA KII7), and blood-based tests are more difficult to use and vulnerable to user error (Ritchwood et al, 2019).

> *"People don't want to prick themselves. We were targeting construction workers and mine workers who do manual labor - their skin is hard. We were forced to buy a high proportion of INSTI kits. If we had been given the liberty to procure less, it would have been better. Some expired, some were used with an HTS counsellor."* -- SA FGD1

Despite overall progress in scaling up self-testing, manufacturers also reported concerns that market conditions are compounded by continued ambiguity in forecasting and regulatory environments (KII9). High and consistent demand for HIVST kits – along with higher demand for HIV testing in general – is needed to provide the incentive necessary for a viable self-sustaining market (PSI, 2021). Furthermore, the cost of HIVST kits remains higher than the cost of professional-use HIV rapid test kits, which was raised as a significant concern by stakeholders in the large-scale up donor organizations. STAR Phase 3 is working on additional opportunities for price reductions for the oral and blood-based tests as countries begin to scale volumes. Without ongoing intervention, these challenges have the potential to constrain market growth, leading to higher prices, an insecure supply, and a lack of product choice that will leave users' needs unmet. To improve the quality and availability of information about the HIVST market, Unitaid and WHO have developed a series of HIVST landscape reports and an HIV testing dashboard in addition to convening sessions with manufacturers and policymakers. These fora and annual documents and reporting include a summary of the evidence to support the use of HIVST and were viewed as helpful, but manufacturers identified a mistrust in forecasts without purchase commitments (KII 8).

Supply & Delivery

Supply & Delivery is defined as: "*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 chain exists to meet global needs*" (Unitaid, 2017).

The development of procurement and forecasting systems was well integrated into the STAR project. The evaluation team's evaluation of STAR Phase 2's performance against this market barrier was 'fully achieved' with minor areas for improvement in metrics noted in the recommendations.

Four new HIVST products were available with WHO pre-qualification (one during STAR Phase 1 and three during Phase 2). Additionally, 100% of project countries forecasted integrated HIVST into their national HTS programs, as well as 100% of national PSM systems were procuring recommended WHO quality assured HIVST kits. STAR Phase 2 strengthened the entire regulatory system for in-vitro diagnostics in project countries, beyond HIVST regulatory systems.

However, STAR project supply stockouts were experienced in eSwatini and Lesotho. Reasons given included rapid uptake of HIVST; a communication breakdown at one point in eSwatini; and continuing

lack of capacity for forecasting and quantification in Lesotho (eS FGD1, LO KII1). In eSwatini, distribution of HIVST was rapidly rolled out once acceptability and feasibility had been established, and greatly increased during COVID-19 restrictions both in facilities and communities. As a result of this, as well as problems with forecasting and supply chain, stock-outs were experienced (eS FGD1; PSI 2020a). Stock-outs were also experienced in Lesotho, where there was excellent uptake in 2018, and a request for the front-loading of kits the following year (LO FGD1). Some level of stock-out was inevitable in the light of responsive and unpredictable distribution models, and they did not negatively impact project outcomes. Unitaid key informants stated that the supply chain system, product distribution and quantification for STAR Phase 2 was not envisioned as a full-supply system, as this is would have been too challenging and expensive for a product introduction project.

National supply systems were supported and enhanced by STAR, and integration of HIVST distribution into national health systems was a key area of success. For example, supply systems improved in eSwatini, with STAR-supported systems to funnel all stock through the MoH Central Medical Stores and support centralized distribution by all partners (eS FGD1). Where human resources in public health were limited, government staff turnover high, or capacity building insufficient, fully established supply, quantification, and forecasting systems were not institutionalized and fully functional by the end of STAR. This was particularly found in Lesotho. Similarly, the project team was not able to supply the evaluators with multi-country project-level quantitative data on expired products, stock-outs, or other metrics used by Global Fund and other scale-up partners, which could have been a useful way to monitor for issues in the supply chain, although difficult to operationalize for product introduction projects. Handover to WHO was intended to ensure sustainability and continuity.

Impact

This evaluation determined that STAR Phase 2 **largely achieved** Impact, as the intervention made a lasting difference. The evaluation team found that the STAR HIV project was a high-impact project that met its objective to catalyze the HIVST market and achieved its goal to reach the poorest and most underserved populations. The project and HIVST implementation made an impact on closing the HIV testing gap; however, challenges remain regarding a significant global funding gap for HIVST through 2025.

Table 8. Key Informant Quotes Related to Impact for STAR Phase 2 Evaluation (2021)

Country	Theme	Quote	Source
All	Catalytic investments and impact measurement	*"When you start using the language of impact, that's when things start to get confusing - what are you trying to impact? Because you're not budgeting money for service delivery… you are trying to impact the market…in trying to prove impact in the theory of change, they [Unitaid] can send their grantee on a wild goose chase."*	FGD5
Malawi	HIV testing targets (95-95-95)	*"The impact is huge because even with respect to the old UN targets 90-90-90 those were beaten by Malawi, some of it is down to the HIV self-testing implementation. Before self -testing was there these targets were not met at all and now they are been over archived."*	KII20

During this evaluation, the evaluation team found many positive aspects of the Impact Assessment Models developed by PSI in 2019 and later expanded upon by Unitaid in 2021, with full details of the evaluation team's assessment available in a separate annex provided directly to Unitaid. In summary, the calculations behind the models were well documented, the sources of assumptions clearly identified and the impact estimates conservative. However, the public health impact model is relatively simple and relies on the results of a single publication based in a single country to estimate

the public health benefit of each additional HIVST. As a result, there is no sensitivity analysis, and no range or confidence level reported with the estimated impact, limiting utility. The evaluation team recommends that Unitaid conducts a more robust, external, and dynamic model at the end of Phase 3; several recommendations to improve future iterations have been provided in the modelling annex. This includes adding more dynamic modeling to account for a number of factors, including updated estimate of HIVST procured as a result of the project; number of other tests carried out annually; the impact of the project on the testing landscape by looking at year-on-year trends and comparing project to non-project countries; and updating assumptions to reflect more recent publications. More information could also be added from the UNITAID/WHO 2020 HIVST landscape report, including the need estimates broken down by specific at-risk or hard to reach populations, where testing may lead to public health benefits not included in the current model. Emerging research on the accuracy of HIVST, as compared to CBTs, could also be included to assess the impact of false results. Finally, a thorough search of the literature should be carried out to locate emerging research which can improve the cost estimates at a societal level.

An estimated 15,551 lives will be saved, 97,762 HIV infections averted and 46,500 DALYs averted as a result of STAR Phase 2 investments (Unitaid Impact Calculation Maps, 2021). HIVST managed to reach populations that did not usually access traditional testing platforms and stakeholders felt this had a real impact on reaching the first 95 testing targets (KII 16). This impact on the first 95 encouraged the shift to self-care, allowed individuals to seek out more information and take ownership of their own health. This impact was highest among those who do not access healthcare frequently, primarily men and youth. STAR was also successful in putting health decisions in the hands of individuals and giving patients more options.

KPI 4.1 Increasing Public Health Impact

The STAR Initiative set out to achieve direct public health impact by reducing the number of new HIV infections and averting deaths due to HIV infection by increasing demand for and access to HIVST and onward treatment and prevention services (PSI, 2017).

STAR's Impact on Closing the Testing Gap

Impact towards closing the testing gaps (contributing to the 95-95-95 target) was observed in Zambia and Zimbabwe. Malawi respondents noted they have already reached their 90-90 targets and may be able to reach the 95 targets before 2025 (KII 20). Although some stakeholders expressed that it is not clear the extent to which HIVST directly contributed to this. The South African Department of Health stated that their data reflect STAR's 2 million kits did indeed contribute to closing the testing gap (SA KII1). In eSwatini, where the country has already reached ahead of their 95-95-95 target, HIVST is seen as a valuable alternative, with the potential for helping to reach the last 5%. In Lesotho, however, sustained contribution of HIVST to achieving the 95% testing target is seen as unlikely without a transition process:

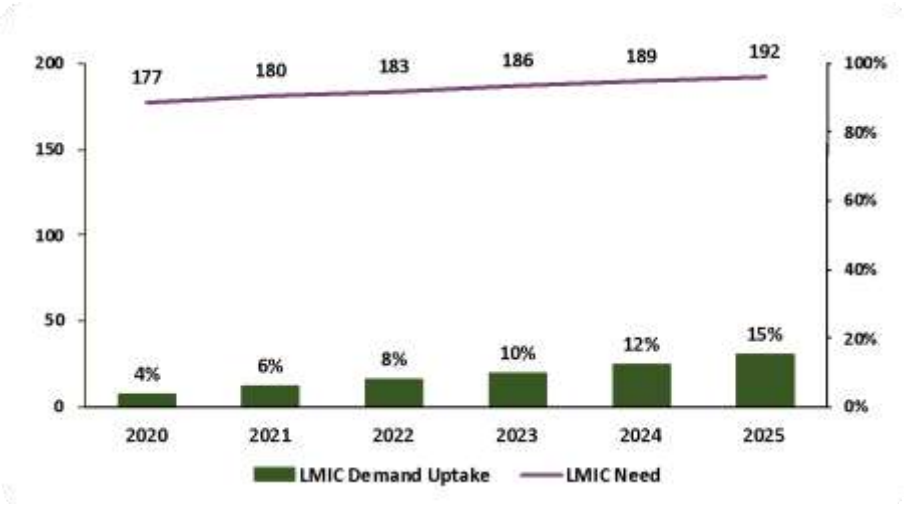
> "*HIVST will help us to achieve the target under the assumption that there is sustainability - otherwise no. If there is supply chain, M&E, demand creation, and community distribution transition - otherwise no*." (LO KII1)

Overall, the evaluation found that STAR Phase 2 helped reach the "final mile" and was an important tool for reaching the unreached by traditional testing. There remains a large funding gap for HIVST which, if appropriately funded, could significantly decrease the testing gap. As of 2020, three of the six STAR Phase 2 countries met the 90-90-90 testing and treatment targets (Zambia, Zimbabwe, and eSwatini) and one country is very close to doing so (Malawi). In South Africa and Lesotho, there is still progress to be made towards these targets and looking ahead to the 95-95-95 targets by 2030 (UNAIDS, 2020). These gains have been made by many projects working in close collaboration to save

lives, of which STAR was clearly a key partner. Further modeling is required to accurately assess the unique contribution of HIVST to the improved cascade of care and to clearly articulate the return on investment in different contexts.

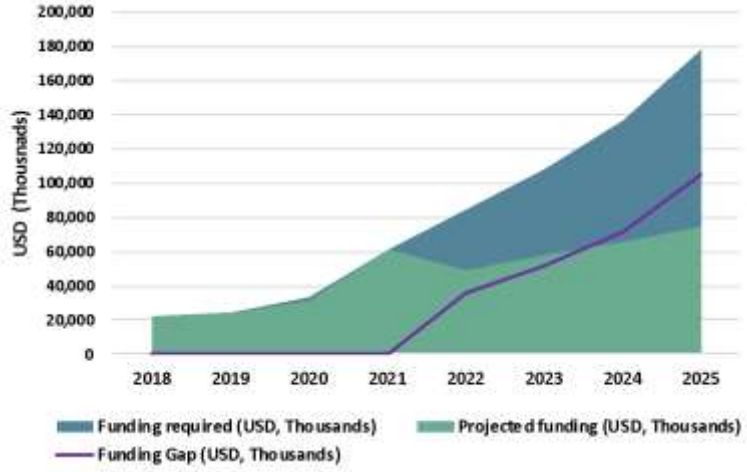
The WHO Market and Technology Landscape Report noted low but increasing LMIC demand volumes as a percentage of need anticipated, reaching 15% of the total need by 2025 as outlined in Figure 6 (Unitaid & WHO, 2020). While demand is expected to grow rapidly, the need for testing is also expected to grow. The report concluded that there was still a significant opportunity for HIVST scale-up as part of the overall HIV testing strategy.

Figure 6. LMIC HIVST Demand Volumes as a Percentage of Need (WHO, 2020)



Authors further noted that the funding allocated to HIVST implementation has increased rapidly but expected future demand will require continued growth to address funding gaps. Figure 7 outlines the forecasted demand of 29 million HIVST in 2025, which will require estimated funding of US$180 million to implement. This is assuming an average cost of implementation of HIVST at US$5.46 per test remains constant (Unitaid & WHO, 2020).

Figure 7. HIVST Funding 2018-2015 (Unitaid & WHO, 2020)



KPI 4.2 Generating Efficiencies & Savings

As fewer undiagnosed PLHIV remain in the population, the cost-effectiveness of HIV testing has decreased. However, as the COVID-19 pandemic has stressed global resources and reduced access to

health care services, making choices regarding which HIV testing modalities to scale up or scale down is urgent. While HIVST provides an alternative to standard facility testing that STAR has found to be private, convenient, and minimizes direct health worker contact, multiple studies conducted during the STAR initiative have identified that costs vary substantially by distribution model and by country (Cambiano, et al, 2021; Maheswaran, H., 2017, Indravudh, P., 2021).

The South African MoH, with STAR and the HIVST TWG, provided convincing evidence in an investment case for treasury, resulting in approval of HIVST, despite a per kit cost of ten times the cost of a rapid professional use test kit (SA KII9). The justification required proof that these kits reach the 'high hanging fruit' – people such as youth, men, and key populations, who would not ordinarily have access to testing, and who are at high risk of HIV. The case demonstrated the long-term cost-benefit of early diagnosis, rather than waiting for people to be forced into the health system through illness (SA KII1). In addition, integrated use of HIVST with PrEP (which requires regular confirmed negative testing) offers acceptable prevention efficiencies for HIV-negative people in high-risk populations (SA KII1, Holmes, et al, 2020). Indeed, once-off self-testing may offer little value and minimal contribution to 95% targets, unless it builds up to routine, efficient distribution for regular self-testing, especially for high-risk people who are not in regular contact with the health system (eS FGD3).

One cost efficiency is that testing can be achieved in facility reception areas with 1/8th of the staff input, using previously unused space – with the added value of immediate access to confirmatory testing and ART initiation (LO FGD1). While replacement of routine testing with self-testing has been rejected as inefficient, in a context where routine testing is not being offered in practice due to time, staff, and space constraints, HIV self-screening (HIVSS) of non-target populations does offer a cost-efficient option (SA KII1, 5). Whether in facilities or communities HIVST offers human resourcing efficiencies by relieving pressure on health personnel, space, and systems. Respondents agreed that HIVST triages out HIV negative tests, thereby increasing the yield of facility confirmatory testing, and focusing health resources where they are most needed. Efficiencies are also generated in comparison with the expected high costs of reaching less accessible populations, and the reduced health systems costs of community or self-testing in facilities. These are offset against higher costs per kit. Further efficiency would be generated with concerted task-shifting to trained peers and community health workers for assistance and demonstration, thereby reducing tester error, and optimizing distribution through target networks.

KPI 5.1 Investing in the Poorest & KPI 5.2 Investing in the Underserved

Overwhelmingly, stakeholders supported that STAR did invest in the poorest and underserved and improved access to HIVST for populations not accessing health services in more traditional settings. As described in the relevance and coherence sections, implementing in more non-traditional settings, such as the workplace initiative, was able to reach those in the informal sector i.e., farmworkers, miners, marketers, etc. Stakeholders were unanimous in their assessment that the STAR initiative created distribution channels and created platforms for populations that would otherwise not have access. For instance, by reaching into male-dominated sectors such as the military, police clinics, construction sites, and mines, and including secondary distribution to their family members, (PSI, 2020), STAR increased access to HIVST for men (SA KII5). Some stakeholders noted that they would like to see Unitaid expand this key populations approach to other technology grants and described STAR as a best practice in equity-oriented evaluations.

Sustainability

This evaluation found that STAR Phase 2 **largely achieved** its objective for sustainability. The project created an enabling environment for scale-up of HIVST in project countries by building national

capacity and making significant progress in developing regulatory systems to support self-testing implementation in each country with legacy impacts for other health products.

Table 9. Key Informant Quotes Related to Sustainability for STAR Phase 2 Evaluation (2021)

Country	Theme	Quote	Source
All	Tension between rapid implementation and transition to government	"If you want to go slow go together if you want to go fast, go alone"	FGD3
Zambia	Capacity strengthening	*"The beginning is very difficult when starting a new program. For HIV self-testing STAR provided the support to the government. Today the government is stronger, and we can attribute that to STAR"*	KII12
Malawi	Securing funding Supply chain management	*"Initially the kits were being brought in using STAR but later on MOH actively started procuring using global funds as well as their resources, that pointed to commitment. All that applies to support procurement, sustainability, I think the will has been there."*	KII18
Malawi	Scale-up readiness	*"By the time we were concluding for Phase 2 Malawi already had a policy and guideline for scale up they were approved and in place. The M&E tools were integrated into the system, we were also in the process of integrating and forecasting and supply chain system...Global institutions started supporting trading for government distributors across the country to ensure that self-testing is integrated."*	KII18
Zambia	Government ownership	"One important thing is the government ownership, life became easier for Zambia when the government supported it, the Permanent Secretary there at the beginning of phase two to support the country."	KII12
Lesotho	Sustainable transition	*"Sustainability will be a bit difficult without further inputs"*	eS KII3

Evaluation findings indicate that the STAR project strengthened the capacity of governments to scale up self-testing and contributed to an enabling global environment for its scale-up. The project attained stronger partnerships among global actors in the self-testing sector through communication and advocacy of evidence generated by the consortia. Through STAR Phase 2, key policies and tools were developed to uphold the continued scale-up of the initiative. Respective countries instituted policies and strategies such as the self-testing toolkit, cost operational plan, integration into a national testing algorithm, and transition strategy. For countries such as Zimbabwe, self-testing received specific funding through PEPFAR and similar mechanisms.

Furthermore, the project ensured that supply and delivery mechanisms at various ministries of health were strengthened by ensuring that HIVST forecasting was integrated into national HTS forecasting processes. In addition, STAR Phase 2 was successful in creating access for national procurement and supply management systems at all levels to procure recommended WHO quality assured HIVST kits.

Much of STAR's success has been in multiple community-based distribution models; however, as previously discussed there were concerns that national governments and donors plan to focus primarily on scaling up facility-based HIVST. While partners do have intentions to distribute through community-based partners and networks, there is a reluctance to relinquish control due to "the yield mantra", that all test results should be captured as data and all testers should be accessible for follow-

up services. Furthermore, in the case of national governments their resources are primarily deployed and managed in health facilities or mobile clinics. These restrictions obstruct the full intended purpose of HIVST to reach reluctant and elusive populations, provide a testing option that allows people to take control of their health with anonymity and confidentiality.

Ultimately, health systems, policy, inclusion of HIVST into national budgets, concept notes, and funding applications all show that national governments have strongly endorsed HIVST, see its value, and have been able to fast-track it into mainstreamed systems. Unitaid was appreciated among partners in terms of providing global policy and systems support (eS KII2). This will have a high and lasting impact, even if not at the level achieved by STAR. Although STAR commodities were appreciated and catalytic, other major global partners will be able to provide commodities, along with human resources for basic delivery models. HIVST, when used as a test for triage, also has the potential to reduce costs and save time for the health delivery system and end-users. HIV self-testing's contribution to closing the testing gap is viewed as critical for achieving the global HIV treatment and prevention goals, including the United Nation's (UN's) ambitious 95-95-95 targets by 2030.

Enabling Environment for Scale-Up

As part of STAR, PSI and Unitaid supported the formation of vital technical working groups within ministries of health and developed a transition matrix that greatly improves project sustainability. Towards the end of the STAR program, stakeholders reported that additional partners were providing ongoing support to ministries of health using the STAR models of distribution for HIVST. Some country-level stakeholders also reported seeing a successful transition directly to ministries of health to scale up HIVST.

> *"The project was supposed to be designed with the Ministry of Health because researchers come up with ideas but cannot work within the health system."* -- KII10

The catalytic approach of the project and the technical working groups engaged the government throughout the process of design, planning, implementation, monitoring and evaluation. The project ensured that there was a deliberate alignment with the national health systems from working with MoH staff to influencing policy change at national and sub-national levels. Through the use of distribution models (outlined in Annex 9), the project built a value-add case to the already existing HIV testing strategies in the respective countries. STAR also enabled system strengthening through supply chain management improvements and the supply of HIVST kits. Policies on supply chain management, monitoring and evaluation, integration into the national testing algorithm, and cost operational plans were all a part of ensuring that government health systems were strengthened. Although the extent to which these models are sustainable in the respective countries varies, the project catalyzed the need to scale up HIVST. As a result of this interaction, governments have been able to institute elements of self-testing in their national health system. Furthermore, the project contributed to filling in the HIV testing gap and eased the burden on the health system in terms of human resources required to undertake conventional HIV testing.

This success did not come without challenges. Some governments found it difficult to supplement and sustain these project efforts without ongoing funding. It was also indicated by some respondents that the transition process was abrupt and might have required a bit more time to harness the gains of the project. For example, there was a concern in Zambia that not enough effort was drawn in the direction of strengthening the monitoring and evaluation, data, and knowledge management at the MoH. This was generally perceived as a weakness of the project across other countries too. To a large extent, this is due to inadequate staff at ministries of health to take up such functions as opposed to their level of technical capacity.

Furthermore, challenges related to the tracking of individuals who have used HIVST kits were stressed by respondents from the government. It was mentioned that, unlike the traditional testing processes, HIVST made it difficult to loop individuals into the continuum of care and prevention. This challenge was juxtaposed by the fact that the initiative could reach people who were not coming to health facilities to test. An international respondent in health systems support observed that:

> "*HIVST needed to prove itself and hasn't yet – it remains a more expensive, less reliable test in a world of restrained commitment to testing*." - SA KII2

Scale-up through the private sector

Some stakeholders also felt there were many missed opportunities to engage the private sector in creating an enabling environment. STAR engagement with the private sector focused on pharmacy distribution and a successful partnership with the Pharmacy Council in South Africa. There was also an excellent innovation demonstration with a private-sector workplace wellness provider in the mining and construction sectors in South Africa, showing the potential for distribution in employed, male-dominated industries, where people have minimal access to public health facilities.

These examples highlighted the potential for HIVST to be far more widely promoted in the private sector, such as through private health insurance or 'Medical Aid Schemes', into the state National Health Insurance systems, across all pharmacies, into workplace wellness programs of male-dominated industries, and through private sector health providers. These spaces were under-represented in the STAR range of innovations, and have the potential for marketing, partnership, and promotion going forward and will be further explored in Phase Three.

Whether in a workplace setting, clinical space, or community-distribution, once established, HIVST should be integrated into comprehensive primary healthcare services. Coherent initiatives support self-care, and integrate mental and physical health, health promotion, harm reduction, monitoring, and support for HIV and other chronic conditions (SA KII5).

Building national capacity

Support in the creation of policies, systems, and guidelines was appreciated and institutionalized in all countries. Capacity building was described as highly effective in eSwatini, for example, where MoH leaders received training from Phase 1 partners in Zimbabwe and were supported through a secondment to establish HIVST systems in the MoH.

> *"HIVST is now in the National Strategic Plan and the health sector strategy plan and is being programmed within all those policies. There are training materials, SOPs and guidelines. They took us [MoH] to many workshops and training, and allowed us to work, present at workshops and learn from other countries. They did a lot. We learned. We were part of the team." -eS KII*

This appreciation was also noted in Zimbabwe, Zambia, and South Africa, where capacity gaps were identified, and guidelines developed to integrate HIVST in the public health system.

At the project country level, presentations were held to review other implementers' models of implementation, and STAR project implementers had opportunities to inform national implementation and policy development, as well as how other people work around self-testing. STAR Phase 2 contributed to readiness for scale-up in project countries. Project teams supported government and CSOs to not only develop HIVST policy but also improve supply chain management and forecasting.

Prior progress varied widely between countries when STAR Phase 2 began. eSwatini had placed a ban on the distribution of HIVST pending a more convincing rationale but had engaged with MSF on the

potential of HIVST (eS KII2, eS FGD2). South Africa had already worked closely with WHO and CHAI and HIVST was mentioned in the national HTS policy and WHO product QA guidelines had been adopted (SA KII1). The concept was largely new for Lesotho at the start of STAR and gaining access and momentum in government was slow (LO FGD1).

STAR supported excellent achievements in terms of policy and officially endorsed national roll-out in all six countries (PSI 2020a). In Malawi, a range of policies and guidelines had been embedded in state systems. eSwatini was able to establish a policy endorsed by MoH and parliament, integrate HIVST into the Central Medical Stores distribution system, and roll out HIVST in facilities while authorizing it for community distribution (eS KII3). In South Africa brief mention of HIVST in the national HTS policy was expanded into detailed guidelines with STAR support, with CHAI being an ideal consortium partner to continue work they had already been involved with (SA KII1). In Lesotho, the introduction of HIVST is credited to STAR, but the development of government systems for continuity, supply, and management was relatively weak, although STAR was not seen to contribute to recovering flagging Global Fund commitment to HTS in the country, with HIVST being included in the next Global Fund grant. (LO KII1).

Where research agencies developed expensive or complex systems, these were unlikely to be taken over by the government. Even where national governments stated that an approach was not of interest, there was a tendency to explore methods out of academic rather than pragmatic interest. While valuable for learning, these approaches were not designed for sustainability. In one example:

> "*The mhealth – online tool will not be sustained. It caused a lot of problems. It is still part of systems that will try to transition to NDoH (MoH) but will die a horrible death. The moment we transition it to NDoH it will gather dust. It should have been cheaper and integrated, or better yet, put money into what the department already has and improve that."* - SA KII9

Regulatory systems

For all countries, support to regulate HIVST commodities was provided and greatly appreciated (LO FGD1), and progress was seen towards developing product regulation standards and systems for all health products. Malawi, South Africa, Zambia, and Zimbabwe now have fully functional regulatory frameworks and systems with clarity concerning roles, responsibilities, and communications with significant legacy impact beyond STAR. (PSI 2020a). Prior to STAR, unregulated and non-quality assured products entering the market through pharmacies was a concern for all countries.

> *"Pharmacies were selling non-qualified kits and they were removed from the shelves. We worked to establish a regulatory body."* - LO FGD1

With STAR support, access to WHO-approved kits has been largely mainstreamed (SA KII1). LSTM supported existing or developing regulatory mechanisms to integrate and approve HIVST commodities and assisted work with Pharmacy Councils to reduce unregulated products on the market. Unitaid may want to create metrics related to this work, such as quantifying unlicensed products before and after interventions, to further expand this best practice to other grants.

Progress in regulatory systems was incomplete in Lesotho and eSwatini by the end of STAR (LO FGD1). Incomplete regulatory systems were attributed in some part to the rejection of no-cost extensions (eS FGD1). PSI's 2020 report states that ongoing support from WHO and the Pan African Harmonization Working Party on Medical Devices (PAHWP) for finalization of regional medical device regulations and a post-market surveillance system has been agreed (PSI 2020a).

Procurement and supply chain support

One of STAR's unique contributions and critical investments was to improve supply chain management. Overall, most respondents were very appreciative of the sustainable systems that were built to improve procurement and supply chain for new technologies in the six countries and identified this as a catalyzing intervention. Sustainability in procurement and supply chain support was largely achieved in all countries, although areas for improvement were noted in Lesotho, where key informants felt that PSI focused on implementation, which could have been provided by various other partners, but failed in supporting supply chain systems, which was seen as their niche offering (LO KII1).

> *"STAR ended when [MoH supply chain] was about to get going. I was expecting more support for some time to make sure that we have a smooth flow during transition to be sure we will be able to sustain the program."* - LO FGD2

Quantification, M&E, and data management

Inclusion of HIVST data into both supply forecasting and health information systems has been a challenge in South Africa, Lesotho, and eSwatini. eSwatini Central Medical Stores has mainstreamed quantification and will manage commodities to be provided by PEPFAR and the Global Fund, as well as more niche HIVST distributors such as MSF. Systems are sufficiently established and have enabled a coordinated, centralized system to be established. In Lesotho, support has been minimal, and procurement services remain without tools or data on quantification and do not have basic systems for calculating needs, stock, and distribution systems (LO KII1). Substantial TA is still needed for effective adoption of HIVST into a functioning system. In South Africa, HIVST public sector commodity supply has been seamlessly integrated into existing procurement and supply chain systems, and STAR's support to collated programmatic data during the project was invaluable. For the purposes of the national government, the data received in South Africa were ideal for the investment case, procurement inputs, and analysis of the HIVST roll-out.

In many countries, the STAR monitoring and evaluation system was not viewed as compatible with national health information systems (NHIS), although this was not seen as a shortfall by any of the country respondents (SA KII1). STAR data was more granular than national health information systems (LO FGD2), and sufficient data were being integrated into national systems to monitor HIVST contribution to overall testing rates. In South Africa, for example, the only NHIS indicator collected is the total number of people tested by any method, with HIVST now included in the HTS register which captures these statistics (SA KII9). While partners themselves may desire distinct operational data for their purposes, the STAR combined offering meets the needs of the national program (SA KII1). Concerns remained from global stakeholders that equity-oriented disaggregated data that ensures key populations are reached may not be sustained.

KPI 3.1 Securing Funding

This evaluation found that Unitaid's KPI 3.1 was **fully achieved** with respect to project countries as outlined in Table 13 from PSI's 2020 Transition Report.

Table 10. Funding Security, by Country (PSI, 2020)

Country	Inclusion of ST-specific funding in grant documents and/or in the national medium-term expenditure documents
eSwatini	Nearly 450,000 HIVST kits were procured between PEPFAR, the Global Fund, and CDC for use by June 2021.
Lesotho	The Global Fund and PEPFAR procured over 240,000 HIVST kits by Quarter 3 2019.
Malawi	Global Fund and PEPFAR contributed 1.5 million HIVST kits from September 2019-June 2020.
South Africa	Global Fund, PEPFAR and the National Department of Health have all made commitment to procuring HIVST kits to be made available by Quarter 3 2020 (exact figured are unavailable).
Zambia	Nearly 1.3 million HIVST kits were procured by the Global Fund and PEPFAR for 2019.
Zimbabwe	The Global Fund and PEPFAR procured 9.3 million HIVST kits (exact dates not available).

The fact that governments have secured funding through the Global Fund and PEFPAR for HIVST, and through treasury in South Africa, shows a high level of commitment and sustainability for the principle of HIVST as a component of the HIV response.

> *"In less than 18 months we were able to convince the government that HIVST works. We had an investment case and the fiscus (National Treasury) is itself procuring test kits. That was a major win"* (SA FGD1)

Innovations within facilities will be sustained and will increase testing rates somewhat (about double), with greater uptake by men and adolescents with easy access. There have been sustainable gains, and they are valuable. These gains fall a long way short of the dream of access for those who have never tested, do not go near facilities, have distance or work-time restrictions, or do not receive normal health marketing. STAR showed that they could be reached more than ever before, but this level of innovation may not be sustained by those funding HIVST into the future.

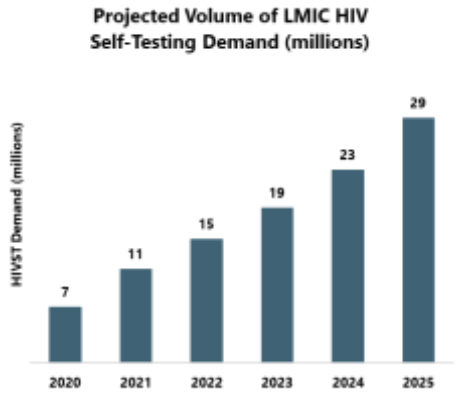
Securing global funding beyond the Phase Two project countries remains a key aspect of STAR Phase Three. Although HIVST is not intended to replace traditional testing, only 2.5% of PEPFAR's US$80 million for HIV testing in 2021 is in HIVST, demonstrating that substantial gaps in global scale-up funding remain (PEPFAR COP21).

KPI 3.2 Scaling Up Coverage

This evaluation found that Unitaid's KPI 3.2 on scaling up coverage was largely achieved. In project countries, all national governments have expressed an interest in providing targeted HIVST through their facilities. Political support at the highest levels greatly enhanced STAR's success in Lesotho, eSwatini, Zimbabwe, Zambia, Malawi, and South Africa. Parliament, Treasury, and top-level MoH have backed HIVST, and guideline approval and/or budget authorization provides a strong basis for scale-up and national adoption in Lesotho, eSwatini, and South Africa (eS KII3, SA KII8, LO FGD2).

Figure 8 displays the number of HIVST available in the six project countries and all LMICs.

Figure 8. Total LMIC HIVST Demand (WHO, 2020)



The HIVST Market is expected to grow at a Compound Annual Growth Rate of around 37.3% between 2020 and 2025 (PSI, 2019) and 90% of the estimated global LMIC demand will come from the 25 Focus Countries (PSI, 2019). Due to STAR interventions, a total of 135 countries are eligible for a significant price reduction in relation to the HIVST blood-based products market intervention, 2021 (under Unitaid classification). These 135 countries include 78 LIC; 47 UMIC; and 10 restricted countries.

The main limitation to impact is that ongoing scale-up is unlikely under either MoHs or PEPFAR and will depend on other motivated funders, the private sector and consortium of partners entering the arena. With most of the advantages in terms of accessibility being achieved through innovative and determined community distribution, the potential HIVST is unlikely to be realized unless concerted efforts are made to reach hard-to-reach people, in hard-to-reach places. This level of accessibility was partially explored by STAR and is unlikely to be deepened without a committed global partner. With a strong preference for proven linkage and facility-based distribution by ministries of health and PEPFAR, community distribution is only likely to continue as a relatively small proportion of future HIVST in all countries, despite innovation and reach into remote and under-serviced populations depending on these modalities.

Lessons Learned

In addition to the major successes that the STAR Initiative has had since its inception, this evaluation aims to provide recommendations and lessons that can be adapted to other projects. Throughout the findings section of this report, the evaluation team has highlighted learnings from STAR themed according to the OECD DAC evaluation framework and Unitaid's KPIs. This section aims to provide a summary of key lessons learned for Unitaid to examine and adapt when implementing future projects, as well as the completion of STAR Phase 3.

Project Inception: One of the key lessons learned during Phase 2 implementation was the importance of mapping out key stakeholders during the planning stages to enable the platform to engage with those outside the STAR consortium of implementers. The inclusion of other key partners leveraged support from the wider HIV response players. By engaging the national government in some countries during project implementation, the project avoided resistance and fostered positive working relationships with national stakeholders, seen as essential to transition. Governments in Zimbabwe, Malawi, and Zambia adopted HIVST activities and pledged to take steps that would enable its inclusion into the health system. STAR crucially involved the national ministries of health at the programmatic level where policies and national reporting systems are developed.

Phased implementation was also cited as a major success of the STAR initiative. By starting with Phase 1 to prove usability, feasibility, and acceptability, project implementers were able to move quickly into Phase 2 to implement HIVST. There was a significant rippling effect with implementation being phased in six specific countries and then further scaled beyond those six in Phase 3.

> *"[It was] The perfect storm of getting HIVST products introduced, addressing policy issues, informing guidelines for WHO, [engaging in] country-level policy development… [STAR was able to] very quickly provided the results that stakeholders wanted to see"* -KII 7

Future projects may benefit from a more strategic regional approach to country selection, looking for a balance of regions and countries viewed as leaders who often provide regional technical assistance. Similarly, Unitaid may want to engage national and regional technical partners more explicitly with specific country-level context and experience earlier in their projects.

Consortium and partnership approach: One of the key successes of the project was the early engagement with WHO and the Unitaid investment in dedicated WHO staff time to the project. This was viewed as a highly effective strategy, allowing STAR access to accelerated WHO guidelines, and setting the stage for global scale-up. Similarly, the early engagement with scale-up partners like PEPFAR and the Global Fund was described as a key success unique to STAR. The immense success of the consortium was enabled by a collective impact approach that included a clear agenda with targets, early engagement of all partners, meaningful investment in time and resources convening people together and a true spirit of partnership throughout. While the COVID-19 pandemic may leave the impression that future meetings can be virtual, this would be a missed opportunity to build meaningful trust and collaboration in future projects. The time spent both during and after STAR forum meetings, often aligned to existing academic conferences to keep costs low, was viewed as the "secret ingredient" to the project's impressive success.

Throughout STAR there was collaboration between implementors, policymakers, and research teams as they co-developed the research agenda. High quality, rigorous research was informing implementation and implementation was informing new research. It should also be noted as a lesson learned that this kind of relationship also presents challenges and was perceived by some stakeholders as a conflict of interest. Unitaid should consider creating clear agency level training and guidelines for technical United Nations partners and implementers about co-authorship with external researchers and ensure that existing STAR authorship guidelines and best practices are well communicated to external stakeholders. Similarly, other projects should be actively encouraged to publish null findings, as was done in STAR, and engage in similar open science framework approach to increase trust and transparency.

Strong leadership and gender equity: Multiple stakeholders identified the leadership of women as a unique strength of STAR, which many respondents described as the "powerhouse women of STAR'". The WHO Global Health Workforce Network's Gender Equity Hub has described the global health sector as "delivered by women, led by men" (WHO, 2019). Unitaid may want to identify further gender equity policies across the organization to carry forward the successes of the STAR project to future grants. Similarly, lessons from STAR's work with key populations could be extended beyond STAR to improve agency-wide equity-oriented key performance indicators (KPIs) to reduce inequities related to age, gender, socio-economic status, and ethnicity to further catalyze their strategic goals.

M&E and reporting: Given their strategic interest in sustainability, Unitaid may want to develop more consistent quantitative metrics related to product distribution and supply management across grants such as stock-outs, expired products, and percentage of consignments delivered on time in full (OTIF) with clear delivery date benchmarks. These could be aligned with scale-up partners to assist with

transition. Similarly, it seems the STAR project was a sector leader in delivering an equity-oriented approach to reach the most underserved populations. Unitaid may want to identify key health equity performance indicators including clear expectations for funding applications and grants to report on disaggregated results and differentiation of unique subgroup needs (age, gender, ethnicity, rurality, etc.). Another area of challenge identified was the need for a relatively small HIV testing pilot to demonstrate country-level impact related to HIV treatment and retention in care. Overall, as a funder, Unitaid must decide if they are an innovation agency that permits experimentation and failure or a bridge to scale up focused on impact. It is hard to do both successfully.

Regulation, Quality, and Safety: While STAR clearly demonstrated that HIVST could be implemented safely during trial conditions, several important post-market safety and quality assurance questions remain. An area for growth for Unitaid includes ongoing quality assurance or careful handover of this area to a relevant scale-up partner with follow-up. Similarly, a significantly large supply of unsafe and illegal HIVST products was found in some countries and this was noted as an area of intervention piloted by the STAR project that could be analyzed more systematically. Future technology grants could include an audit of unsafe products pre- and post-implementation to ensure regulatory systems include an ongoing post-market auditing and enforcement arm. Quality improvement should be seen as an ongoing, iterative process, not as a KPI that can be dropped after one phase but rather built into every phase of a project.

Dissemination of evidence, information, and data: Global stakeholders largely reported that there was continuous interaction with partners, ample sharing of pros/cons, and failures/successes of the project in a transparent manner. Stakeholders reported feeling that all levels of stakeholders were welcome and encouraged to participate and share openly.

> *"The information flow [throughout the implementation of STAR Phase 2] was superb...and we were proactively informed about what was happening"* (FGD1)

This level of effort to support knowledge translation, convening forums, and open and honest dissemination and effective communication between all partners should be replicated in other Unitaid-funded initiatives, and viewed as a key factor in the success of the project.

Sustainability: From the point of view of many in-country stakeholders, the project was well designed for Unitaid funding to build national capacity and hand over to local stakeholders. Local engagement with national academic institutions and policymakers was seen as a big success for STAR. Some felt that even more local engagement at the provincial, district, and community levels was needed. Others also questioned why Unitaid prioritized transition to scale-up partners instead of working more directly with national governments or local partners, which also applies to all Unitaid funded work, as it is the current model. There may be opportunities for Unitaid to engage in some critical reflection on decolonial approaches to global health and to leverage some of the key best practices from STAR (local research partners, implementers based in-country, direct engagement between Unitaid and government) to further catalyze growth in this area for future grants (Khan, et al, 2021).

Although STAR was not designed to include the private sector, this may be an area of consideration going forward. The transition matrix was also viewed as a useful tool; however, many respondents identified the need to have more flexibility to allow for a smoother transition in different countries and longer bridging funds. When introducing a new program, provincial and district structures may need additional support to ensure that workshop training translates to action. True sustainability can only be achieved by engaging with national governments and the private sector, an area of improvement for many funders to build on. The following section summarized key recommendations

for Unitaid along key themes identified by the desk review, secondary data analysis, modelling review, and qualitative data collection.

Recommendations

The following key recommendations have been themed and analyzed for the agency's consideration in relation to future grants.

#	Recommendation	Who to Implement	Linkage to Findings
HIV Self-Testing			
1	Advocate for sustainability of high-impact community based HIVST models and clearly communicate the equity imperative to scale up funders and national governments**.** Expand partnerships with a wide range of potential scale-up partners, including the private sector, to expand reach and sustainability.	Expanded partners or implementing agencies with various conditions and monitoring systems, as well as established scale-up partners; Unitaid Senior Leadership & Unitaid Board	It was reported that scale-up partners would be more likely to continue to provide funding for facility-based distribution models of HIVST, through select partnerships with NGOs, using established yield and linkage conditionalities, in selected priority districts. MoHs would scale up exclusively from facility-based test sites and their linked outreach or mobile services. There is a risk that hard to reach, reluctant target populations who insist on confidentiality would be missed without a range of flexible models. There was limited exploration of partnerships with the private sector, which was reported as a missed opportunity for STAR Phase 2.
Funding & Grant Management			
2	Streamline funding approval processes and limit layers of approval to improve timely replies to grantees. Ensure grantees have adequate autonomy for adjusting plans with limited bureaucracy in keeping with a catalytic, innovative granting agency.	Unitaid Secretariat, Senior Leadership and Project Management Teams	Grantees lost implementation time due to slow approval of project budgets or changes, particularly where approvals went through multiple intermediaries. While funds were intended to be flexible, in practice there was substantial room for improvement in flexibility to adapt, innovate and adjust plans and associated budgets.
Monitoring & Evaluation			
3	Scale up novel approaches to monitoring impact (such as forecasting and community level monitoring) to ensure metrics don't stifle innovation and that they promote access to HIVST, rather than obstructing it. Develop evaluation frameworks that allow for increased experimentation and risk taking.	Unitaid M&E Team. Implementing agencies with various monitoring systems, as well as established scale up partners	Some stakeholders were very interested in being able to prove linkage to care or preventative after distribution of HIVST. While valid for some users, for many this lack of confidentiality ultimately limits the intervention and fails to engage hard-to-reach populations. Individual follow-up and unique patient identifiers may apply to a biased sample of users. Monitoring at area or population-level against distribution and uptake would triangulate and/or compliment individuals metrics. Similarly, partners wanted to be able to transparently measure failed innovations to celebrate experimentation (for instance, models piloted and abandoned).

4	Leverage equity lessons from STAR and improve agency wide health equity key performance indicators (KPIs) to better reflect strategic objectives, including clear expectations for grants to report on disaggregated results and differentiation of unique subgroup needs (age, gender, ethnicity, rurality, etc.)	Unitaid M&E Team and Secretariat	Need to develop an agency wide equity framework with more extensive metrics beyond "serving the poorest and underserved" and support innovations with the private sector and with other nontraditional partners. Ensure metrics don't mask hidden inequities in different geographic, ethnic or gender groups. STAR was seen as a best practice in this area compared to other grants.
5	Develop more transparent quantitative metrics related to supply chain and procurement (e.g., stock outs, expired products, % of consignments delivered on time in full (OTIF)).	Unitaid M&E Team and Secretariat	Grantees were unable to provide key quantitative metrics aligned with other scale up partners to proactively monitor supply chain and build strength in this area prior to transition. Stakeholders reported stock outs and expired product in some countries but high-level metrics were not available.
Catalytic Models			
6	Identify and share lessons from HIVST that could be applied to other self-testing technologies for other diseases: • digital health tools to support patient navigation; • frameworks for identifying right mix of self-testing and provider testing; • focus on regulatory barriers and rigorous research with direct links to WHO guideline process and national policy makers; • Research consortium approach with frequent in-person meetings to build trust among a large network of stakeholders	Unitaid staff, Research Consortium	Between STAR Phase 1 and 2, a tremendous amount of research has been produced about the acceptability, feasibility, cost, and implementation of HIVST in close partnership with key national and global policymakers.
7	Clearly scope and define Unitaid's role in the development ecosystem and review best practices and innovations in catalytic funding models.	Unitaid Secretariat & technical partners	Concerns were raised about a catalytic funder placing so much emphasis on long-term impact and on overly bureaucratic funding structures. Indeed, excessive focus on impact and results, rather than on innovation and context-relevance, would tend towards measurements that can impede program goals.
8	When selecting countries in future consider both disease burden but also qualities of regional leadership and expertise. Fund a mix of different countries in various regions with diverse needs that could clearly catalyze a new technology. Develop guidance for choosing countries for new funders.	Unitaid Project Teams/Secretariat	Stakeholders reported concerns that all countries were in one region (Southern Africa) and that the selection of countries was more opportunistic than strategic. Some respondents encouraged Unitaid to look for countries regarded as regional leaders who typically provide technical assistance in each region for future technology projects.
9	Continue to fund operational research but develop agency guidelines and training to minimize perceived conflict of interest between the funder, UN partners, grantees, implementers, and academic partners. STAR developed project-level guidelines, which could be adapted for future Unitaid projects.	Unitaid Project Teams, UN partners, grantees	UN family, and grantees were co-authors on a large portion of published STAR research, and the majority of this research presented strongly positive results; with strong emphasis on impact. This created a perceived risk of conflict of interest by some stakeholders which sometimes unnecessarily undermined the credibility of the high-quality research.

10	Continue to partner closely with scale up partners, in addition to improving partnerships with national governments, local innovation partners, and the private sector to ensure sustainability.	Unitaid Secretariat, Project Teams & technical partners	MoHs, Global Fund and PEPFAR consistently took responsibility for scaling up across all countries, which is regarded as a significant STAR success. In addition, major NGOs have been able to raise funds to continue programs started in partnership with STAR. A vast range of service providers outside of the STAR network are active and involved and could be encouraged to scale HIVST in multiple ways.

Conclusion

In 2013 and prior to the STAR project, only 55% of PLHIV knew their status when UNAIDS released their HIV elimination strategy. With no effective vaccine or cure, early diagnosis and treatment remain the cornerstone of control efforts as the world aims for awareness of status among PLHIV of 90% by 2020 and 95% by 2030. HIV self-testing has been considered since the 1990s; however, implementation was stalled by concerns over accuracy and potential social harms, including suicide, coercive testing, and intimate partner violence (Corbett, 2021).

The findings of this evaluation show that overall, the aims of STAR Phase 2 were met. STAR funded WHO guideline development, with supportive HIVST guidelines released in Dec 2016 and updated to full endorsement in Dec 2019 (WHO, 2016; WHO, 2019). In July 2017, WHO prequalified the first HIVST kit (OraSure HIV Self-Test) developed with input into instructions-for-use and packaging by STAR partners (Simwinga et al, 2019). This was offered to LMICs for US$2/kit following investment by the Bill and Melinda Gates Fund, with the manufacturer's press release directly acknowledging the role of STAR (Orasure Press Release). Supported by STAR, multiple manufacturers now offer Emerging Markets Small (EXW) prices in affordable ranges (US$2-$1.50) compared to baseline prices of US $40-15 prior to STAR market interventions (PSI, 2020).

STAR is lauded as one of the most successful examples of policy impact by multiple funders (Corbett, 2021). The substantial research investment, including randomized control trials, allowed for strong recommendations to be made by WHO Guideline Development Groups using the GRADE system. STAR was decentralized to allow each country to submit protocols around common research questions and harmonized tools without jeopardizing progress in any other country. Without the emphasis on research and developing supportive policies and regulatory frameworks within STAR it is highly unlikely that HIVST would have penetrated LMICs: in 2015, three years after FDA approved the OraSure In-home kit, sales within the United States were far below expected. Prior to STAR only three high-income countries were actively implementing HIVST services as part of their HIV response, and WHO had no formal position and no mechanism to pre-qualify self-test products. As of July 2020, 45 countries had policy allowing for HIVST, 41 countries had implemented HIVST, and an additional 33 countries had HIVST policy in development[5]. From a handful of tests in 2013, over 8,482,700 test kits have been procured in 25 different LMICs in 2021 (WHO, 2021). As of 2020, three of the six STAR Phase 2 countries have met the 90-90-90 testing and treatment targets (Zambia, Zimbabwe, and eSwatini) and one country is very close to doing so (Malawi). In South Africa and Lesotho, there is still progress to be made towards these targets and looking ahead to the 95-95-95 targets by 2030 (UNAIDS, 2020). These gains have been made by many projects working in close collaboration to save lives, of which STAR is an important contributor.

HIV remains a leading cause of death globally and early diagnosis is crucial to linking patients to treatment, prevents deaths, and onward transmission. The STAR initiative provided rigorous scientific evidence combined with innovative knowledge translation and collaboration to catalyze HIVST and enabled novel delivery strategies. STAR demonstrated that HIVST was safe, accurate, often preferred, and could be cost-effective, and even cost-saving, in the right delivery models and right contexts due to increased uptake of HIV treatment. The COVID-19 pandemic has created an urgent need for community-driven solutions that can be implemented outside the strict confines of health care services. Beyond HIV, STAR has catalyzed growth in self-testing and increased faith in community-owned solutions to complex diagnostic problems.

[5] Out of a total of 194 WHO reporting countries.

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Annexes

Annex 1. OECD Framework Table

OECD DAC Evaluation Criteria	Unitaid KPI	Evaluation Questions	Sub questions
Relevance: is the intervention doing the right things?	n/a	To what extent did the objectives & design of STAR respond to the needs of...	...key populations?
			...men and young people?
			...community and civil society orgs?
			...government/national health systems?
			...scale-up partners?
		Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context?	Policy level
			Emerging/competing technology
		To what extent has STAR design and implementation identified and addressed issues using innovative global market-based approaches?	Issues related to gender
			Issues related to social inclusion
			Issues related to equity
Coherence: how well does the intervention fit?	n/a	To what degree does STAR fit with other HIV testing, linkage and prevention initiatives?	In the target countries
			In the target sectors
			In the target institutions
		To what extent is STAR adding value (and not duplicating efforts or establishing parallel systems)?	
Efficiency: how well are resources being used?	n/a	How timely was implementation?	
		How cost-efficient was implementation?	
		How cost-effective was implementation?	

		What factors have been considered to ensure that value for money has been achieved from an efficiency standpoint?	
		Was the funding allocation/split to cover commodities/supplies versus other costs efficient to achieve project objectives?	What best practices could be learned for similar grants in the future?
		How well did the grant implementers collaborate with national authorities and each other to promote integration into existing health systems?	In project planning?
			In implementation?
			In assessment?
Effectiveness: is the intervention achieving its objectives?	KPI 1: Catalyzing Innovation KPI 2: Overcoming Market Barriers	To what extent did the STAR Initiative achieve its objectives and expected outcomes in addressing targeted access barriers within the specified timeframe and budget?	Affordability: To what degree has the STAR Initiative contributed to making HIVST products available at lower prices that are affordable for governments and other donors?
			Demand & Adoption: What progress did the STAR Initiative make in facilitating increased demand and uptake for scale- up of cost-effective HIVST products within target countries and beyond?
			Supply & Delivery: To what extent did the AfI/grant improve supply and delivery systems to ensure that products reach those in need in a reliable and timely way?
		What were the main factors influencing the achievement or non-achievement of the intended outputs or overall outcomes?	
		How was the implementation approach effective on promoting global policy adoption and country adoption in project and non-project countries?	
		How effective was the implementation in driving and catalyzing the global market and supply in terms of volume, diversity and prices?	...in terms of volume?
			...in terms of diversity?
			...in terms of prices?
		How effective were the delivery models and which ones have been well integrated into existing health system and what best practices can be learned from the process?	

Impact: what difference does the intervention make?	KPI 4.1: increasing public health impact KPI 4.2: Generating efficiencies and savings KPI 4.3: Delivering positive returns KPI 5.1: Investing for the poorest KPI 5.2: Investing for the underserved	To what extent has the STAR Initiative generated, or is expected to generate, global/national-level effects across Unitaid's four dimensions of impact?	Public health impact
			Economic impact
			Equity
			Strategic benefits and positive externalities
		What is the estimated contribution of the HIVST on closing the testing gap?	90-90-90 targets for 2020?
			95-95-95 targets for 2030?
Sustainability: will the benefits last?	KPI 3.1: Securing funding KPI 3.2: Scaling up coverage	How has the STAR Initiative contributed to an enabling global environment for scale-up with regard to generating...	...evidence?
			...normative guidance?
			...affordable pricing?
			...tools to support country adaptation?
			...uptake and advocacy?
			...stronger partnerships among global actors?
		To what extent has the STAR Initiative helped established country readiness for scale-up with regard to...	...securing ongoing political and financial commitments by national governments and other partners?
			...supportive policies and enhanced health system capacity for delivery?
			...partnering with communities and civil society to mobilize ongoing community demand and engagement?
		To what extent have core elements of the intervention been transitioned to ensure that the benefits of the intervention will continue beyond the life of the investment?	
			Have lessons learnt been widely disseminated by grantees?

		What have been the lessons learned and how have they been incorporated in the lifetime of the grants or across other interventions?	Have lessons learnt been widely disseminated by Unitaid?
		How effectively have strategic, implementation and sustainability/scalability risks been identified and managed over the course of implementation	

Annex 2. Detailed Key Informant Interview & Focus Group Discussion List

Organization type	Country (if applicable)	Method	# and gender
Research	global	KII	1 Female
Research	global	KII	1 Male
Donor	global	FGD	2 females
Donor	global	FGD	2 females
Donor	global	KII	1 Female
Implementer	global	KII	1 Female
Implementer	global	FGD	3 males 1 female
Donor	global	FGD	5 females 2 males
Donor	global	FGD	2 males 2 females
Donor	global	FGD	2 females
Donor	global	KII	1 male
UN	global	FGD	2 females
Manufacturer	global	KII	1 male
Implementer and Consortium Partner	South Africa	KII	1 male
Implementer and Consortium Partner	South Africa	KII	2 females
Government	South Africa	KII	1 female
Government	South Africa	KII	1 female
Coordinating structure	South Africa	FGD	3 females
Implementor	South Africa	KII	1 female
Implementer and Consortium Partner	South Africa	KII	1 female
Implementor	South Africa	KII	1 female
Community representatives	South Africa	Voicenote	1 female
International partner agency	South Africa	KII	1 male
Coordinating structure	eSwatini	FGD	5 females 4 males
Implementer and Consortium Partner	eSwatini	KII	4 females 2 males
Government	eSwatini	KII	1 male
International partner agency	eSwatini	KII	1 male
Community representatives	eSwatini	KII	5 females 3 males
Government	Lesotho	KII	1 male
Government	Lesotho	FGD	3 females 1 male
Implementer and Consortium Partner	Lesotho	FGD	3 females 1 male
NGO	Zambia	KII	1 female
Research	Zambia	KII	1 female
Policy Maker	Zambia	KII	1 female
UN/WHO	Zambia	KII	1 male
NGO	Zambia	KII	1 male
NGO	Zambia	KII	3 males 1 female
Community	Zambia	FGD	3 male 2 female 1 TG
Research	Zimbabwe	KII	1 female
Government/policy maker	Zimbabwe	KII	1 male
Research	Zimbabwe	KII	1 female
NGO/Implementer	Malawi	KII	1 male
Research	Malawi	KII	1 male
Government/policy maker	Malawi	KII	1 female
NGO/Implementer	Zimbabwe	KII	1 male
Community	Malawi	FGD	4 females 2 males
Research	global	KII	1 female
Donor	global	KII	1 male

Annex 3. Key Informant Interview Guide

Introductory welcome: Thank you for agreeing to meet with me/us. I am here collecting information for an evaluation of Phase 2 of the Self-Testing AfRica (STAR) Initiative, implemented in South Africa, Zambia, Zimbabwe, Malawi, eSwatini and Lesotho. The period which will be evaluated was implemented from August 2017 to July 2020 in the six previously mentioned countries. The objectives of the evaluation are: To consolidate knowledge on good practices with regard to Unitaid's implementation of Phase 2; and to provide Unitaid with an assessment of the overall success of the projects and lessons learned with focus on what the contribution of HIVST has been on closing the testing gap.

I am interested to learn about how self-testing was designed and agreed in this country, how it's being implemented and how the delivery of services is being monitored. The information gathered will be used to inform Unitaid's future investments. This evaluation will take place from February to April 2021, with an Evaluation Report as a final deliverable.

We appreciate your presence in our discussion. Please understand that your involvement in this discussion is purely voluntary and that you can end this meeting at any time. You do not have to answer all questions, but it will help our work greatly if you share your thoughts, opinions and experiences regarding our questions on implementation of the HIV self-testing initiative. We may choose to audio record this session for our own records but understand that nothing you say in this discussion will be attributed to you in our report and all comments will remain anonymous. Do you understand and agree to participate in this discussion?

Do you have any questions for me at this stage? Shall we begin?

1. Please tell me about the role you have played or continue to play in relation to HIV self-testing or the STAR project?
2. Can you tell me about any key successes that have occurred as a result of the STAR project?
3. Can you tell me about any challenges that have occurred in the STAR project?

Relevance

4. To what extent is the STAR initiative doing the right things? (Probe: is it meeting the needs of communities? Government? Is it filling testing gaps? Have they course corrected and adapted?)
5. To what extent has the STAR project's design and implementation addressed barriers to HIV self-testing to reach the most disadvantaged populations in developing countries? (Probe issues related to gender, social inclusion and equity)

Coherence

6. To what degree does STAR fit with other initiatives? (Probe – what other initiatives – HIVST? Other HIV testing initiatives? PrEP initiatives?
7. To what extent is STAR adding value (and not duplicating efforts or establishing parallel systems)?

Efficiency

8. How well are project resources being used? (probe: value for money, efficiency, timeliness, cost effectiveness) Was the funding allocation/split to cover commodities and supplies versus other costs efficient to achieve project objectives? What best practices, if any, could be learned for similar grants in the future?
9. How well did the grant implementers collaborate with national programs and other consortium members to promote integration into existing health systems?

Effectiveness

10. Is the intervention achieving its objectives to catalyze innovation in self testing?
11. What were the main factors influencing the achievement or non-achievement of the intended outputs? (Probe as needed on each:
    1. Supportive environment for introduction and integration of HIVST is established in national policies, strategies, plans and regulations.
    2. Selection, adaptation, and scale-up of effective HIVST and linkage models.
    3. Evidence dissemination and resources to support transition and scale-up identified and mobilized.
12. What were the main factors influencing the achievement or non-achievement of the project's outcome goal to increase access to HIVST, prevention and treatment?
13. How was the implementation approach effective in promoting global policy adoption and country adoption in project and non-project countries?
14. How effective was the implementation in driving and catalyzing the global market and supply in terms of volume, diversity and prices?
15. Which delivery models have been well integrated into the existing health system and what best practices can be learned from the process?

Impact

16. What difference did the STAR intervention make? (Probe: Increasing public health impact; Generating efficiencies, Investing for the poorest and the underserved)
17. What is the contribution of the HIVST on closing the testing gap? (Probe: 90-90-90 targets for 2020? 95-95-95 targets for 2030?)

Sustainability

18. How has the STAR Initiative contributed to an enabling global environment for scale-up? (Probes: generating evidence, normative guidance, affordable pricing, tools, stronger partnerships among global actors?)
19. To what extent has the STAR Initiative helped established country readiness for scale-up? (Probes: securing ongoing political and financial commitments, supportive policies, enhanced health system capacity, partnering with civil society to mobilize ongoing community demand?)
20. To what extent have core elements of HIVST been transitioned to ensure that the benefits of the project will continue when the funding ends?
21. What kind of lessons have been learned in the implementation of this project/scale-up of HIVST? How have these informed other interventions/grants/programs?

22. How well has this project managed risks? (probe for strategic, implementation and sustainability risks, diversion, wastages and other losses due to supply and delivery inefficiencies)

WRAP UP

23. What are some key lessons that can be passed on to other similar projects or to Phase 3?

Thank you for your time.

Notes from KI interviews should be entered into separate Word documents, using a coding system, such as KI1, KI2, etc. for filenames. The names and titles of KIs should be kept on a handwritten page in a notebook or elsewhere, together with the code for their interview. In this way, if a computer is hacked, there is no way to attach the words of KIs to their names.

Annex 4. Focus Group Discussion Guide

Introduction

Hi, I'm from a company called APMG Health and I'd like to thank you for participating today. I am here collecting information for an evaluation of Phase 2 of the Self-Testing AfRica (STAR) Initiative, implemented in South Africa, Zambia, Zimbabwe, Malawi, eSwatini and Lesotho from August 2017 to July 2020.

I am interested to learn about how self-testing was designed and agreed in this country, how it's being implemented and how the delivery of services is being monitored. The information gathered will be used to inform Unitaid's future investments and help improve services.

Please understand that your involvement in this discussion is purely voluntary and that you can leave at any time. You do not have to speak but it will help our work greatly if you speak up and let us know your thoughts on the following questions. Also understand that nothing you say in this group will be attributed directly to you in our report.

Do you understand and agree to participate in this discussion?

Do you have any questions for me at this stage? Shall we begin?

Questions

1. Can you tell us about any key successes that have occurred as a result of the STAR project?

2. Can you tell us about any challenges that have occurred in the STAR project?

Relevance

3. To what extent is the STAR initiative doing the right things? (Probe: is it meeting the needs of communities? Government? Is it filling testing gaps? Have they course corrected and adapted?)
4. To what extent has the STAR project's design and implementation addressed barriers to HIV self-testing? (Probe issues related to gender, social inclusion and equity)

Coherence

5. To what degree does STAR fit with other initiatives (Probe: not duplicating efforts or establishing parallel systems, probe: HIV testing initiatives, PrEP, other linkage and prevention initiatives)

Efficiency

6. How well are project resources being used? (probe: timeliness, cost effectiveness, funding allocations, efficiency, value for money)

7. How well did the grant implementers collaborate with national authorities and other consortium members to promote integration into existing health systems?

Effectiveness

8. Is the intervention achieving its objectives to catalyze innovation in self testing?
9. What were the main factors influencing the achievement or non-achievement of the overall outcomes?
10. How effective was the implementation in driving and catalysing the global market and supply in terms of volume, diversity and prices?
11. How effective were the delivery models and which ones have been well integrated into the existing health system and what best practices can be learned from the process?

Impact

12. What difference did the STAR intervention make? (probe: Increasing public health impact; Generating efficiencies, Investing for the poorest and the underserved)
13. What is the contribution of the HIVST on closing the testing gap? (probe: 90-90-90 targets for 2020? 95-95-95 targets for 2030?)

Sustainability

14. To what extent has the STAR Initiative helped established country readiness for scale-up?

WRAP UP

15. What are some key lessons from the STAR project?

Annex 5. Focus Group Discussion Guide (Community)

Introduction

Hi, I'm from a company called APMG Health and I'd like to thank you for participating today. I am here collecting information for an evaluation of Phase 2 of the Self-Testing AfRica (STAR) Initiative, implemented in South Africa, Zambia, Zimbabwe, Malawi, eSwatini and Lesotho from August 2017 to July 2020.

I am interested to learn about how self-testing was designed and agreed in this country, how it's being implemented and how the delivery of services is being monitored. The information gathered will be used to inform Unitaid's future investments and help improve services.

Please understand that your involvement in this discussion is purely voluntary and that you can leave at any time. You do not have to speak but it will help our work greatly if you speak up and let us know your thoughts on the following questions. Also understand that nothing you say in this group will be attributed directly to you in our report.

Do you understand and agree to participate in this discussion?

Do you have any questions for me at this stage? Shall we begin

Questions for Beneficiaries

1. What HIV testing services are available for your community?
2. (If participants fail to mention any self-testing services, ask specifically about their availability.)
3. What are the greatest challenges faced by your community in accessing HIV self-testing services?
4. Can you provide examples of how these challenges have impacted on your community's daily lives, in particular in access and use of relevant HIV services?
5. How do these challenges compare to those of five years ago? In other words, is it getting easier or harder to access testing and linkage services? In what ways (as specific as possible)?
6. Are self-testing services affordable? Do you have to pay (and how much) for any of these services? What about transport costs? What does it cost to access these services?
7. What do you think of the quality of HIV testing and linkage services? Are there ways they could be improved? Are you able to access other health services and support you need when you need it?
8. Would you like to add something to the topic of today's discussion?

Notes from FGDs should be entered into separate Word documents, using a coding system, such as FGD1, FGD2, etc. for filenames. The place and key population should be kept on a handwritten page in a notebook or elsewhere, together with the code for the FGD.

Annex 6. Modeling Analysis Report

Note: This modeling analysis report was developed prior to May 5, 2021, when the evaluation received updated Impact Calculation Maps for STAR Phase 2 (Unitaid, 2021a).

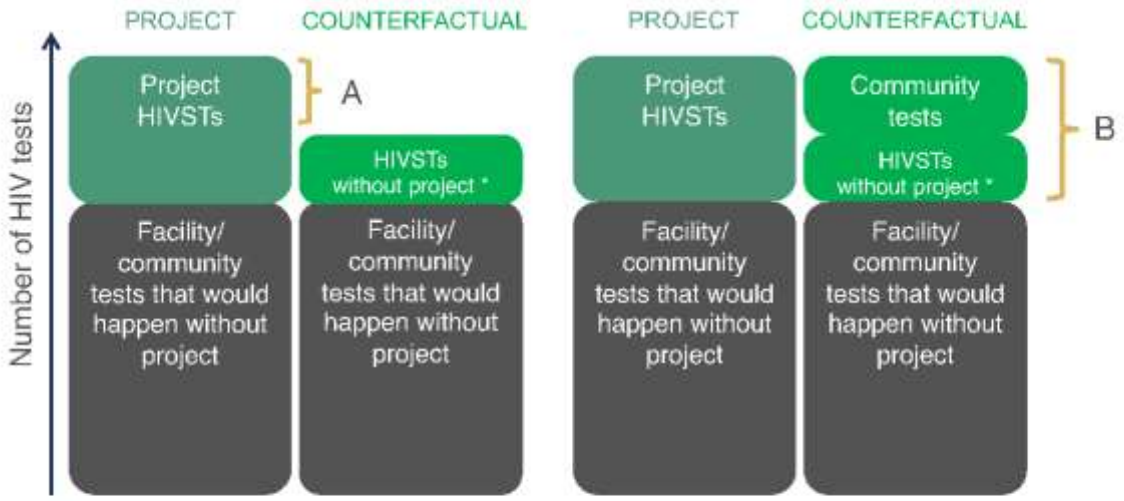
Characterizing the model

In the absence of a single document or report describing the model, we gathered information across several documents and report a summary of this research here. After describing the model, we evaluate the model in section 2.

The model assesses both economic and public health impacts (**Figure 1**). Public health impact was characterized as the added benefit of the tests that were predicted to be procured as a result of the project, compared to the number of tests that would be procured in the absence of the project. Economic impact was calculated as the costs of carrying out the tests procured as a result of the project, compared to the cost of carrying out the same number of tests in the absence of the project (through alternatively procured HIVSTs [HIV self -tests] and additional community-based tests [CBT]).

The first version of the model was completed and reviewed in 2017. In 2019, an updated model was created, reflecting increases in expected funding associated with the project.

Figure 1: How impact was estimated in the model.



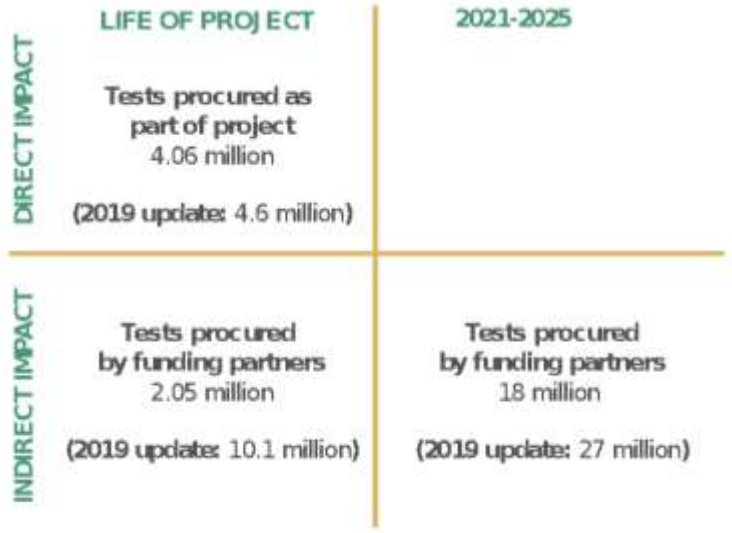
** In the 2019 model, the HIVSTs in the counterfactuals were removed. In the economic model they were replaced with community tests.*

Both the health and economic impact parts of the model rely on several key assumptions. These assumptions are mutually exclusive across models. The exception to this is the volume of HIVSTs in the model, which is central to both the economic and public health calculations. Therefore, before we describe the separate models, we describe how the volume of HIVSTs was modeled.

Estimating the number of HIVST

The number of tests predicted to be procured per country was estimated using the PSI Market Sizing Model[6]. In this 2016 report, the market sizes of several countries were estimated, based on the number of tests required to meet the first 90 of the 90-90-90 target by 2020. Three HIVST scenarios were then developed, of which two were used in the Health Impact Model.[7] In the moderate model, HIVSTs would be offered through multiple channels and the first 90 target could be met by 2020, whilst in the conservative model, HIVSTs would be offered in CBT channels only. The conservative model was used to predict the number of HIVSTs that would be procured in the absence of the project. The moderate model was used to predict the number of HIVSTs that would be procured as a result of the project. The moderate model was adapted for use here, specifically, the private sector impact was removed, additional information on pending funding requests was added, and Lesotho and Swaziland were added to the model. The model included both tests funded through the project (direct impact, **Figure 2**), and those funded via funding partners (indirect impact). For 2021-2025, the model predicted that the volume of HIVSTs would continue at the 2020 level.

Figure 2: Estimating the number of HIVSTs procured as a result of the project



In the first quarter of 2019, the model was updated to reflect changes in the number of HIVSTs procured during the life of the project.[8] The biggest difference in the model was in the indirect impact, both during the project (2.05 to 10.1 million tests) and after the project (18 to 27 million). Therefore the impact of the project in the 2019 model was based on almost double the number of projected procured HIVSTs.

The 2019 model also removed the conservative HIVST scenario. For the counterfactual model, the estimate of HIVSTs carried out in the absence of the project was set to zero. This increased the public health impact as the number of tests carried out without the project was reduced and increased the economic impact as more CBTs would need to be purchased to meet the testing level of the project.

[6] https://www.psi.org/wp-content/uploads/2020/02/HIVSTReport_V6.pdf

[7] Source: Impact_Assessment_2017.doc

[8] Source: Summary of updates to the VfM model Mar 2019.docx

Public health impact

Methods

For both the original model and the 2019 model, the estimated public health impact of a single HIVST was multiplied by the number of HIVSTs in the project scenario, compared to the counterfactual. The number of deaths averted, the number of infections averted, and the disability-adjusted life years (DALYs) for each HIVST was estimated using a published study investigating HIVST in Zimbabwe[9]. This study estimated that for each HIVST, 0.0005 DALYs, 0.0010 infections, and 0.0002 deaths would be averted. See **Table 1** for the estimated impacts.

Table 1: Public health impact of the project, as estimated in the original and updated, 2019, model.

	Original model			2019 model		
	2017-2020	2021-2025	Total	2017-2020	2021-2025	Total
Deaths averted	1,761	2,371	**4,133**	3,223	5,296	**8,520**
HIV infections averted	11,073	14,908	**25,981**	20,265	33,295	**53,560**
DALYs averted	5,267	7,091	**12,358**	9,639	15,837	**25,476**

Key assumptions

In addition to the volume of HIVSTs, the public health model relies on the following assumptions:

- The public health impact of each HIVST as quantified in Cambiano et al. (2015).
- In South Africa, testing optimization would lead to increased yield, leading to a greater public health benefit per HIVST.

Economic impact

Methods

In the original model, the cost associated with project HIVSTs was calculated and was compared to the cost of the non-project HIVSTs and CBTs in the counterfactual. In the 2019 model, the counterfactual did not contain any HIVSTs. Therefore, key assumptions in the 2019 model concerned the cost of various testing methods.

[9] Cambiano, V., et al. (2015). Assessment of the potential impact and cost-effectiveness of self-testing for HIV in low-income countries. *J Infect Dis*, 212, 570–7.

In the original model, WHO guidelines were used to estimate cost of HIVSTs[10], and published research was used to estimate the costs of CBTs[11]. In 2019, PSI conducted a review of costing research[12], and updated the costs of HIVSTs to reflect this new research. Test yield was estimated for 2015 PEPFAR data, and for HIVSTs, the cost of a CBT was included for each positive result. The estimated yield for all tests was estimated to reduce year-on-year.

Three sources of cost savings were modelled **(Table 2**). The first was the saving associated with a scale-up of the project, directly comparing the costs of carrying out the test scale-up with and without the project. The second was the savings associated with the testing optimization in South Africa. This part of the model considered how many fewer HIVSTs tests would be needed to achieve the same number of positive results and compared the cost with this optimization compared to the project cost without it. The third source was the savings associated with HIVST price reductions resulting from the project, savings that would not happen without the project.

Table 2: Economic impact of the project

	Original model			2019 model		
	2017-2020	2021-2025	Total	2017-2020	2021-2025	Total
HIVST scale up	$29M	$50M	**$79M**	$33M	$88M	**$121M**
Testing optimization	$31M	$47M	**$78M**	$31M	$51M	**$82M**
HIVST price reductions	$7M	$27M	**$34M**	$9M	$17M	**$26M**

M = million

The authors also carried out a sensitivity analysis for the original economic impact model, due to uncertainty in the costing assumptions[13].

For the sensitivity analysis, various aspects of the model were changed within a range, to see the impact this had on the economic impact. The economic impact of a low and high estimate for each variable was calculated. **Figure 3** shows the difference, in terms of costs savings, of the low and high estimates. From this, we can see that by far the variable which had the greatest impact was the cost of community testing.

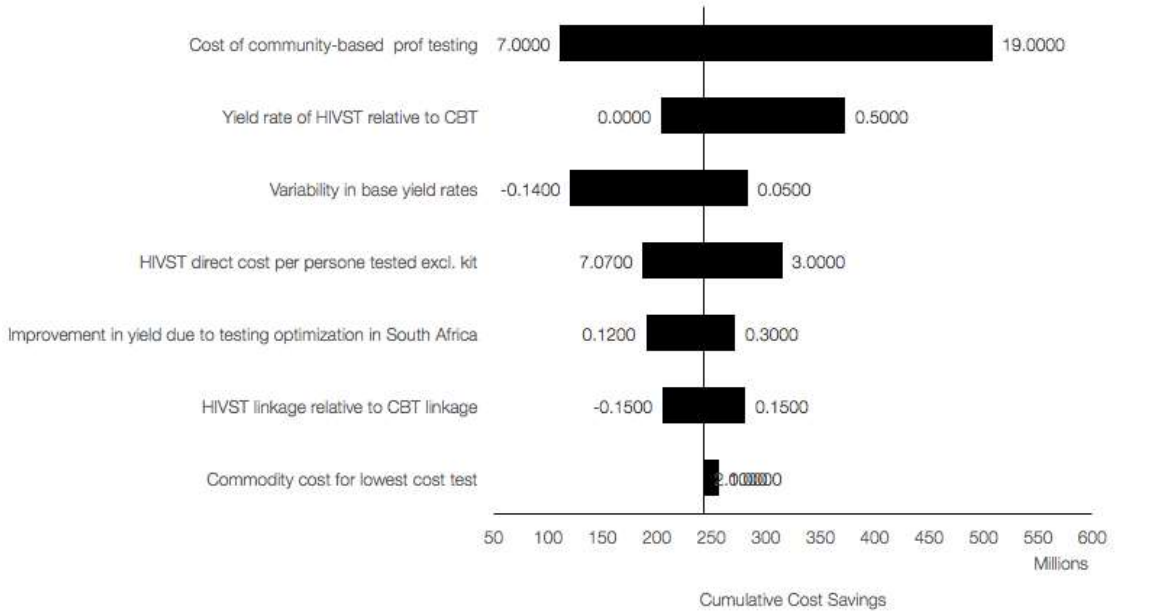
[10] https://www.ncbi.nlm.nih.gov/books/NBK316021

[11] Maheswaran, H., Petrou, S., MacPherson, P. et al. Cost and quality of life analysis of HIV self-testing and facility-based HIV testing and counselling in Blantyre, Malawi. BMC Med 14, 34 (2016)

[12]: http://regist2.virology-education.com/presentations/2018/interest/34_mangenah.pdf.

[13] We note that what we consider the complete model is not the same file that contains the sensitivity analysis. Copy of UTD HIVST VfM Phase 2 Calculations_v22_sensitivity.xlsx contains the sensitivity analysis, the model as reported in the documentation is UTD HIVST VfM Phase 2 Calculations_v22 4.18.17_reviewed.xlsx

Figure 3: Sensitivity analysis of the economic impact model



For the updated 2019 model, a simpler sensitivity analysis was carried out, varying only the cost of the community testing and the cost of HIVSTs, to see the impact this had on the economic estimate. As a result of these sensitivity analyses, a wide range of cost savings are estimated for the original model, from $166 million to $445 million. For both models, as long as the cost of HIVSTs was less than the cost of CBTs, there were economic benefits associated with the project.

Key assumptions

In addition to the testing volumes, the economic impact model relies on several key assumptions:

- Yield rates for adult HIVST and community-based testing can be estimated by the number of undiagnosed adult people living with HIV in a country not on ART divided by the total adult population.
- Yield rates for all testing modalities will decrease as the number of undiagnosed cases declines
- In the absence of HIVST, countries would need to scale-up community-based testing including door to door or mobile testing
- In the absence of the project, it is unlikely that the six countries would scale-up HIVST
- In the 2017 model, the cost of HIVST was predicted to be $8.92, in 2019 this was updated to $8.74. The estimated cost of CBT was $11.
- Inflation can be assumed to be 3% per year
- The price of the oral fluid HIVST was reduced to US$2 - an investment that was as a result of the evidence developed under STAR. In the absence of the project, prices would have remained at $3.15.
- As a result of testing optimization, yield rates in South Africa will increase by approximately 20%.

Model evaluation

During our evaluation, we found many positive aspects of the Impact Assessment Model. The calculations behind the models are well documented within the spreadsheets, and the sources of assumptions clearly identified. There was a great deal of effort and research in creating these assumptions, and this model is the result of a large body of work by PSI, well beyond the immediate scope of the project. For example, the 2016 Market Development Approach report by PSI was used to estimate the HIVST volumes, and a 2018 cost analysis of HIVSTs was used to estimate the costs in the 2019 model. Moreover, the assumptions are the results of careful analysis of published literature and available reports from reputable sources. The economic model relies on many assumptions, and a sensitivity analysis was used to demonstrate the impact of the model if these assumptions were adjusted. In addition, many of the original decisions were conservative, and if anything, led to an underestimation of the model impact. This is supported by the increase in the 2019 model impact predictions, compared to the original model.

In this section, we will first consider some potential caveats in the model that were identified by the model authors and noted in the documentation. Second, we provide a novel critique of the model, and use this to suggest ways the model could be finessed in future iterations.

Reported caveats

There are two main features of the model that are highlighted in the documentation as caveats to be noted are the potential overestimation of test costs[14], and the potential over-simplicity of the cost savings model[15].

For the calculation of test costs, top-down cost estimates were used rather than ingredients-based costing. In the summary of their costing research, PSI noted that ingredients-based costing could lead to lower estimates of both HIVST and CBT. As a result, they conducted a sensitivity analysis of costing research in both the original and 2019 model, and showed that, independent of the cost, as long the HIVST was lower than the CBT, there would be economic benefits to the model. However, this uncertainty of the accuracy of the cost estimates does lead to some concern over the accuracy of the model.

With respect to oversimplicity, the model includes cost savings associated with testing itself (i.e. how much does a HIVST cost compared to a CBT), and the cost savings associated with optimizing testing in South Africa. There is likely downstream savings that could be modeled, for example, improvement in health facility efficiency associated with increasing HIVSTs. Societal level factors that could cause further savings include the potential increase in yield associated with HIVSTs, sue to different populations accessing the tests, decreasing supervision costs for HIVSTs, and potential increases in HIVSTs procured by other donors or governments as a result of the project.

Novel critique

The main limiting factor of the current model is the lack of formal reporting. No one document that contains all information, but instead several documents that provide overlapping information. These documents are mostly the excel calculation documents, with a couple of short reports, updates, and slides. This reduces the accessibility of the findings, as information has to be incorporated over several sources, and some modeling decisions or calculations are not reported. For this reason, we did not

[14] Source: Summary of updates to the VfM model Mar 2019.docx

[15] Impact Assessment_2017.docx

consider completion of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist a useful tool at this stage, as much of this checklist requires a formal report or manuscript.

We note several decisions or steps that are opaque. The first step that we cannot fully trace, is how the scenarios from the Market Development Approach were converted into test volumes for the project. The modifications to the moderate scenario are verbally described, but we do not have access to a document quantifying this adjustment. It is also not documented how the direct and indirect test volumes were calculated, and whether they were both informed by the moderate model.

A second piece of information that we cannot source is the decision to remove the HIVSTs from the counterfactual in the 2019 model. Other changes to the model, such as changing the estimated HIVST cost, and increasing the HIVST volumes are well documented, but we can find no explanation of why the HIVSTs were removed from the counterfactual. A final piece of missing information concerns differences between the two documents containing the original model. There are two documents that contain this model (labeled v22), and both contain information we have sourced here. One version contains the sensitivity analysis but reports a slightly different base model to the file which contains the base model as reported in slides. The difference seems to be driven by different assumptions about testing optimization in South Africa, but this does cause some confusion.

In addition to the lack of formal reporting, we also want to highlight certain aspects of the model that should be presented alongside the results in order to assist interpretation of the model for a naïve audience. Key to accurate interpretation is an understanding of what the counterfactuals of the model are. For example, for the 2019 model, the public health impacts should be framed as impacts of the extra tests, assuming that there would be only a small (3%) increase in testing without the project, and the project HIVSTs would be carried out over and above tests that would happen without the model. The model does not account for any change in community or facility testing that may result from the project. We note that this supporting information would need to be slightly modified to describe the 2017 model.

For the economic impact model, it is important that the counterfactual is made clear. For the 2019 model, it is estimating the cost of carrying out the project HIVSTs, compared to carrying out the same number of tests as CBTs. It is not that the project will save money compared to no project, but that it will be cheaper to carry out these extra tests as HIVSTs. Furthermore, it should be made clear that is it cost savings directly associated with the estimated cost of testing, and no downstream costs savings are considered.

With respect to analytical aspects of the economic model, the model performs what it was intended to do, and if anything, was a conservative estimate of the project impact. The model is tested with a range of assumptions and is based on information that was available at the time of the model design. Importantly, the model did not include factors that may influence the impact, but for which there was no evidence or information. The public health part of the model makes fewer assumptions, reflecting the scarcity of research on the benefits of HIVSTs. The estimation for the public health outcomes was based on a single publication based on a single country, and as a result, there is no sensitivity analysis, and no range or confidence level reported with the estimated impact. This lack of information, whilst reflecting information available to create the model, does raise a flag, and limits the utility of this aspect of the model.

Advice for future iterations of the model

In order to learn from this model, and fully evaluate which aspects of the model had high predictive accuracy, we suggest that the model is updated with more current information. The project did

happen, and so it is not possible, nor necessary, to update the counterfactuals. However, a large proportion of the model predicts time that has now passed, so predictions can be replaced with actual numbers. In fact, this was highlighted by the large change in the number of tests that were estimated to be procured in the 2017 model versus the actual number of tests procured by 2019, as shown previously in **Figure 2**. The following could be integrated into an updated model, and the predictions of this model, that is closer to the real world, compared to that of the original and the 2019 model.

- Updated estimate of HIVSTs procured as a result of the project;
- The number of other tests carried out annually, as reported by PEPFAR, to assess if the model accurately predicted the increase in testing rates, and if the project impacted the number of CBT or facility-based tests carried out;
- The potential impact of the project on the testing landscape could be modeled by looking at year-on-year trends, and comparing these to countries that did not participate in the project;
- Assumptions could be updated to reflect recent publications and reports on HIV testing, for example, there is a more recent publication on the impact of CBTs[16].

In addition to learning from this model, there are additional assumptions which could be built into models designed to predict the impact of future projects:

- Information from the UNITAID/WHO 2020 HIVST landscape report will be useful to accurately assess project impact. This includes need estimate, broken down by specific at-risk or hard to reach populations, where testing may lead to public health benefits not included in the current model;
- Emerging research on the accuracy of HIVSTs, as compared to CBTs, can be included to assess the impact of false results;[17]
- A thorough search of the literature should be carried out, to locate emerging research which can improve the cost estimates at a societal level.

[16] Cambiano, V., Johnson, C., Hatzold, K., Terris-Prestholt, F., Maheswaran, H., Thirumurthy, H., Figueroa, C., Cowan, F., Sibanda, E. L., Ncube, G., Revill, P., Baggaley, R. C., Corbett, L. and Phillips, A.; for Working Group on Cost Effectiveness of HIV self-testing in Southern Africa. The impact and cost-effectiveness of community-based HIV self-testing in sub-Saharan Africa: A health economic and modelling analysis. *J Int AIDS Soc*. 2019; 22(S1):e25243

[17] https://hivstar.lshtm.ac.uk/files/2017/09/P2.4-Elliot-Cowan.pdf

Annex 7. Models of HIVST Distribution Implemented, STAR Phase 2

MODEL of HIVST DISTRIBUTION	MODEL DESCRIPTION	POPULATION	RATIONALE	STATUS AFTER PHASE 2
COMMUNITY-BASED MODELS				
PrEP demand creation	Community health care workers distribute HIVST to high-risk adolescent girls and young women (and men) interested in PrEP	Adolescent girls and young women Men	Removes HIV testing barriers for these target populations, increasing uptake of HIV testing and PrEP referral uptake	New, not yet evidence of impact; to be evaluated in the Initiative
Community-led distribution	HIVST kits are provided to communities; communities determine the best way to distribute the tests and manage all distribution activities	Young people (15-24) Adult men and other highly vulnerable groups	Significantly reduces the cost of HIVST delivery, while simultaneously increasing community ownership	New, not yet evidence of impact; to be evaluated in the Initiative
HTS outreach services integration	Integration of HIVST into HIV testing outreach activities. Using HIVST in the HTS outreach activity to increase the number of people who can be tested in a given day and promoting the availability of HIVST to draw new testers	Dependent on targeting in outreach. Can reach young people (15-24), men, and other highly vulnerable groups	Increases the number of people tested in a given outreach by triaging out negatives. If promoted before the outreach, may increase testing in populations that would be uncomfortable with traditional testing	Preliminary evidence of impact; included in STAR Phase 1
Secondary distribution by FSWs	FSWs distribute HIVST to male clients	Male clients of FSWs	Increases uptake by high-risk men	New, strong evidence of impact, Kenya, NOT included in STAR Phase 1
Partner notification	Newly identified PLHIV are provided an HIVST to give to their sexual partner(s)	Partners of PLHIV	Increases couples testing and partner notification	Preliminary evidence of impact from limited distribution under STAR Phase 1
Social Network Distribution FSWs	Sex worker network: to peers, secondary only; integrated into existing FSW program	Peers and partners of sex workers	Increases uptake by high-risk sex workers and their sexual partners.	
KP direct and indirect distribution	Direct and secondary distribution to KP	KP (sex workers, truckers, other KPs)	Increased uptake and targeted intervention to attract KPs	Preliminary evidence of impact; included in STAR

				Phase, optimization in STAR phase two
Mass Distribution at Taxi ranks	Transport hub: busy taxi ranks etc., primary; off-site only	High risk men and other populations at increased risk of HIV infection.	High turnover platform, hotspot location, easy to reach working, high risk men	New, limited evidence due to limited implementation; NOT included in STAR Phase 1
Fixed point Distribution	busy thoroughfares, primary + secondary; on site and off; HCT on site. Provide HIVST on site and confirmatory testing on site	High risk men and AGYW	Provides opportunity to test on site, attractive to high-risk men and AGYW who fear stigma if they take test home. Can access confirmative testing directly on site.	New, limited evidence due to limited implementation; NOT included in STAR Phase 1
FACILITY-BASED MODELS				
Provider-initiated testing and counseling (PITC)/drop-in centers (vertical model)	HIVST is integrated with PITC services, replacing steps in the PITC process, applied in high volume clinics	All target groups	By decreasing the health worker time required for HIV testing, more people are tested at lower cost within facilities	Limited evidence due to limited implementation; Included in STAR Phase 1
Reproductive health/contraceptive services	HIVST is delivered alongside reproductive health services	Young women (15-24)	Further HIV/reproductive health integration by increasing uptake of HIV testing alongside reproductive health services	New, limited evidence due to limited implementation; NOT included in STAR Phase 1
Partner notification (horizontal model)	Newly identified PLHIV are provided an HIVST to give to their sexual partner(s)	Partners of PLHIV	Increases couples testing and partner notification	New, limited evidence due to limited implementation; NOT included in STAR Phase 1
Distribution through ANC/PNC, pregnant and lactating mothers (horizontal model)	Distribution through ANC/PNC, pregnant and lactating mothers (horizontal model)	Male partners of pregnant and lactating mothers/.	Increases couples testing and partner notification	New in STAR Phase two, limited experience in trial in STAR phase 1.