

**Unitaid HIV Self Testing
(HIVST) area for intervention
– Joint end of project
evaluation**

Final Report



10 June 2022

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Background and Context



of PLHIV know their status, compared to an estimated 77% in West and Central Africa.

Meeting the ambitious UN HIV targets requires innovation to reach new people with testing. HIVST was first recommended by the World Health Organization (WHO) in 2016 and HIVST is emerging as an accessible, convenient and confidential method to:

- diagnose people living with HIV;
- support prevention of HIV in high-risk HIV-negative individuals;
- ensure access to treatment or preventative services;
- expand coverage of HIV testing (including for KPs); and
- improve the efficiency and effectiveness of health systems.

Knowledge of HIV status is critical for curbing the HIV epidemic and is the first of the UN 95-95-95 targets: for 95% of people living with HIV (PLHIV) to learn their HIV status by 2030. In 2015 prior to any Unitaid investment in HIV self-testing (HIVST), UNAIDS estimated that of 36.9 million PLHIV, 46%, did not know their status. While this decreased through global efforts to 16% in 2020, progress towards the first - 95 target has been slower than in other areas of the HIV cascade and the COVID-19 pandemic has further delayed progress.

Certain groups remain underserved with conventional testing approaches, including key populations – female sex workers (FSW), men who have sex with men (MSM), transgender (TG), people who inject drugs (PWID) – as well as high risk groups including partners of PLHIV, adolescents and men. There are also significant regional disparities in the knowledge of HIV status. In Eastern and Southern Africa, 89%

% PLHIV not aware of their status (globally)

46% → 16%
2015 2020

HIVST has emerged as an innovative method to reach new people with testing and support the efforts of the global 95-95-95 targets

Progress achieved by early Unitaid HIVST grants

Unitaid has invested US\$120.2 million in HIVST

Important progress was achieved through the early grants of STAR Phases 1 and 2 in terms of evidence generation, global guidelines development and market development.

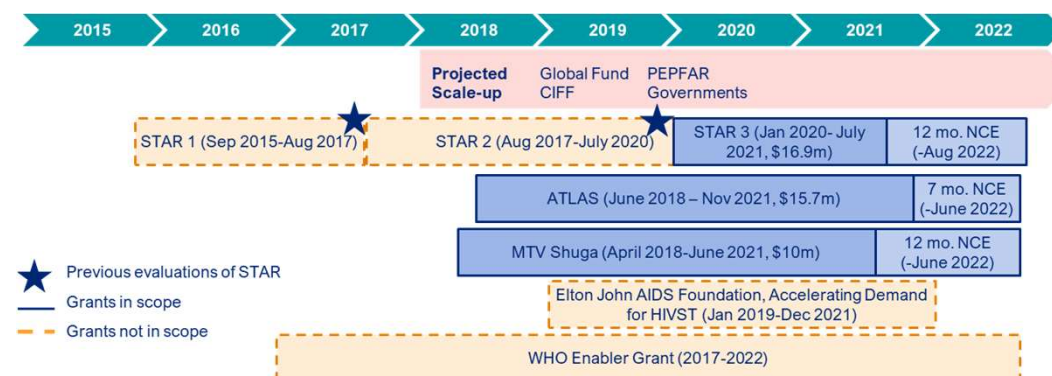
Beginning with the STAR initiative in 2015, Unitaid has made investments amounting to US\$120.2 million to expedite access to HIVST across Africa and Asia and overcome barriers related to demand and adoption, supply and delivery, and affordability.

STAR was led by PSI in Phase 1 and PSI and SFH in Phase 2, with a consortium of global and country research partners and WHO. STAR was found to have generated a strong evidence base on the acceptability, feasibility, usability and cost effectiveness of HIVST and optimal distribution models to close the testing gap. It also successfully built national supply chains and regulatory capacity. By the end of STAR Phase 2 in July 2020, 88 countries had policies which allowed HIVST and 31 had policies in development (up from 3 countries with HIVST policies in October guidelines on HIVST, and the updated 2019

2015). STAR evidence contributed to informing the 2016 WHO normative guidance (*with strong recommendation*). STAR also contributed to catalysing the market for HIVST products and by 2019 four products had received WHO Prequalification (PQ).¹

Despite these advances, global scale up had not yet been achieved. Key barriers included how to fully integrate HIVST into existing country HIV testing services (HTS) programs to deliver HIVST most effectively and cost-effectively, the need for evidence on different delivery models to reach different populations, and regulatory and registration bottlenecks. Further market volumes had not significantly diversified, with most HIVST priced too high for LMICs Unitaid has since made new HIVST investments, including STAR 3, ATLAS and MTV Shuga to address outstanding barriers to HIVST scale-up, and which are the focus of this evaluation (Figure 1.1).

Figure 1.1: Timeline of Unitaid's HIV Self Testing Grants



1. Additional findings and recommendations from evaluations of STAR 1 & 2 are presented in Supplementary Appendix H.

01 Evaluation Design

Evaluation Objectives and Scope

Figure 1.2: Project implementation countries for Unitaid's HIVST grants



- STAR 1 & 2
- STAR 3, MTV Shuga, and ATLAS¹

1. South Africa was part of STAR 2, the EMVA intervention (within STAR 3), and MTV Shuga.

Evaluation Objectives

To provide Unitaid with a joint end of project evaluation for grants in the area for intervention (Afi) of HIVST across OECD DAC evaluation criteria, including lessons learned with a focus on Unitaid's contribution to closing the testing gap through HIVST. The findings will inform Unitaid's future investments including where possible course correction for the ongoing grant implementation.

Evaluation Scope

The evaluation covers Unitaid's HIVST grants since 2018: STAR 3, ATLAS, MTV Shuga, and a market-side intervention under STAR 3.

- The evaluation consolidates lessons from evaluations of STAR 1 and 2.
- It considers synergies between Unitaid's HIVST and PrEP investments, and the contribution of HIVST grants to PrEP uptake.
- Quantitative assessment of public health and economic impact are not in scope, however qualitative impact, including equity aspects are in scope.
- The WHO enabler grant for HIVST is not in scope, but WHO's contributions to HIVST have been considered.

Grant descriptions

STAR 3 (US\$16.9m; PSI) aimed to establish the structures, systems and oversight mechanisms necessary for long-term sustainability of HIVST in Cameroon, India, Indonesia, Mozambique, Nigeria Tanzania and Uganda. This was partly to pave the way for a Global Fund/CIFF Matching Fund catalytic investment in the STAR 3 African countries. STAR 3 included an Early Market Access Vehicle (EMAV) to improve supply security and affordability of HIVST kits, including up to \$2M of catalytic investment to lower the price of BBT <US\$ 2.

ATLAS (US\$15.7m, Solthis) introduced HIVST in Côte d'Ivoire, Mali and Senegal in order to assess the feasibility and effectiveness of HIVST in reaching specific population groups in concentrated epidemics and in the West African context.

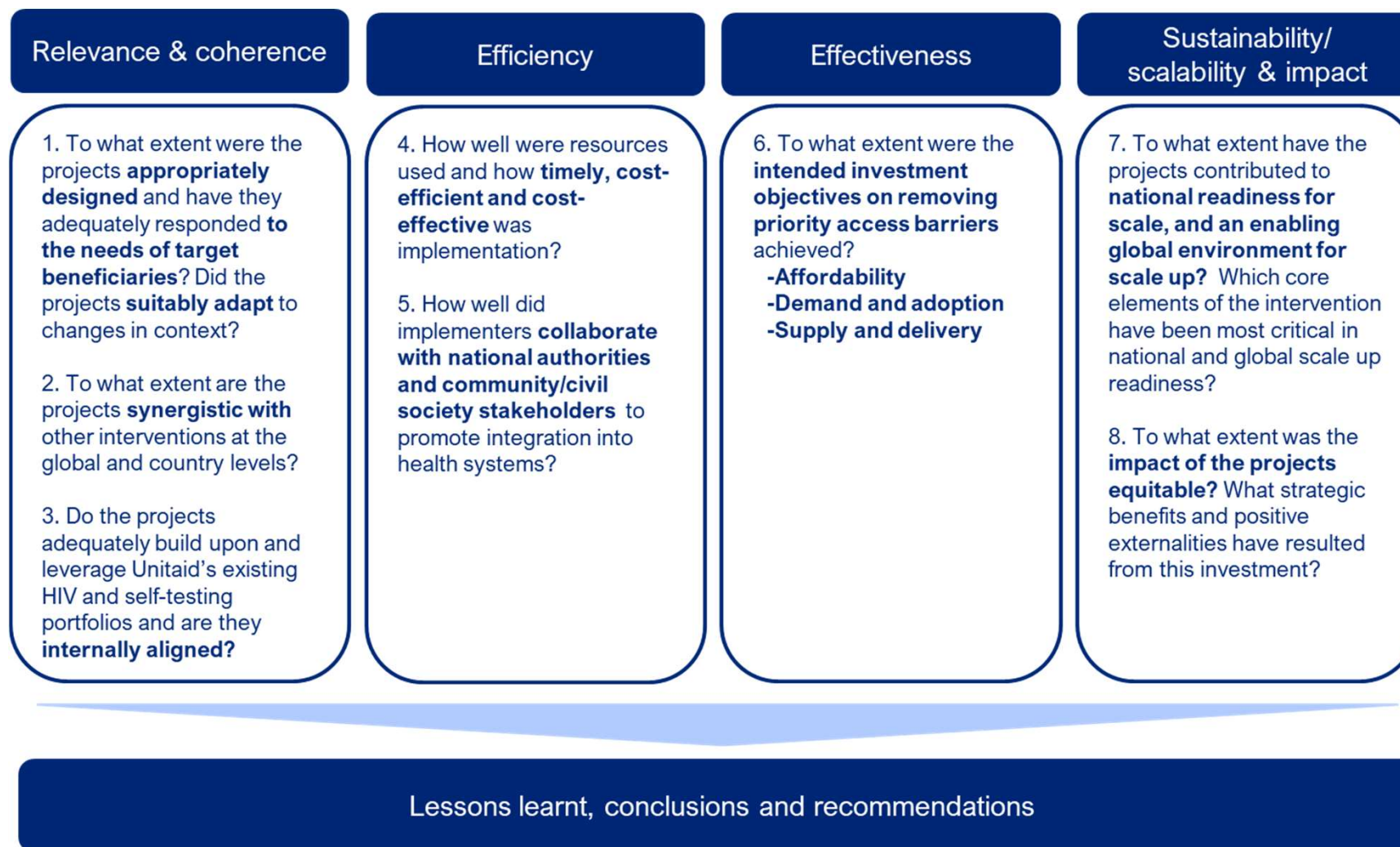
MTV Shuga (US\$10m; MTV SAF) aimed to increase awareness and generate demand for HIVST, PrEP (in South Africa only), and HIV services in general, including linkage to prevention and care, among young people aged 15-24 years in South Africa and Côte d'Ivoire through a mass media behavioural change campaign.

Evaluation framework and approach

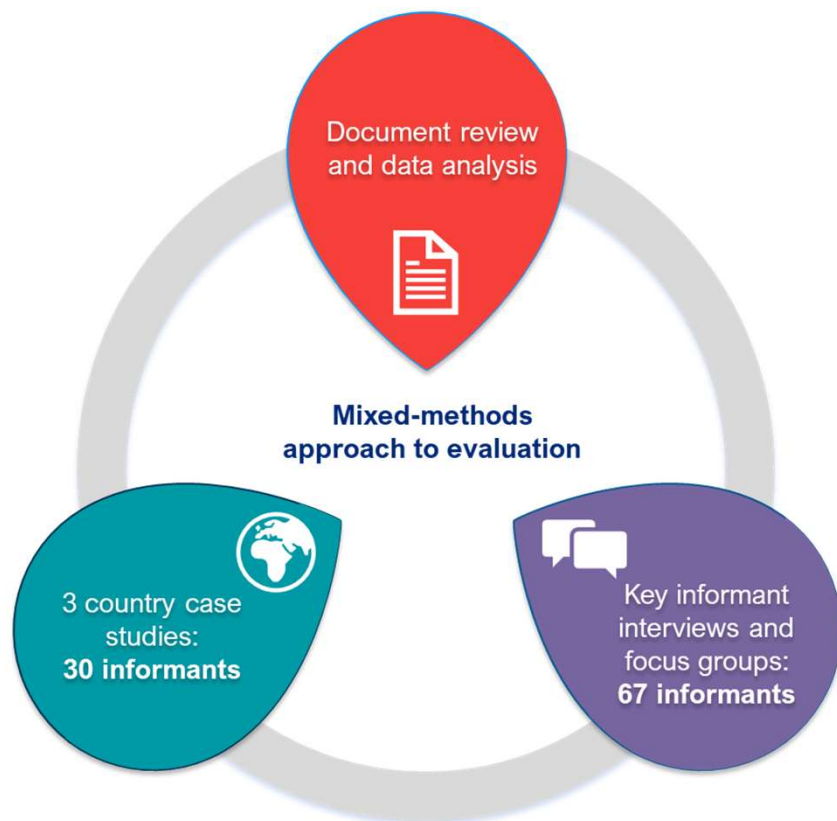
The evaluation framework is structured around the OECD DAC evaluation criteria, grouped into four dimensions: (i) relevance and coherence; (ii) efficiency; (iii) effectiveness and (iv) sustainability/ scalability and impact.

A theory-based evaluation approach has been employed, drawing on the Theory of Change (TOC) developed by Unitaid for its HIVST Afl (Appendix D). The theory based approach entails reviewing whether the pathways to impact are borne out in practice.

Figure 1.3: HIV Self Testing Evaluation Framework



Evaluation Methods



Comprehensive document review of HIVST Afl materials including the TOC, STAR Phase 3, ATLAS, MTV Shuga materials (project plans, logframes, budgets, reports and previous evaluations) and relevant Unitaid HIV Strategy material.



Wider document review of materials from other key stakeholders including the Global Fund, PEPFAR, and WHO, supplemented with academic and grey literature.

Semi-structured key informant interviews were conducted to gather a range of perspectives and insights.

Internal consultations: STAR, ATLAS, MTV SAF grantees/sub-grantees including civil society organisations (28); Unitaid (12)



External consultations (in addition to country case studies described below): Funders (7), Technical/Advocacy partners (11), HIVST manufacturers (5), Government stakeholders in countries in addition to the case studies (4).

Country case studies were conducted in **Cameroon, Côte d'Ivoire, and India** (average of 10 interviews/country) in collaboration with in-country CEPA associates



Key informants included: Ministry of Health and other government stakeholders; donors; lead HIVST grantees, sub-recipients, and consortium partners; technical partners; and key population-led civil society organisations.

Limitations: Possible respondent bias given a number of key informants are implementers and/or recipients of funding. Some key informants have also not been available for interviews: In Côte d'Ivoire (MTV SAF, MTV Shuga-stakeholders and the PNLS), HIVST manufacturers (Abbott and Chembio). As projects will end in 2022, program reporting up to the end of 2021 was available.







Mitigating measures: Evidence from key informant interviews has been carefully triangulated across and with document review. Interviews supplemented the 2021 annual reports with more recent project progress.

Robustness Assessment Framework

Findings have been assessed for robustness based on both the quality and quantity (e.g. triangulation) of evidence, as per the scale outlined in Table 1.1 below.

- We assessed *quality of evidence* by considering aspects such as the source and reliability of the quantitative data and qualitative information, and involvement of the consultee providing feedback on a specific issue.
- *Quantity of the evidence* was assessed by considering to what extent findings are consistent after being triangulated across sources of information.

Table 1.1: Robustness rating for findings

Rating	Strength of evidence
Strong 	<ul style="list-style-type: none"> • The finding is supported by data and/or documentation which is categorised as being of good quality by the evaluators; and • The finding is supported by majority of consultations, with relevant consultee base for specific issues at hand.
Moderate 	<ul style="list-style-type: none"> • The finding is supported by majority of the data and /or documentation with a mix of good and poor quality; and/or • The finding is supported by majority of the consultation responses.
Limited 	<ul style="list-style-type: none"> • The finding is supported by some data and/or documentation which is categorised as being of poor quality; or • The finding is supported by some consultations as well as a few sources being used for comparison (i.e. documentation).
Poor 	<ul style="list-style-type: none"> • The finding is supported by various data and/or documents of poor quality; or • The finding is supported by some/few reports only and not by any of the data and/or documents being used for comparison; or • The finding is supported only by a few consultations or contradictory consultations.

02 Key findings

1. To what extent were the projects appropriately designed and have they adequately responded to the needs of the target beneficiaries? Did the projects suitably adapt to changes in context?



Finding 1. Overall, Unitaid’s HIVST portfolio was highly relevant and fit-for-purpose to the objectives of bringing HIVST to scale in high burden countries with a large testing gap and creating sustainable market conditions for a new and innovative diagnostic tool. The investments highlight the complexity in moving from evidence to policy, and country readiness, and encouraging donor financing for scale.

Co-creation of STAR 3 with the Global Fund and CIFF, alongside WHO, was highly significant to address country operational bottlenecks and the need to encourage scale-up funding. It was strongly aligned to Unitaid’s role as a catalytic partner and well regarded by all stakeholders as responding to the needs of STAR 3 countries and the Global Fund. Collectively, STAR 3 countries accounted for nearly 40% of the testing gap in LMICs. While India and Indonesia have moved significantly slower, this was to some extent expected and they remain regarded as key HIVST markets.

In Francophone West Africa, HIVST volumes are not expected to significantly influence the market, however ATLAS

was widely viewed by informants as important to improving equity in access to HIV testing and services in Africa. The significant research component (led by IRD) and dissemination activities responded to the need for local evidence in the region. There was also a component to provide TA to neighbouring countries to promote scale up (discussed further under EQ6 on access barriers).

The market intervention/early market access vehicle (EMAV) by PSI and Unitaid for BBT responded to the need to diversify the HIVST market with affordable, QA products given the OraQuick oral fluid test was still the only product priced <US\$2 with WHO PQ at the time of the EMAV (discussed further in Finding 5).

The use of mass media and peer-education through the MTV Shuga 360 approach, evidenced¹ to effect HIV-related knowledge and behaviours, complemented Unitaid’s HIVST projects in two African countries (and the Wits-PrEP project in South Africa) by reaching youth and wider audiences beyond facility- or community-led outreach.

1. Banerjee, Abhijit; La Ferrara, Eliana; Orozco-Olvera, Victor H.. 2019. *The Entertaining Way to Behavioral Change : Fighting HIV with MTV. Policy Research Working Paper;No. 8998. World Bank, Washington, DC.*



Finding 2. The phasing of the HIVST grants was appropriate as they leveraged the foundation created by early STAR phases and catalytic impact of the 2019 WHO guidelines on donor readiness.

While some global partners considered that STAR 3 could have happened sooner, the 2019 WHO HIVST guidelines (informed by STAR 1&2) are regarded as pivotal to the Global Fund's readiness to expand HIVST within its New Funding Model 3 (NFM3) round and form the STAR 3 partnership.

Introduction of WCA countries, through ATLAS in 2018, seized on HIVST pilot experience in the region, STAR evidence, and the 2017 WHO PQ of the OraQuick HIVST. It was also prioritized through the WHO/UNAIDS meeting in Dakar that highlighted that only 42% of PLHIV in WCA were aware of their status.

The grant to MTV SAF aimed to harmonise with Unitaids's Wits-PrEP project and STAR 2 in South Africa which had begun to distribute HIVST. In Côte d'Ivoire, MTV Shuga and ATLAS were initiated in the same year, with the intent for a first MTV Shuga series prior to HIVST introduction (discussed further in the next finding and under EQ3 on internal coherence).



Finding 3. PSI, Solthis and MTV SAF were appropriate partners for the HIVST grants, suitably expanding and partnering with relevant sub-grantees in select countries.

Continued partnership with PSI for STAR 3 was an obvious choice given their leadership in STAR 1&2. The decision to identify co-partners PATH (India, Indonesia, Uganda) and Jhpiego (Nigeria), leveraging their country relationships and institutional HIVST experience was appropriate and strategic for new STAR 3 countries.

Solthis was also known to Unitaids through the OPP-ERA viral load testing project in Guinea. Solthis specialised in HIV and had experience providing TA to governments and working with CSOs, and under ATLAS expanded its Mali country presence to Senegal and Côte d'Ivoire. The project's approach to work with existing country HIV testing partners was sensible and appropriate.

MTV SAF was a new Unitaids grantee, with a large MTV Shuga viewer base and strong brand recognition in South Africa. Côte d'Ivoire was the first MTV Shuga francophone country, though MTV SAF held relationships with local broadcasters who had aired previous Shuga series.



Finding 4. HIVST projects were suitably tailored to reach high-risk populations not accessing conventional HIV testing services, including in highly stigmatised contexts.

Table 2.1 describes the HIVST channels and priority populations for STAR 3 and ATLAS. Both grants tailored channels to priority populations and built on existing HIV services. For instance, community distribution included peer-to-peer models, hotspot distribution, and door-to-door targeted distribution as well as index case testing. Uniquely, ATLAS placed an emphasis on reaching peripheral populations through secondary distribution of HIVST by KP-networks. This was a bold and highly relevant approach to reach first time testers in the WCA context.

MTV Shuga was implemented in the countries with the largest epidemics in their regions (South Africa, also the biggest HIV epidemic globally where AGYW are disproportionately affected, and Côte d'Ivoire). Adaptations relevant to local context included running a two-step campaign under the Shuga Babi series in Côte d'Ivoire to first provide foundational messaging on HIV prevention, testing and stigma, ahead of introducing the concept of HIVST.

Table 2.1: Distribution channels and priority populations for STAR 3 and ATLAS

Country	Distribution channel	Priority populations (at country level)
STAR 3		
Cameroon	<ol style="list-style-type: none"> Community-led (primary and secondary) Facility-based (secondary) Workplace 	Partners of positive pregnant women, partners of people living with HIV, men over 35, high risk sexually active men, high risk AGYW
India	<ol style="list-style-type: none"> Community-led (primary and secondary) Private sector Online Workplace Community pharmacies 	FSW, MSM, H/TG, PWID, migrants and at-risk population, partners of KPs and PLHIV
Indonesia	<ol style="list-style-type: none"> Community-led (primary and secondary) Facility-based (secondary) Online Workplace 	MSM, TGW, FSW, and High-Risk Men
Mozambique	<ol style="list-style-type: none"> Community-led (primary and secondary) Key population-led Workplace 	Adolescents, men
Nigeria	<ol style="list-style-type: none"> Community-led (primary and secondary) Facility-based (secondary) Key population-led Private sector Workplace 	KPs, men, adolescents
Tanzania	<ol style="list-style-type: none"> Workplace Pharmacy 	Adolescents, KPs, high risk sexually active men
Uganda	<ol style="list-style-type: none"> Public sector facility-based Community-led (primary and secondary) Private sector Online Workplace 	Adolescents, KPs (FSWs, MSM)
ATLAS		
Côte d'Ivoire, Mali, Senegal	<ol style="list-style-type: none"> Facility-based (primary and secondary) Community-led (primary and secondary) 	KPs (FSW, MSM, PWIDs) and their sexual partners, peers and clients; sexually transmitted infection (STI) patients and their partners; and the partners of PLHIV



Finding 5. The catalytic EMAV for blood-based tests (BBT) has been highly relevant for expediting access to HIVST by creating conditions for a more diverse range of available products. However earlier intervention to lower the price of BBTs may have mitigated current lower demand for BBT.

The market intervention responded to a variety of needs including encouraging multiple product types that are essential for building stable and sustainable markets and addressing the previous market domination of one product. It also paved the way for a wider array of HIVST modalities and sample types to help meet differing preferences of diverse end-users. This expands testing reach and potential impact while increasing demand and volumes.

BBT faced stiff challenges in market entry given the US\$ 2 pricing agreement for the OraQuick HIVST had been in place since 2017 and WHO PQ BBT were priced at US\$ 3-3.50. The <US\$ 2 price point negotiated in 2021 with Viatrix/ Mylan, with a \$1M catalytic investment (EMAV), has made BBTs more feasible and thus is viewed as helping build

experience and confidence in BBTs. A second BBT, manufactured by Abbott, participated in the tender process for the EMAV though no catalytic investment has been made and the product since achieved WHO PQ in 2022. Stakeholders expect the Abbott BBT HIVST to be priced <US\$ 2, bringing more choice to the market. According to global stakeholders, a small number of other lower priced BBTs and oral fluid tests are also in various stages of development.

Despite the welcomed EMAV, the sole use of oral tests in earlier STAR phases (despite efforts to established country experience with BBT and evidence of safety and user preference), may have created complacency amongst countries and unwillingness to diversify their supply by the time of the market intervention – as indicated by a range of global and country level interviews. While donor commitments for HIVST were not as robust in earlier STAR phases, a larger effort on use of BBT/ emphasis on product choice may have increased equivalence in decision-makers' minds and sensitised programs to the importance of a product mix for both market and end-user optimisation.



Finding 6. The HIVST portfolio responded to several STAR 1&2 evaluation recommendations, including a greater focus on demand generation via the MTV Shuga grant. Notably, private sector models were introduced in the final year of STAR 3.

Current HIVST grants have responded to STAR 1&2 evaluation recommendations including flexibility in M&E – particularly for the ATLAS secondary distribution models, working more with communities, and to a degree, greater autonomy for grantees to adapt, best illustrated through Unitaid's responses to the COVID-19 pandemic.

Multiple stakeholder groups welcomed the inclusion of private sector distribution in Uganda, Nigeria and South Africa² in the final year of STAR 3 through a grant amendment (2020), responding to lessons from previous evaluations. ATLAS has also progressed work to make HIVST available in private pharmacies. Interviewees underscored the importance of the private sector for growing HIVST volumes for a stronger market, reaching men and certain groups (e.g. wealthier/higher status), decongesting health facilities, and overall expansion of self-care services.

1. South Africa private sector distribution was initiated under STAR 2

2. To what extent are the projects synergistic with other interventions at the global and country levels?



Finding 1. The HIVST portfolio was highly coherent with global partners in that it intentionally sought to establish alignment with HIV scale-up donors (Global Fund, PEPFAR) and a multisectoral HIV response via ILO collaboration.

STAR 3 was designed with an intent to transition to partners that would drive scale up. To this end, STAR 3 was jointly planned by Unitaid, the Global Fund, CIFF and WHO in the lead up to NFM3, with CIFF providing a US\$ 25m matching grant to the Global Fund earmarked for HIVST scale in STAR 3 countries (NFM3). This synergistic approach was highly regarded by global and country stakeholders and recognized as a departure from the evidence generation focus of STAR 1 and 2. Both STAR 3 and ATLAS also engaged with PEPFAR Country Operational Plan processes (COP) (to a varying degree by country), and ATLAS supported country NFM3 bids.

Workplace models under STAR 3 integrated HIVST within the ILO's HIV programme in formal and informal workplaces. These were positively regarded by stakeholders, in particular valuing the convenience of HIVST for improving access among workers in the informal economy.



Finding 2. At country level, there was strong synergy with existing HIV service provision and partners. Linkage to prevention services was weak in some contexts and also limited by service availability.

To a large degree, STAR 3 and ATLAS HIVST models were implemented by Global Fund PRs/SRs and PEPFAR Implementing Partners and/or sub-grantee community-based partners, and with intentional geographic complementarity vis-à-vis where PEPFAR partners were implementing. As a result, many community and civil society partners either had direct HIVST experience or were sensitized on HIVST.

STAR 3 design documents describe a goal of improving evidence on linkage to care and prevention services after HIVST. In practise, the availability of prevention services varied by context. In Uganda, country stakeholders report prevention services linked to HIVST service models were: condoms, PrEP and VMMC. However in Cameroon, individuals testing negative following HIVST were referred to counselling on safe sex practices only. Condoms and PrEP services was not available (discussed further in EQ6 on access barriers).

3. Do the projects adequately build upon and leverage Unitaid's existing HIV and self-testing portfolios and are they internally aligned?



Finding 1. Unitaid's HIVST investments have been conceptually coherent as a portfolio and are being leveraged for other Unitaid self-testing investments. At an operational level there are some examples of synergies between the HIVST investments but also missed opportunities.

STAR 1&2 and its influence on global evidence and development of HIVST tools served as the blueprint for ATLAS and STAR 3, giving the project countries a 'leg up' on the crucial preparatory groundwork to deploy HIVST. Respondents from STAR 3 countries highly valued inter-country learning and have said the design of STAR 3 models greatly benefited from STAR evidence.

Operational synergies within the HIVST portfolio included ATLAS leveraging STAR's research Technical Advisory Group (TAG) and working with the same STAR 2 team of economic modelers. In the WCA region, there was cross-learning between ATLAS and STAR given similarities in the epidemic and context. ATLAS shared lessons from reaching KP with the Cameroon STAR team and drew on STAR's experience with

facility-based secondary distribution (for partners of PLHIV and positive pregnant women) as well as the workplace channel, where Solthis has since prepared a concept note with WHO and ILO for Côte d'Ivoire.

MTV Shuga strategically supported the overall HIVST portfolio to address demand creation (a gap identified previously in STAR 1&2) and aimed to leverage the efforts of the STAR 3/ATLAS investments to drive demand in South Africa and Côte d'Ivoire for HIVST and HIV services. In Côte d'Ivoire there were challenges in aligning the second MTV Shuga series that introduced HIVST with the ATLAS HIVST supply channels. Firstly as the series could not prominently feature KP-storylines (e.g. MSM) on mass media channels, and second in that the HIVST channels supported by ATLAS did not have a youth focus and so did not explicitly supply HIVST to places frequented by young people/young-KP. The ongoing evaluation by LSHTM of the MTV Shuga project will provide insights to possible spillover effects between the two grants.

In South Africa, where AGYW were a focus of earlier STAR phases (led by Society for Family Health (SFH), the PSI affiliate), there were few instances of direct collaboration linking demand generation by MTV Shuga to HIVST availability. As a whole, MTV Shuga was of the view its demand generation channels were insufficiently leveraged to direct young people to sites where HIVST was accessible (this is elaborated in the next finding and under EQ 6 on access barriers). It was also reported that working-level interactions between SFH and MTV Shuga in South Africa were limited.

The EMAV was strongly coherent with STAR 3 by helping to lower the price of HIVST BBT to <US\$ 2, and through PSI, supplied different HIVST products to STAR 3.

While Unitaids' enabler grant to WHO is not in scope for this evaluation, WHO's support to HIVST grants was highly rated and valued by stakeholders. Examples include WHO technical review of MTV Shuga scripts and development of national HIVST strategies and operational guidelines in the ATLAS project countries.

Coherence with Unitaids' self-care portfolio

Unitaid investments in COVID-19 and HepC self-testing have strongly leveraged and benefitted from the HIVST portfolio. This includes operational synergies (e.g. layering HepC and COVID-19 projects onto STAR 3 country grants), and the expedited WHO guideline process for HepC self-testing, which benefitted from applicable evidence generated under STAR 1&2 (discussed further in EQ 8 on positive externalities).



Finding 2. Demand creation for PrEP and HIVST through the MTV Shuga platform was a novel channel supporting the goals of Unitaids' Afls and promoting self-care in target populations.

MTV Shuga developed storylines that included both HIVST and PrEP, tailored to target populations. The recognised MTV Shuga brand enabled Unitaids to reach key audiences across digital, social media, television and radio channels, and to show people taking HIVST and PrEP, underpinning the concept of self-care.

Investment in the evaluation by LSHTM contributed to strengthening the evidence-base on the contribution of edutainment and media on awareness and use of new testing and prevention tools, as well as HIV-preventive behaviours. This is relevant to other Unitaids disease areas, particularly those with overlapping vulnerabilities to HIV, and Unitaids' self-care/self-testing investments more broadly. Importantly, the evaluation also found need for stronger linkage between MTV Shuga's demand platform and supply (elaborated in EQ 6).

4. How well were resources used and how timely, cost-efficient and cost-effective was implementation?



Finding 1. Across the portfolio, grants underestimated the time required for preparatory groundwork prior to HIVST delivery. Notwithstanding these delays, as well as the COVID-19 pandemic, milestones were largely on track at the end of 2021.

A prolonged inception period was required for nearly all countries, irrespective of the HIVST policy environment at the start of the projects. In STAR 3, informants pointed to Tanzania and India having exceptionally long start-up periods; in Tanzania delays were attributed to the need for engaging with multiple levels of government, and in India to the highly involved process for approval of imported medical commodities.

Some stakeholders view that these risks might have been foreseen and better handled particularly in the case of STAR 3 with historic experience. The delays had a knock-on misalignment effect in that NFM3 grants were written prior to initiating HIVST projects.

In Côte d'Ivoire, MTV Shuga experienced bottlenecks in establishing new partnerships, the need to understand a new context and to create materials in French. This was not the case in South Africa where MTV Shuga were already well-established.

Stakeholders from ATLAS reported 9-12 months were needed to achieve the key preparatory milestones prior to HIVST distribution, which began in early Q3 2019. As a result, HIVST distribution in the first full project year was 19% of the annual target (26,250 of 136,857 HIVST kits, 2019).

A No-Cost Extension (NCE) was made to all 3 projects in 2020 to compensate for the effects of the COVID-19 pandemic. This is discussed in the next finding.



Finding 2. Risks due to the COVID-19 pandemic were well-managed by implementers and Unitaid. The COVID-19 pandemic most significantly disrupted the Global Fund/STAR 3 timelines and ATLAS research.

Overall, HIVST programmes adapted well to COVID-19 which varied by country during 2020 and into 2021. Adaptations included transition to virtual (MTV Shuga) and online (India) models.

Unitaid’s responsiveness and flexibility in the first year of the pandemic was well regarded by grantees, particularly the decision to implement a No-Cost Extension (NCE) of 7-12 months, flexibility within grant budgets, and procurement of PPE for stakeholders engaged in HIVST distribution.

The NCE extended the timeline of MTV Shuga from June 2021 to June 2022; of ATLAS from November 2021 to June 2022; and of STAR from August 2021 to August 2022. It was an effective response to diverse needs of projects and the difficult operational environment due to COVID-19.

Milestone analysis

As shown in Figure 2.1, a large portion of project milestones across the 3 grants were completed by the end of 2021 despite initial project delays.

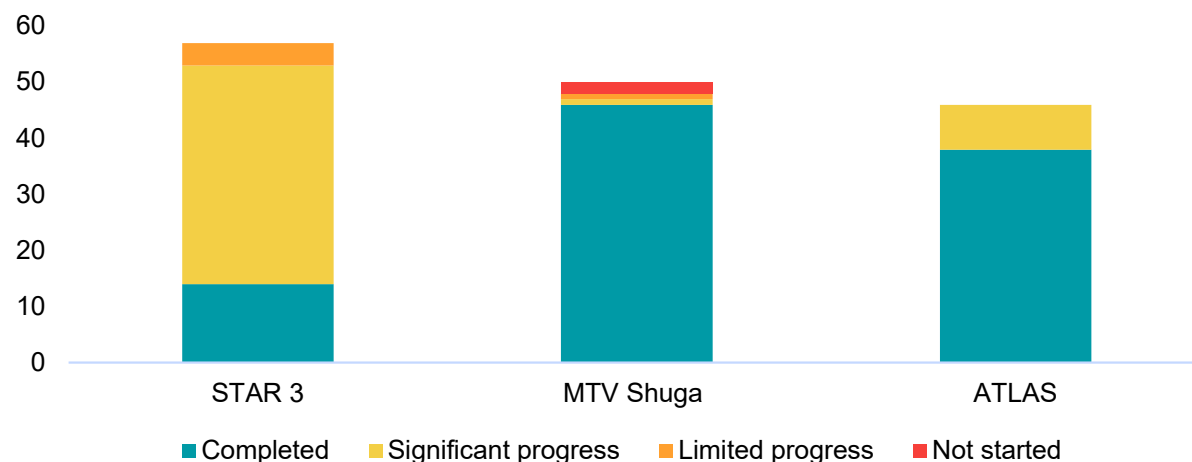
The high proportion of STAR3 milestones reported as having ‘Significant progress’ rather than ‘Completed’, is due to one or two countries not having achieved the milestone, with the majority of countries achieving. STAR 3 milestones where ‘Limited progress’ has been made as of December 2021 include final-year activities (e.g.

dissemination work, development of national scale-up toolkits and post-market surveillance systems).

For MTV Shuga, some research activities in Côte d’Ivoire were delayed and will be completed under the NCE.

ATLAS projects it will complete all milestones by its end date of June 2022.

Figure 2.1: Achievement of project milestones STAR 3, MTV Shuga, ATLAS (as of Dec 2021)¹



1. For MTV Shuga, one milestone reported as ‘limited progress’ in 2021 was excluded as it pertained only to activities in Nigeria.

The NCE for ATLAS was principally to extend the time for IRD research activities, as strict COVID-19 safety protocols limited field work in 2020, making it unlikely the critical research component would be completed within the original timeline. The NCE also responded to COVID-19-related impacts on the evaluation of MTV Shuga in Côte d'Ivoire though research activities by LSHTM were regarded by stakeholders as having adapted well overall to online data collection methods. STAR 3 programming had been significantly impacted with many STAR 3 activities and milestones originally planned for 2020 delayed until 2021. Programme materials show timelines in Indonesia and India were the most affected by the pandemic. Overall, STAR 3 preparatory work for NFM3 in 2020 was delayed by the challenging conditions, including switch to virtual planning, lockdowns, and national provision of COVID-19 responses, and ultimately NFM3 launch was delayed.



Finding 3. Across the portfolio, there were intentional approaches that helped ensure value for money and work towards affordable and sustainable models.

The design of the HIVST country projects to insert HIVST as an additional tool as compared to introducing a vertical project, and to closely engage civil society and community partners, are key aspects that are regarded as bringing in efficiencies in HIVST delivery. Further the projects aimed to ultimately reduce costs by being integrated in the HIV services of all HIV country partners.

The market intervention was a cost-effective addition to STAR. Once the market intervention was planned, the pricing agreement negotiations were implemented through a timely, efficient, and transparent approach that engaged all manufacturers and set the stage for collaborative negotiations moving forward. In addition, volume guarantees were not included to keep down cost commitments from Unitaid.



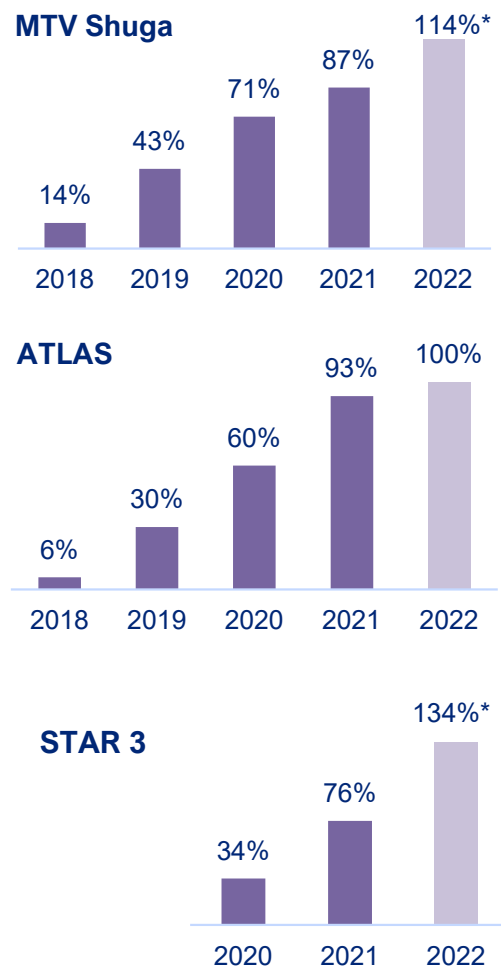
Finding 4. Grant expenditure reflects the slower pace of project delivery during year 1, rising in subsequent years. The composition of grant budgets across Unitaid categories was regarded as appropriate by stakeholders and key to the overall success of grants.

Expenditure analysis and methods are described in detail in Appendix J.

Figure 2.2 indicates that while the delays previously described caused significant Year 1 and Year 2 under-expenditure, all grants accelerated implementation in later years, aligning to the achievement of milestones described in Figure 2.1. Values for 2022 are based on projected expenditure as reported in 2021 Annual Reports.

Finally, the composition of grant budgets across Unitaid categories were regarded as appropriate by stakeholders (further details in Appendix J).

Figure 2.2: Cumulative expenditure as a percentage of total project budget (2018-2022 (actual and projected (2022))



* The MTV Shuga and STAR 3 2022 projected expenditures exceed 100% of the HIVST program budget as they reflect inclusion of new outputs (e.g. HCV and COVID-19 self-testing activities within STAR 3) which could not be disaggregated owing to limitations in grantee reporting of projected expenditure.



Finding 5. Overall, Unitaid management of the HIVST portfolio was regarded as highly supportive and responsive. Some decision-making processes however were viewed as lengthy, resulting in uncertainty, misalignment and compressed timelines for grantees.

Unitaid’s strong technical grasp of HIVST and proactive work to connect its HIVST grantees with one another, share information, and establish connections with external stakeholders such as WHO were all highly regarded by grantees.

An issue flagged by grantees however was delayed decision-making by Unitaid, with inadequate information on progress to decision-making, leaving considerable uncertainty for grantees. For example, Unitaid approval for the MTV Shuga research component was delayed, with inadequate information and progress updates provided to the grantee leading to considerable uncertainty and compressed timeline for the work.

5. How well did implementers collaborate with national authorities and community/civil society stakeholders to promote integration into health systems?



Finding 1. STAR 3 and ATLAS are widely regarded as ‘government owned and led’ through intentionally integrating the projects within national HIV programmes.

STAR 3 and ATLAS were situated as TA to government-led design and delivery of HIVST distribution (including through CSOs and CBOs). For example, ATLAS established MoUs with the national HIV programmes and the MoH was responsible for approving and executing project plans. HIVST elements were embedded within national Technical Working Groups (TWGs) such as in PSM, M&E and training. Project monitoring was through DHIS2 which included new HIVST indicators. Supervision of project sites was co-led with the government and regarded as helping with follow-through of recommendations. In the five STAR 3 African countries, programmes report 40 provincial and district health offices were supported to develop local implementation plans in 2021. Further, a number of STAR countries and all ATLAS countries deliberately engaged government officials in research teams, to strengthen the link between evidence generated by the HIVST projects and national policy.



Finding 2. Overall, there was strong engagement of civil society and community-based organisations involved in national HIV responses, reflecting the focus of the HIVST portfolio to reach KP and AGYW communities.

Civil society and community-based organisations and actors were engaged either as service providers in HIVST projects, and/or within country TWGs and had a fundamental role across project design, delivery and review. This integration is regarded as crucial for responding to the needs of target populations. STAR programme materials report 54 implementing partners (of a target of 37) for the distribution of HIVST kits were trained and/ or sensitized on HIVST.

While inclusion in the HIVST projects has helped establish HIVST experience among these stakeholders, several interviewees voiced the need for explicit capacity strengthening of community organisations given their crucial role in reaching people not using conventional HIV testing services.

6. To what extent were the intended investment objectives on removing priority access barriers achieved?



Finding 1. The HIVST portfolio of grants has significantly “moved the needle” on the enabling national policy environment for HIVST.

As of end 2021, all ATLAS and STAR countries, apart from India, have included HIVST within national guidelines on HIV Testing Services (HTS). In Q2 of 2022, India will also release a NACO white paper on HIVST, and the government is engaged and awaiting the results of the project data (see box at right for details)

A key achievement of the grants is to have supported countries to be ‘operationally ready’, with national HIVST training guidelines and tools alongside cascade training of providers initiated in a majority of project countries, plus revised data collection and reporting tools and indicators developed as well as delivery channels validated.

“the enabling environment work in STAR 3 has been fantastic.”

*–Government stakeholder
from project country*

India remains the only STAR 3 country that has not yet integrated HIVST into national HIV testing policy.

There has been hesitancy to move ahead in India with HIVST, due to concerns with acceptability, and the integration with wider HIV services.

A central principle of India’s HIV program, has been the provision of pre- and post- test counselling, raising questions as to HIVST and linkages to counselling/treatment and risks of social harm. Equally, given the size and diversity within India, the government requires evidence from India to inform its policies. The STAR 3 demonstration study is establishing the groundwork for a future introduction of HIVST and better understanding of the service delivery models. Progress, although slower than other STAR countries, is being made, and the next steps will be to ensure the evidence generated by STAR 3 effectively informs advocacy for policy change.

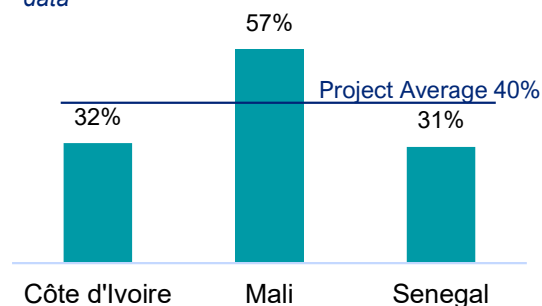


Finding 2. Unitaid catalytic funding for HIVST in West Africa has helped “break the barriers” to country demand and adoption, with the ATLAS project demonstrating feasibility of HIVST in a concentrated epidemic and providing engaged TA across multiple countries to facilitate wider regional uptake.

Reflecting the HIV epidemic in West African countries, the main focus of ATLAS was KPs (FSW, MSM, PWIDs) and their sexual partners, peers and clients; sexually transmitted infection (STI) patients and their partners; and the partners of PLHIV.

ATLAS focused significantly on secondary distribution models for HIVST to reach “hidden” groups and first-time testers.¹

Figure 2.5: Proportion of first-time testers among individuals having performed an HIVST- ATLAS project data



Across the three ATLAS countries, the program reports **40% of people using HIVST are first time testers**, with a high of 57% in Mali (Figure 2.5). Interviewees report this estimate was obtained through a first of its kind phone survey in the region to understand the profile of HIVST users through secondary distribution (Kouassi Kra, ICASA 2021 poster). Interviewees also report ATLAS uniquely developed a new channel of HIVST distribution to the partners of people diagnosed with an STI, with results to be published.

Based on interviews and documentary evidence, the shift to a conducive policy environment in West Africa has been significantly facilitated by Solthis provision of TA. Countries supported include Mauritania, Sierra Leone, Burkina Faso, and Guinea, where Solthis support included situation analysis for Global Fund bids and evaluation of HIVST projects. As a result, close to 90% of WCA countries have included HIVST introduction/ pilot or scale up within Global Fund NFM3 grants. Collaboration between Solthis, WHO and UNAIDS in the region has informed priority countries for TA and development of HIVST technical materials in French.

ATLAS evidence generated to date has been disseminated, with final studies led by IRD to be completed in 2022. Interviewees regard adequate evidence dissemination is crucial to benefit other countries with similar challenging contexts.

In Cote d'Ivoire, differences in monitoring approaches between PEPFAR and the ATLAS/PNLS models were a challenge for PEPFAR grantees. In line with WHO recommendations for HIVST, the models developed under ATLAS (and as such by the government) do not systematically collect tracking data on use of HIVST, HIVST result, and linkage to prevention and treatment services.² The Côte d'Ivoire case study highlighted how this differs from PEPFAR's M&E requirements, which was a challenge for PEPFAR recipients involved in the ATLAS project. ATLAS has proposed an alternate “triangulation method” which triangulates routine HIV indicators with HIVST distribution data to attribute changes in prevention and treatment uptake to HIVST. Used of this approach is under discussion with PEPFAR.

1. According to program materials and interviews, 86% of HIVST in ATLAS countries were distributed through secondary distribution. These engage FSW and MSM networks who in turn invite the sexual partners and clients of KP to redistribute kits to their peers, partners and relatives.
2. HIVST dispensing agents are invited to provide their contact information for support and all ATLAS countries have a free national hotline.



Finding 3. STAR 3 programmatic data indicate evidence of good linkage to treatment in many settings, though weak linkage to prevention (VMMC and PrEP). While overall country partners highly regarded HIVST as a valuable addition to HTS, concerns were raised regarding confidentiality and linkage approaches, and messaging within the workplace model.

Across the STAR 3 countries, program data indicate 76% of individuals receiving a confirmatory test following a HIVST were linked to treatment. This varied widely by country (Figure 2.6) with Tanzania and Nigeria linking 100% of people to treatment.

STAR 3 projects included, to varying coverage, linkage to prevention services which was significantly lower than treatment in all countries apart from India (Figure 2.6). (Note PrEP and VMMC availability differed by country, with VMMC generally not applicable in concentrated epidemics). Countries used different means of tracking HIVST depending on the distribution channel, with some following up over telephone (e.g.

Mozambique and Cameroon). In Cameroon, an ‘assisted’ HIVST linkage strategy that relied on follow up was regarded as posing a potential threat to confidentiality and undermining access by target populations. This is discussed further in the case study (Appendix B).

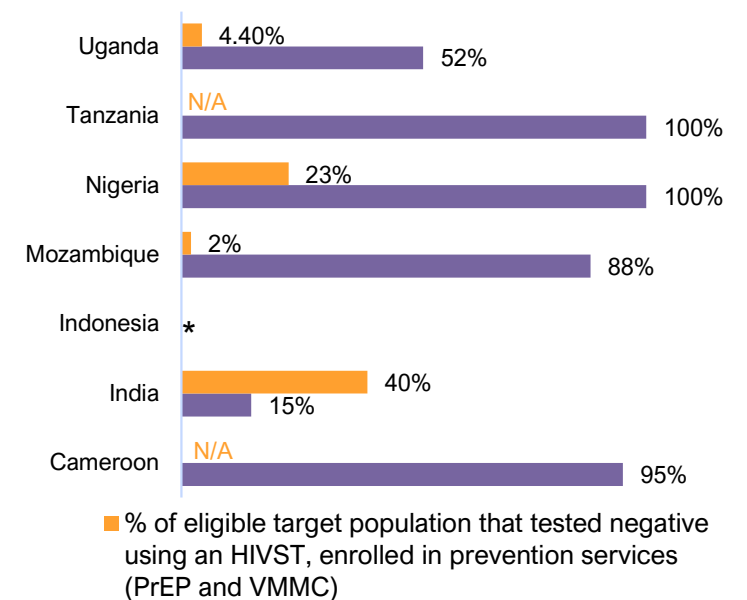
Workplace models in partnership with the ILO and its local partners were implemented in all STAR 3 countries.¹ Tanzania distributed the highest number of HIVST kits through the workplace model which was one of two models implemented (with pharmacies as the other). Country stakeholders in Tanzania were highly enthusiastic regarding demand for HIVST within the workplace model, however they were also the only group to suggest confirmatory testing had an undermining effect on confidence in HIVST. This suggests improved training of workplace peer educators and IEC materials within the workplace intervention may be of value going forward.

Overall, HIVST was regarded by partners already involved in the country HIV response as providing another tool/approach to include within

index testing strategies. Of HIVST, one country stakeholder highlighted its utility in enabling partner disclosure (a pattern of usage also reported in the STAR 2 evaluation).

“...another 26% that tested positive were positive before they received the test but didn’t disclose their serostatus because of stigma and fear around disclosure” - CBO stakeholder Mozambique

Figure 2.6: STAR 3 Linkage to care and prevention



* No data due to delay in HIVST distribution

1. The modalities of the workplace models differed across STAR 3 countries: In Cameroon the ILO and local constituent partners were ultimately not engaged (discussed in the Cameroon case study Appendix B); in Nigeria, India and Indonesia resources came from the ILO; in Uganda, Mozambique, Tanzania resources came from STAR 3.

Finding 4. The MTV Shuga demand creation model was positively associated with HIVST awareness and use, and with knowledge of PrEP, however in South Africa young people did not have confidence in supply.

The LSHTM evaluation ¹ of the MTV Shuga grant showed the effectiveness of targeted demand generation and the importance of media in introducing new health services, reaching both men and women equally. Exposure to the MTV Down South 2 series (DS2) was associated with higher knowledge of HIV status versus those who were not (58% vs. 35%), increased awareness of HIVST (60% vs 28%) and use of HIVST (29% vs 10%). (Fig. 2.7).

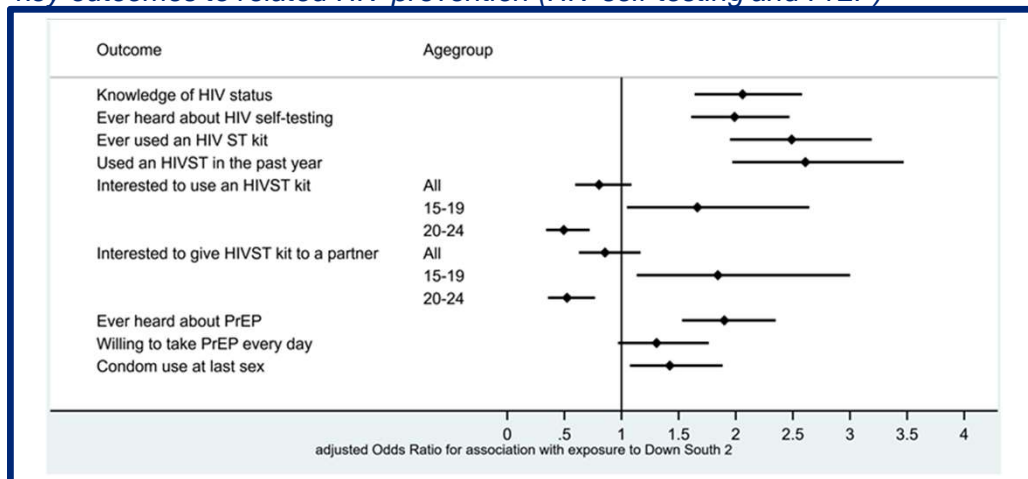
One-third of respondents were aware of PrEP, with higher proportions among DS2-audiences (52% vs 27%).¹ By packaging the information in teen-friendly content, the study reports MTV Shuga campaigns proved to be most effective for generating awareness with youth first-time users of HIV-testing and PrEP. However, confidence in service availability remained low.

Although MTV Shuga made efforts to work closely with the STAR South Africa project to align messaging with the youth target groups and relevant distribution channels, according to interviews the MTV Shuga demand creation efforts had no direct linkages with the supply of HIVST kits or access

to PrEP. Moreover, confidence in services was undermined by instances where the MTV Shuga series created demand but then the product was not available or too expensive. The series depicted HIVST kits at universities alongside PrEP distribution, however these services were not always available. HIVST was also shown in the series at pharmacies, but the pharmacy price point was viewed as too expensive for young people. An exception to this was STAR HIVST distribution at taxi ranks which MTV Shuga actively linked audiences to through activation events and digital content.

In South Africa, the LSHTM evaluation found DS2 helped raise awareness of HIVST, but its limitation was the lack of influence on supply where viewers were skeptical about the existence of services, real or perceived, in their region. Interviews conducted for this evaluation are consistent with this finding.

Figure 2.7: Associations between exposure to MTV Shuga Down South 2 and key outcomes to related HIV prevention (HIV self-testing and PrEP)¹



1. Birdthistle et al. Effects of a multimedia campaign on HIV-self testing and PrEP outcomes among young people in South Africa: A mixed-methods impact evaluation of ‘MTV Shuga Down South’ BMJ Global Health 2022;7



Finding 5. More upfront work to prime programs for introduction and use of Blood-based tests (BBT) (both at the end-user and programmatic levels) may have paved the way for more rapid demand and uptake of BBTs.

Willingness of countries to adopt BBTs has been a challenge, especially since the BBT ex-works pricing does not offer a cost advantage over the oral HIVST. As discussed under EQ1 on relevance, incorporation of BBTs into earlier HIVST efforts (e.g., initial pilot studies, guideline meetings, etc.) and emphasis on the importance of product mix for market stability may have mitigated current concerns. As of December 2021, Uganda, Nigeria, Mozambique, and Tanzania have registered at least one BBT, and the registration process in India, Indonesia is ongoing.¹

Though no ATLAS countries have registered a BBT, Cameroon is preparing a feasibility study with multiple BBTs. In the longer term such country experiences may help to influence the region to diversify HIVST.

Unitaid and partners have responded to address government concerns with BBTs, however stakeholder concerns (e.g., acceptability, feasibility, waste management) remain strong. Still, it is likely that these reservations can be overcome in many countries with additional communication and education on the value of multiple product choices. The acceptance of BBTs may be additionally accelerated if they become less expensive than the current oral tests.

Upcoming Global Fund guidelines for NFM4 will include a policy to allow alternate procurement of oral or BB HIVST in country grants, which should help ensure continued expansion of the BBT market and demand.

1. Mozambique and Indonesia used only oral fluid HIVST in the STAR 3 delivery models.



Finding 6. The market intervention was critical in achieving price parity between blood based and oral fluid HIVST (< US\$2), facilitating integration of BBTs into the global HIVST arena and country experience with BBT. This likely would not have been possible without the Unitaid investment. Work to improve understanding and transparency of HIVST pricing has been beneficial, including with regards to its cost effectiveness, but the more expensive HIVST sticker price remains a concern for some stakeholders.

Prior to the Early Market Access Vehicle (EMAV), a deadlock existed for BBT (i.e., weak demand for BBT because of higher prices and inability to lower price due to low demand). Unitaid’s Mylan/ Viatris pricing agreement to lower the cost of the Mylan BBT to <\$2 addressed this bottleneck, set the stage for more country experience with BBTs, and generated of demand. At present, the Mylan HIVST is only BBT priced <\$US2, with the Abbott HIVST price to be confirmed (table 1.1).

Table 2.2: Approved (WHO PQ or ERPD) HIVST products for LMICs¹

HIVST Product	Type	Manufacturer	LMIC Price (USD) ²
CheckNOW	Blood	Abbott Rapid Diagnostics	To be confirmed
Mylan	Blood	Atomo Diagnostics Pty Ltd, Leichhardt, Australia	\$1.99 (public sector in 135 eligible countries)
INSTI	Blood	BioLytical Laboratories, Richmond, Canada	Public sector \$3-6 Retail \$6-14
EXACTO TEST HIVST	Blood	Biosynex SA, Strasbourg, France	Volume dependent
SURE CHECK	Blood	Chembio Diagnostic Systems, Medford, USA	\$2.99 (public sector)
OraQuick	Oral	OraSure Technologies Inc, Bethlehem, USA (manufactured in Thailand)	\$2.00 (all public sector purchasers of WHO PQ product)

PSI’s cost benchmarking and negotiations for components along the supply chain has significantly raised the awareness of global and country stakeholders (including manufacturers) on the need for transparency and attention to all-in prices for diagnostic products. However, some stakeholders view that pricing expectations for some components (e.g., local distributors) were unrealistic and unfeasible.

While price trends are headed in the right direction, and there is some appreciation of the cost effectiveness of HIVST, donors and at least one country stakeholder interviewed still regard the continued higher price of HIVST over conventional tests (at ~US\$0.7) a fundamental bottleneck for market growth within public-sector programs where HIV testing budgets are finite.

1.The Global Fund. List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy. Version 44. 30 March 2022

2.Ex-works pricing; information sourced from 2020 WHO HIVST landscape and may not be current



Finding 7. Affordability in the private sector remains a key concern for stakeholders who are highly supportive of expanding HIVST availability in this channel.

Under STAR and ATLAS, all HIVST were provided free of charge across distribution channels, which continues in Global Fund and PEPFAR grants.

As described earlier, in October 2021, STAR 3 launched a Commercial market intervention to increase distribution of HIVST kits through commercial sector models, including pharmacy and online models. While the pharmacy models being tested in Uganda, Nigeria and South Africa are not within the scope of this evaluation, multiple stakeholder groups voiced this is a key area for HIVST market growth and reaching men and other groups not engaging in conventional testing services. ATLAS countries were also progressing work on an enabling environment for private sector sales. However, in Côte d'Ivoire where efforts are more advanced, the consumer ceiling price agreed of CFA5000 (~US\$8) is regarded as too high for most customers.



Finding 8. STAR 3 and ATLAS have demonstrably strengthened national Procurement and Supply Management (PSM) for HIVST. Overall country capacity in procurement and supply chain remains a weaker aspect in the transition to Global Fund grants.

According to interviews and documentary evidence, there has been significant progress in program milestones related to registration, market quantification, and regulation and quality assurance mechanisms (in all countries apart from India). Less progress has been made in developing post-market surveillance systems although work is ongoing.

By the end of 2021, a majority of project countries had ended procurement, with handover to NFM3 and PEPFAR procurement underway or shortly anticipated. This donor procurement is underpinned by significant project support in supply chain planning and quantification for HIVST.

In ATLAS countries, grantees stated that transition has begun to Global

Fund NFM3 procured kits and stop-gap transition stocks were in place. (see box for an example in Côte d'Ivoire).

In STAR 3 countries, despite the significant PSM preparatory work, some countries have since struggled to now lead on HIVST procurement and supply chain management, including Mozambique and to a degree Cameroon (further discussed in EQ7 on scalability) per stakeholder interviews. In STAR 3, PSI directly procured HIVST kits to expedite the HIVST projects required to inform Global Fund grants. For example in Cameroon, PSI/ACMS procured and directly distributed 100,000 kits to project sites, citing the need to quickly start projects. This approach, on top of the relatively short implementation period of STAR 3 technical support may be partly a reason for PSM remaining a weaker issue in some contexts.

With a forward-looking view to expediting new HIVST country registration, STAR 3 program reports note that WHO PQ CRP¹ workshops have been provided in Uganda, Cameroon and Mozambique to accelerate the registration of WHO PQ HIVST kits.

In Côte d'Ivoire, ATLAS has engaged with both the public and private sectors in HIVST supply strengthening.

In the public sector, ATLAS has strengthened the capacity of N-PSP (Nouvelle Pharmacie de la Santé Publique), the Health District Pharmacy Managers and CSOs in HIVST supply management particularly in HIVST quantification, distribution and reporting. ATLAS distribution is planned till the end of February 2022, with an additional 4 months of buffer stock (~30k HIVST kits) across the 52 delivery sites to ensure smooth transition to other planned procurements by Global Fund, PEPFAR and UNICEF.

To diversify HIVST channels, in 2021 ATLAS worked with the National Council of Pharmacists and the PNLs (Programme National de Lutte contre le Sida) on policy change required to make HIVST available in private pharmacies. Distrilabo (Orasure's representative in Côte d'Ivoire) have confirmed ordering 20,000 oral fluid HIVST kits, expected to be available in March 2022 for private pharmacies.

1. WHO Collaborative Registration Procedure

The following enabling factors are regarded as contributing to the effectiveness of the HIVST portfolio:

- A key value add of Unitaid’s HIVST portfolio has been to establish significant **technical capacity in PSI and Solthis for the purpose of transferring their expertise to in-country partners and stakeholders in other countries (and STAR 3 co-partners Jhpiego and PATH)**. This has been crucial to catalysing the HIVST enabling environment in non-project countries and is highly complementary to preparatory work for Global Fund NFM3 and PEPFAR COP22. The ATLAS grant included funds for TA to non-project countries for this purpose.
- **Integration** of both STAR 3 and ATLAS in **government systems** from inception was key in that it gave full leadership to national authorities. This is widely cited by all stakeholders as a key enabling factor.
- ATLAS production and distribution of **French-language** HIVST technical products further accelerated the enabling environment in the WCA region.
- Unitaid facilitation of **close working** between STAR 3, ATLAS, MTV Shuga and with **technical support from WHO** was highly valued by grantees.
- Introduction of HIVST was regarded by target population groups as a **new choice that catered to their needs**, and appreciated by community service providers as adding another tool for HTS.
- A **continuous learning approach** also helped to build ownership and alleviate initial doubts about HIVST in ATLAS countries newer to HIVST.

On the other hand, some factors hindering effectiveness of results are as follows:

- **Weak internal coherence** between demand generation among youth by MTV Shuga and the HIVST distribution models.
- **Late inclusion of private sector models in STAR 3** may have dampened potential market growth of HIVST during the project period and reach new populations not served by conventional testing. This was referred by one country stakeholder as the ‘sleeping giant’ in regard to the potential for HIVST and self-care more broadly.
- The **COVID-19 pandemic delays** on ATLAS research has meant some results will not be published until the end of the grant in 2022. Some stakeholders voiced concerns the dissemination of the final set of learnings from ATLAS may be de-prioritized as a result.
- **PEPFAR monitoring indicators were different than those of the governments involved in STAR 3 and ATLAS** (relevant only for countries with significant PEPFAR support). This manifested challenges for implementing partners involved in HIVST projects (cited in both the India and Côte d’Ivoire case studies where PEPFAR is a significant funder). In the WCA region, ATLAS has proposed a method to triangulate monitoring indicators for the purpose of evaluating HIV services employing HIVST.
- **Structural challenges in WCA** regarding highly medicalized HIV services with clinicians seeking to be the ‘gatekeepers’ of a new technology was a challenge for facility-based models.

7. To what extent have the projects contributed to national readiness for scale, and an enabling global environment for scale up? Which core elements of the intervention have been most critical in national and global scale up readiness?



Finding 1. Unitaid’s HIVST portfolio has significantly accelerated global conditions for scale.

Coordination with donors/partners

Joint design of STAR 3 with Unitaid, Global Fund, CIFF and WHO, paved a direct path from STAR 3 distribution projects to implementation at a much larger scale under NFM3. Interviewees widely regard this approach as the most central component for global scale-up readiness. The Unitaid-Global Fund-CIFF partnership de-risked respective investments and the collective effort, and STAR 3 was critical for supporting active HIVST delivery before NFM3 grants began.

The partnership model was also highly complementary in that the Global Fund highly valued visibility on country progress (e.g. product registration and M&E) through STAR 3. Between NFM2 and NFM3, the Global Fund increased its HIVST investment from US\$ 17m to US\$ 71.8m (the matching CIFF grant comprises US\$ 47.9m of the NFM3 value). The number of HIVST procured through Global Fund has increased from 0.22m (2018) to 5.25m (2021).

The Global Fund is now preparing the Modular Framework for NFM4 (2024) which will require all country HIV funding requests to include HIVST and to report on HIVST, which is not required in NFM3.

In response to overall capacity strengthening needs within countries to adequately plan for HIVST, the Global Fund is providing complementary TA for HIVST delivery within NFM3 through its Differentiated Service Delivery fund (with PSI and Solthis as recipients). This support includes some STAR 3 countries (e.g. Cameroon), which is illustrative of the continuing need for targeted support in some contexts to scale HIVST.

HIVST also supported PEPFAR COP processes through providing evidence on country implementation and HIVST tools. PEPFAR has also increased HIVST financing, and procured 4 million HIVST kits in 2021, as well as complementary support for services.

Knowledge/evidence dissemination

As described earlier, evidence from earlier STAR phases and the 2019 WHO guidelines were catalysts for donor support. One funder cited the well-disseminated evidence by STAR (and a smaller extent ATLAS), and its use and dissemination by WHO, particularly within the global HIV space has been important in decision-making. Further ATLAS evidence is yet to be published.

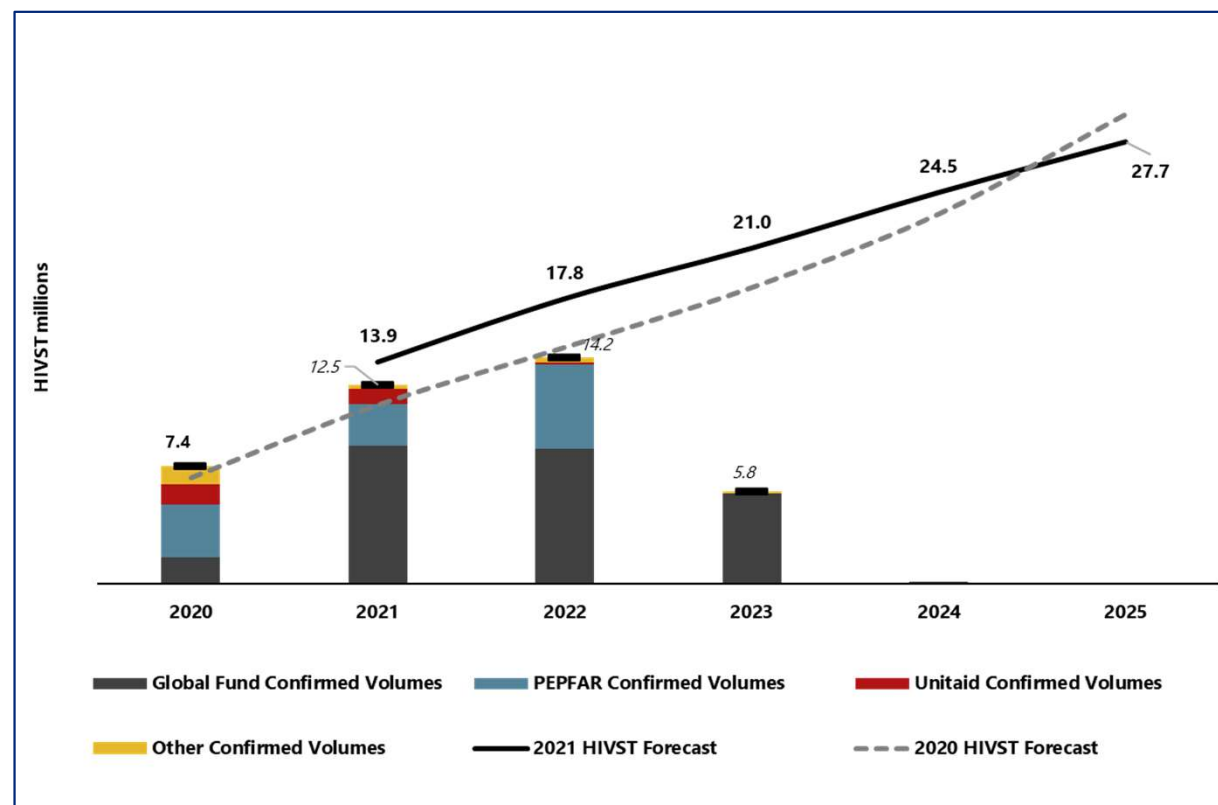
Sustainable access conditions

The EMAV to lower the price of the Viartis/Mylan BBT, together with HIVST volumes financed by NFM3 positively contributed to the HIVST market resilience and consumer choice and has given confidence to manufacturers of anticipated volume growth.

The 2021 WHO HIVST demand forecast projects total LMIC demand to reach 27.7m tests by 2025. This is a slight reduction from the 2020 forecast of 29m tests in 2025 (Figure 2.8), driven by slower growth for early adopter countries and reduced expectations for India, Indonesia and the Democratic Republic of the Congo.

In terms of supplier diversity, global interviewees expect in the long term some BBT manufacturers will not be able to compete at or below the current benchmark of US\$ 2/unit unless volumes significantly increase, given reported tight margins.

Figure 2.8: HIVST demand forecast for 2021-2025 in low- and middle-income countries (LMICs)¹



1. The 2021-2025 HIVST forecast is from the WHO HIVST demand forecast (December 2021).



Finding 2. STAR 3 and ATLAS have significantly contributed to the Unitaid country conditions for scale up. As the projects were sub-national there remains significant work to scale nationally (or in key areas).

Country case studies in India, Cameroon and Côte d'Ivoire, supplemented with interviews and documents in other project countries, were used to assess the achievements of the portfolio against the 3 Unitaid Country conditions for scale up: political and financial support, programmatic/ operational readiness, and community-driven demand (refer to Appendices A-C and N for detailed analysis by country).

Political and financial support

Cameroon and Côte d'Ivoire have significantly advanced the HIVST policy agenda and secured financing for HIVST scale through STAR 3 and ATLAS. Cameroon did not have a permissive policy for HIVST prior to STAR 3, and efforts to register an HIVST had stalled indicating weak levels of political support. STAR 3 has significantly changed the Cameroon HIVST landscape, evidenced by Global Fund HIVST volumes for 2022-2023 of 548k under NFM3 (predicted).

In Côte d'Ivoire, there was already government and donor momentum on HIVST at the start of ATLAS, with PEPFAR planning to distribute 42k HIVST in 2019 and smaller volumes by USAID and Global Fund. As a result of ATLAS quantification and NFM3 proposal support, of 600k HIVST kits requested for 2021-23, approximately 442k are distributed/committed (figure includes 30k HIVST to be confirmed by Global Fund).

In contrast, the policy environment in India has been slow to advance, as anticipated by Unitaid and partners at the start of the project. There is willingness on behalf of the government, though stakeholders are not yet convinced how HIVST fits within existing HIV services. Evidence from the HIVST models will be presented in mid 2022 to advance the political agenda.

Notably, several stakeholders in WCA with insight on NFM3 country proposals report many lacked adequate budgets for wrap-around services, including for training on HIVST. This was regarded by regional informants as a key risk to the successful execution of HIVST.

Some countries were also regarded as too ambitious in their NFM3 proposals and as they move to implementation are using ATLAS evidence to modify approaches and targets.

Programmatic/Operational Readiness

Cameroon and Côte d'Ivoire have both significantly improved operational readiness to scale. Core elements of national HIVST policies, product registration, development of operating guidelines, M&E tools, and local evidence and experience of HIVST delivery models supported by STAR 3 and ATLAS are regarded by interviewees as crucial country 'readiness' factors to precipitate the donor funding secured. India is not as advanced given the absence of a policy 'green light'. Outstanding questions for decision-makers in India include cost-effectiveness of models. No HIVST has been registered yet, with seven HIVST kits (both blood and oral) at various phases of clinical evaluation.

In regards to capacity for scale, the Global Fund indicated increased Unitaid funding of organisations who are PRs/ SRs (particularly local organisations) would be valuable in that it would help prepare GF recipients to maintain the pace of implementation set by Unitaid grantees. When asked about expected challenges in scaling HIVST, country respondents indicated logistics and data-reporting were among the more challenging components.

Community-driven demand

As described earlier (EQ 5), national civil society and community stakeholders in all countries were highly involved in the design of grants with many also involved in HIVST distribution, integrating HIVST within existing HIV programmes serving KP and other vulnerable groups. The engagement of communities was crucial for HIVST distribution being responsive to groups being served with HIVST, supporting linkage to services through information provided by peer networks and CBOs, and sensitizing/skilling community partners in use of HIVST.

The MTV Shuga TV series and related-content developed in South Africa and Côte d'Ivoire have had a much broader reach. Shuga Babi has expanded into wider African francophone markets (see case study Appendix C) and Down South 2 (DS2) was picked up in Zimbabwe and Eswatini. MTV Shuga program reporting indicates Netflix Africa is distributing the MTV Shuga series (including DS2 and Shuga Babi).

In summary, the components most critical for readiness to scale were:

- Co-creation of STAR 3 with the Global Fund and CIFF that linked STAR 3 to NFM3 country proposals, along with continued engagement of PEPFAR and WHO.
- Focus on core country readiness milestones.
- Integration of STAR 3 and ATLAS within the national HIV response.
- Delivery of HIVST projects by existing Global Fund and PEPFAR partners (to a large extent).
- Focus of evidence generation and dissemination, with WHO.
- EMAV to reduce the price of a BBT, with country support for registration and PSM.

Expanding HIVST in Cameroon

STAR 3 provided technical support to Cameroon's NFM3 proposal including i) mapping of KP and priority regions for Global Fund support, ii) quantification of HIVST, and iii) a distribution plan based on geographic need. As of end 2021, HIVST procurement was expected to grow from 70k kits in 2021 (STAR 3) to 548k over 2022-23 (Global Fund).

CAMNAFAW, the Global Fund PR for civil society was a key STAR 3 partner. Following handover, CAMNAFAW and the CNLS were leading NFM3 procurement and scale of HIVST. This transition was not without hiccups as initially an order of BBT were procured by the Global Fund procurement agent instead of oral fluid tests. Continued technical support for M&E and PSM is being financed by the Global Fund (and led by ACMS/PSI).

Interviewees noted the pace of HIVST scale by CAMNAFAW and its community-based partners had been slow and regarded CAMNAFAW's overall capacity as the key risk to meeting national targets. *(Note as of May 2022 CAMNAFAW is no longer the Global Fund PR. Source: PSI communication, June 2022).*

8. To what extent was the impact of the projects equitable? What strategic benefits and positive externalities have resulted from this investment?




Finding 1. The HIVST portfolio has contributed to more equitable access to HIV services and information among different populations and regions, and accelerated access to HIV innovations in under-invested regions.

As noted in finding 3 under relevance, both STAR 3 and ATLAS have increased reach of HIV services to key populations and untested populations. This finding is supported through program evidence and interviews with country stakeholders who view the HIVST models identified new and hidden untested populations within communities.

The EMAV which reduced the price of the Viatrix/Mylan BBT to < US\$ 2 making it more accessible to LMIC markets, and increased transparency in landed costs for HIVST products. Price parity between BBT and oral fluid HIVST is also a step forward in widening choice for communities where there are preferences for BBT over oral fluid HIVST, and overall strengthening resilience and affordability of the HIVST market.

In West Africa, the HIVST distribution projects are regarded as democratizing access to HIV services by developing channels to reach groups who otherwise would not be accessing services given the deep stigma attached to HIV and KP. In general, the portfolio's inclusion of WCA countries resulted in expansion of the MTV Shuga established behaviour change platform to a new market with French-language content contextually relevant to a WCA country. The need for a foundational first MTV Shuga series in Côte d'Ivoire underscores the need in WCA to destigmatise HIV and increase information on HIV prevention and care targeted to young people. The significant research under ATLAS has also strengthened local research capacity in a region with less donor funding, which respondents view as critical for WCA.

In South Africa, the MTV Shuga mass media and demand creation platform reached both young people with key messages on HIV prevention and HIVST and was found to also reach men and women equally, helping connect with young men who are a commonly underserved group.



Finding 2. Unitaid’s HIVST portfolio has contributed to opening the gates for self-testing of other diseases, provided a platform for Covid-19 and HCV self-testing introduction and accelerated global guidelines on self-testing.


The STAR 2 evaluation found HIVST encouraged entry to self-care at the individual level and shifted thinking about HIV testing overall. In WCA, where self-care is less developed, stakeholders regard HIVST as contributing to a mindset shift in self-care, with more work needed to consider the self-care agenda within the weaker health system context. In addition, HIVST delivery channels are regarded by global stakeholders as adaptable to other self-care services, and that technical capacities built within STAR/ATLAS are transferable to support introduction of other self-care technologies.

There has been significant leveraging of STAR for Unitaid’s COVID-19 and HCV portfolios, where Unitaid partners in India, Cameroon and Nigeria are introducing HCV self-testing (also in Vietnam and South

Africa), and COVID-19 self testing in India, Malawi, Nigeria, South Africa, Uganda and Zimbabwe. In Cameroon, ACMS reports the government relationships established for introducing HIVST have aided the HepC project.

HIVST evidence established by STAR has also helped accelerate development of WHO’s HCV self-testing guidelines (2021) which benefited from applicable evidence generated for HIVST. Whereas WHO estimates the 2019 HIVST guidelines took approximately six years given the need to establish the evidence-base, the HCV guidelines released in July 2021 took one year. The STAR research platform in Zimbabwe was a research site for COVID-19 self-testing, contributing to WHO’s Interim Guidance on COVID-19 self-testing using rapid antigen diagnostic tests (March 2022).

WHO also reports they have restructured their work in consultation with Unitaid to more directly link their HIVST and PrEP workstreams, with research how HIVST simplifies PrEP. As noted earlier, WHO guidelines on use of HIVST and PrEP are expected mid 2022.



Finding 3. The COVID-19 pandemic has helped to normalize self-testing, and has been an accelerator for self-care, including HIVST.

Interviewees at global and country level cite the COVID-19 pandemic as giving HIVST a ‘boost’, particularly countries with an enabling HIVST policy environment but limited implementation. In WCA, a stakeholder remarked the pandemic was an “eye opener” for the need for self-care products.

COVID-19 has required projects to adapt their approach and methodologies to be responsive to the waves of the pandemic and respect social distancing and travel restrictions. Given the HIVST policy environment in India is less advanced, the convenience of the COVID-19 home test kits have catalyzed the enabling environment and demand generation for home testing more generally, including HIVST.

03

**Conclusions
and Recommendations**

Conclusions

Unitaid's HIVST portfolio has been highly significant and successful at facilitating the catalytic introduction of HIVST and delivering end-to end support for expansion and scale-up of this innovative technology, especially in the ESA and WCA regions.

The progress achieved through the portfolio will significantly impact the HIV testing gap.

Salient aspects of what worked well and less well are summarized here and in the next slide

What worked well:

1. The STAR 3 partnership of Global Fund-CIFF-Unitaid, directly linked to NFM3, filled the crucial 'country enabling environment' gap that sits between the evidence-base for an innovation and donor readiness to make significant investments in scale. Involvement of PEPFAR and WHO further supported inclusion of HIVST in PEPFAR COP processes and dissemination of HIVST evidence amongst global stakeholders.
2. The time required to integrate HIVST within national programmes and build capacity was underestimated within grant design but has paid off from the perspective of sustainable inclusion of HIVST within government, civil society and community-led HIV testing services.
3. The EMAV investment catalysed price parity between a WHO PQ BBT and oral fluid HIVST. Support for country registration and PSM strengthening was important for sustainability of HIVST supply, building country experience in both product types, and strengthening the HIVST market.
4. MTV Shuga critically demonstrated the value of 'edutainment' in creating demand for HIVST and PrEP and influencing healthy behaviours.
5. ATLAS secondary distribution via KP-networks has demonstrated models for reaching KP and hidden populations in the WCA region and a high proportion of first time testers. Lessons from ATLAS plus provision of TA in the region through Solthis are supporting other countries' HIVST plans.
6. STAR 3 workplace models were an important multisectoral channel for reaching men and workers in the informal economy with HIV services. Solthis has since proposed implementing a similar intervention in Côte d'Ivoire, learning from Cameroon's model.
7. The emphasis of HIVST on reaching first time testers and under-served populations, including groups facing significant levels of stigma contributed to improving equity in access to HIV services.
8. The STAR platform established for HIVST has accelerated self-testing global guidelines for HCV and COVID-19, and benefitted country implementation of Unitaid HCV and COVID-19 self-testing investments.

Conclusions

What worked less well:

1. The pace of implementation has slowed in some contexts following handover of STAR 3 to Global Fund grants and the Global Fund is supporting TA to fill capacity strengthening needs. While acknowledging the significant capacity strengthening within STAR 3 already, in hindsight, potential bottlenecks (e.g. procurement) and capacity needs could have been identified even earlier, with greater resources directed to strengthening of national partners.
2. Some countries remain hesitant to diversify their HIVST supply with BBT, despite the work under STAR 2 to established country experience with BBT and evidence of safety and user preference. Earlier work within the HIVST portfolio to underscore the importance of supply diversity with decision-makers and build experience with BBT in the countries that currently do not authorize use of BBT may have helped to boost BBT orders after the EMAV lowered the unit price.
3. Demand generation through MTV Shuga and the supply of HIVST to target populations could have been more strongly aligned.
4. It remains a challenge to connect high risk individuals who have taken an HIVST to prevention services. In some STAR 3 countries (e.g. Cameroon), this was underscored by limited availability of PrEP services.
5. While the introduction of private sector models was strongly welcomed by country and global stakeholders, they also expressed a desire for this to have come sooner in Unitaids' portfolio. Overall there is a view that the private sector is an untapped platform for HIVST with scope for global leadership to address HIVST access barriers.

Recommendations

The HIVST Afl is the most mature of Unitaids' portfolios within the broader umbrella of self-care, therefore the evaluation considered two sets of recommendations:

1. Specific recommendations for Unitaids and its key partners with regards to HIVST and the current grants ending in 2022, and,

2. Considerations for other investments by Unitaids across its portfolio in general and for self-care in particular.

1. Recommendations for Unitaids in HIVST and current grants

Recommendation 1. Unitaids should 'finish the business of HIVST' with discreet, strategic actions which concern barriers to scale and equitable access, building on Unitaids HIVST and self-care expertise and funder relationships.

Noting the substantial progress Unitaids and its partners have achieved in catalysing the global and country enabling environment for scaling HIVST, with over \$120m invested since 2015, there remains a set of core 'unfinished' issues where Unitaids brings a comparative advantage. Continued Unitaids leadership on the following priorities, in continued close collaboration with WHO and other key stakeholders, would serve to maximise the catalytic effect of Unitaids' significant investments to date and enhance effectiveness and VFM.

1a. Unitaids should consider expanding support for private sector access and scale up of HIVST. This includes existing models under STAR 3 (e.g. pharmacy, workplace) and new platforms which harness the private sector. Unitaids should also consider how HIVST private sector models can include other self-care products and services (discussed further in recommendations for wider self-care investments).

1b. Unitaids should continue supporting dissemination of evidence and country experience (for e.g. in tandem with NFM4/COP22) to:

- Increase the awareness and understanding of governments on the importance of HIVST product mix and diversity for market security (e.g. including the importance of offering product choice);
- Ensure lessons from STAR 3 and ATLAS are included in NFM4 country proposals and COP22 onwards (e.g. funding TA to ensure development of sound and adequately budgeted proposals); and
- Continue advocacy and evidence dissemination on the effectiveness and cost-effectiveness of including HIVST within national HTS.

Recommendations

2. Recommendations for other Unitaid Afls and investments, particularly in self-care:

There are a number of best practises and learnings from the HIVST portfolio that Unitaid should consider in other Afls, particularly self-care solutions. These include:

Recommendation 2. Partner early with scale up funders, collaborate closely with WHO and foster grantee collaboration.

STAR 3 began 1.5-2 years prior to ‘handover’ to Global Fund-supported grants and synced with NFM3 timing. This early planning with funders for scale created confidence amongst countries and manufacturers and served to de-risk Unitaid-Global Fund-CIFF investments. This model of collaboration between Unitaid and key scale-up funders should be considered and replicated for other portfolios/ Afls as appropriate. Further, close working with WHO on HIVST was highly meaningful for governments and funders, and grantee collaborations brought efficiencies to the portfolio.

Recommendation 3. Consider working with the private sector as a service platform.

As identified in the HIVST portfolio, there is a significant gap in product introduction and affordability in the private sector. Given the private sector is a significant provider of health services in LMICs, Afls and country-specific investments should explore where a “total market approach” is appropriate to the context and health priority area. This is an important aspect to consider in coordination with national stakeholders and scale up partners (e.g. Global Fund and PEPFAR).

Recommendation 4. Increase the emphasis within Unitaid grants in local organisational capacity strengthening (grassroots and implementing partners of scale-up funders) and purposely establish a pool of TA resources to transfer knowledge to countries for product introduction and scale.

Unitaid should increase investment in local partner capacity strengthening – both at the grassroots level, and with implementing partners (IPs) of scale up funders. This would serve to build capacities for scale, and ultimately more equitable access to health innovations, given the central role of local partners in reaching under-served and marginalised populations. Second, the model whereby a pool of expert technical capacity was established within Unitaid grantees which served to transfer HIVST knowledge to project and non-project country stakeholders should be considered where relevant to other Unitaid portfolios, given it was highly complementary to the Global Fund and PEPFAR.

Recommendations

Recommendation 5. Expand HIVST channels to be person-centric by bundling products/ services.

Other products where Unitaid's expertise and HIVST platforms can be expanded on, relevant to Unitaid Afls are notably: the use of HIVST within PrEP services; dual HIV and syphilis testing; services for pregnant women (ANC/FP/PrEP). In doing so, Unitaid in collaboration with other partners, should move away from single product-focused investments and models and instead invest in models that start from the client's perspective and products and services relevant to their needs. This could be considered both within supply side investments and follow the synergistic approach of the PrEP/HIVST MTV Shuga demand generation in South Africa.

Recommendation 6. Consider designing a longer period for research and dissemination that continue beyond programmatic activities.

Evidence generation and dissemination require a longer tail to maximise the influence from Unitaid grants.

04 Appendices

- A. India Case study
- B. Cameroon Case study
- C. Côte d'Ivoire Case study
- D. HIVST Afl Theory of Change
- E. Bibliography
- F. Consultations
- G. Acronyms

Appendix A

India Case Study

Unitaid Grantees: PSI
Consortium Member: PATH

Duration: Jan 2020 – June 2021 with NCE to June 2022

Geographies: 14 States

National HIV Funding landscape: Domestic (87%), Global Fund (10%), PEPFAR (3%) not disaggregated by program area.

Background

India has the third largest number of PLHIV in the world, with an estimated 2.1 million people; 5% of the global total of PLHIV.

The epidemic is concentrated among KP-groups, of which only 25% living with HIV know their status and fewer than half are linked to treatment.

On the UNAIDS 95-95-95 targets, 79% of PLHIV know their status, leaving an estimated 500,000 people not aware of their status and not accessing services.

HIV Self-testing Policy and Registration Landscape

Prior to STAR 3, India had no policy on HIVST, but the National Strategic Plan mentioned the need for evidence and the government had attended a regional meeting in Bangkok (2018) to develop a road map for scale-up of PrEP and HIV self-testing.

HIVST products were not registered for approval in India though two qualitative studies had been conducted (in 2020) regarding: i) the acceptability of oral HIVST among MSM and TG populations, and ii) the community perspective of making HIV self-testing accessible as a comprehensive

prevention package. Although the HIVST policy environment was nascent, India was selected for STAR 3 for the following reasons: i) Global Fund/CIFF priority country for HIVST scale-up and as a key driver of global market share; ii) key influencer country in its region, and iii) large contribution to global number of PLHIV unaware of their status.

STAR 3 Objectives

- i. Assess the feasibility, acceptability, and demand of HIVST across specific populations and models.
- ii. Assess the preference for blood- or oral fluid-based HIVST kits and approaches (assisted and unassisted).
- iii. Assess linkage to services, including prevention, confirmatory HIV testing, and treatment initiation, following negative and positive results, respectively, among the HIVST users.
- iv. Identify the challenges to the linkages and any social harm following HIVST.

Key Findings

Finding 1. The STAR 3 demonstration project is highly relevant for India's national plans to develop evidence on HIVST feasibility in the Indian context. India's progress on the -95 goals (79-82-81) has stagnated, with testing as the greatest challenge. A novel approach, such as HIVST, is highly relevant for addressing this gap. The government has shown growing interest in HIVST since 2018 (see previous slide, on India's policy landscape). The project is building on this foundation to provide the evidence-base, required by the National AIDS Control Organisation (NACO), to show that the intervention is effective in India and addresses concerns raised on cultural acceptance, linkages to treatment/counseling and risks of social harm. Further, an important factor for NACO, is to have robust data and a better understand as to whether the HIVST service models are more accessible, and have a greater reach and yield, than Community Based Screening (CBS). Table A.1 details the five distribution models deployed in the STAR 3 India study.

Table A.1: HIVST distribution models deployed across the 14 States

Model	Target Enrollment (Max. 112,000 participants)	Population	Partners	States
Community	Key Population (KP) – 42,500; partners of KPs and PLHIV – 33,500	FSW,MSM, H/TG, PWID, migrants and at-risk population, partners of KPs and PLHIV	Humsafar Trust, SAATHII, I_TECH, JHU, NCPI &VHS	Andhra Pradesh Delhi Gujar Karnataka Madhya Pradesh Maharashtra Manipur Mizoram Nagaland Punjab Tamil Nadu Telangana West Bengal Uttar Pradesh
Private	10,000	At-risk populations including KPs and their clients/ partners & partners of PLHIV	SAATHII, Sai Hospital	
Virtual/online	5,000	At-risk population and KPs who are online	Humsafar Trust, SAATHII, I-TECH, JHU, NCPI & VHS	
Workplace	16,000	At-risk populations	ILO and their partners	
Community pharmacy	5,000	At-risk populations	NCPI & JHU	

Finding 2. The demonstration project in India was highly strategic of Unitaid and launched at an opportune time to foster an enabling environment for HIVST.

Although India are likely to be slow adopters of HIVST, given they are yet to integrate policy into their national plans, it remains highly strategic of Unitaid to have selected India and lay the foundations for the Global Fund-CIFF matching fund that has identified India as a priority for HIVST scale-up.

In addition, three factors have been identified by stakeholders on the timeliness of the study: i) government willingness to consider HIVST, ii) younger populations (age 15 – 29) disproportionately affected by the HIV/AIDS burden are more open to new services (e.g. self-testing and virtual-distribution), and iii) COVID-19 disrupted traditional HIV services, and expediated community acceptance of new models and demand generation for HIVST with a sufficient evidence base.

Finding 3. PATH are recognized as an international organization with highly technical expertise who have facilitated aligning stakeholders within India and brought relevant experience from other country contexts. The involvement of an international organization with lessons learnt from other country settings, e.g. African countries and Vietnam, has provided confidence, and helped coordinate NACO, CSO/CBOs and multisector partners in India to move ahead with the HIVST demonstration project.

Finding 4. Through community engagement PATH adapted the demonstration project to be more comprehensive and contextually relevant. The project has engaged senior community leaders as part of the national, state and district oversight committees to help shape the project e.g. initially HCV was an exclusion criteria to the project but, at the request of CSOs/CBOs, and given the high prevalence of HCV in a few states of India, the study design was adapted to include HCV-positive participants for blood-based HIVST (Hepatitis B and C

remained an exclusion criteria for oral testing with OraQuick).

Finding 5. There was strong alignment of goals and objectives amongst the network of partners implementing the study, although some CSOs reported that the HIVST demonstration project was inconsistent with the PEPFAR testing targets. The comparative advantage of key partners – PATH, Humsafar Trust, SAATHII, ILO, CDC and PEPFAR –was leveraged to enhance the geographical coverage of the project and support the provision of physical and virtual service models for high-risk and key populations. A concern was raised by implementing partners that HIVST did not align with PEPFAR’s programmatic testing targets, and this strained the resources of PEPFAR implementing partners who were required to support the demonstration project and deliver on the targets of their core-work.

Finding 6. The study design has been highly commended for being comprehensive, but implementing partners reported challenges around the budgeting of resources for the M&E framework, partner engagement and completion of the research questionnaires. The challenges raised by stakeholders included: i) Under-estimating the training-requirements, resources, and budget for capacity training; ii) M&E Framework was developed late in the project design; iii) workload for implementing partners was burdensome and underestimated the level of effort and resources required; iv) research questionnaires took too long to administer and contained highly sensitive questions for the context.

Finding 7. The project implementation was delayed from Q1 to Q3 of 2021. This was due to COVID, but also as a result of the national regulatory processes and partnership engagement procedures. As of December 2021, 82,410 (73%) HIVST kits had been transported to 13 states and 2970 (3%) HIV self-tests have been conducted. The delays have included: i) The complex regulatory pathway to approve kits in India, with an uncharted multi-agency approval

process, where WHO-PQ was not accepted as sufficient for regulatory requirements, ii) the importation of kits was bureaucratic and expensive, iii) India was hugely impacted by the second and third wave of COVID-19, resulting in field workers unable to work due to public health restrictions, or illness, leading to delays in the roll-out and field utilization of test kits, iv) extensive partnership engagement and community liaison was efficient for building stakeholder buy-in but led to delays in the project start.

Finding 8. The PATH leadership has been commended for their convening power and knowledge of the Indian context including complex regulatory pathways. A larger team may have improved overall efficiency. PATH India has been led by highly respected leadership and an experienced head of operations (former NACO Testing-Lead), holding close working relations with government and civil society. Respondents shared the view that a larger team may have further supported the leadership and would have been a more efficient use of senior level resources.

Finding 9. Community confidence, and inclusion of KPs in STAR 3 has been well coordinated. However, there were also some challenges with participant recruitment. The community engagement strategy was supported by a strong governance framework to coordinate a network of 250 CBOs, and the leadership of Humsafar Trust and SAATHII. The challenges included: i) aligning different organisational objectives; ii) the inclusion and retainment of PWID; iii) some implementing partners felt that they could have been included earlier; iv) no incentives for participant recruitment and; v) low participation in Q1 of 2022 due to COVID-19.

Finding 10. Structured engagement with the Indian government has kept them informed on STAR 3, helping to build a close working relationship. PATH has engaged with the Indian Government from the project inception, as well as including NACO in the PATH India STAR Project Advisory Group (PISPAG), where the DG attended the first meeting. Through these engagements, the government have been included as active partners in the project and kept in informed with key developments.

Finding 11. The enabling environment for HIVST is building within India, although there is no HIVST policy at present. The key changes in the enabling environment include: i) PATH/STAR 3-partners have given inputs for a NACO white paper on HIVST (to be published online Q2 of 2022) articulating preparatory plans for national readiness; ii) Seven HIVST kits (both blood and oral) are under various phases of clinical evaluation with NARI; iii) NACO-led webinar ‘HIV Self-Testing: Breaking barriers in India’ was conducted on 16th September 2021, with more than 800 participants from all South Asian countries.⁸

Finding 12. Preliminary feedback suggests the demonstration project has led to increased awareness of HIVST with high community acceptance and good government engagement. The key project achievements to-date include: i) STAR 3 has introduced kits into 14-states within India and increased community awareness of the five service models for KP and high-risk groups; ii) CSOs have found community acceptance is high and the kits have received good publicity through word of mouth among social and sexual networks of MSM and FSW. One challenge has been the language as the informed consent and

communication materials are not available in all regional languages; iii) Government of India are engaged and awaiting the evidence to be generated by STAR (30th June 2022).

Finding 13. The affordability of kits is an important driver of uptake in India, especially where facility-based testing is free and there is limited domestic manufacturing of HIVST. Given the current unit cost of HIVST, the price point of kits would need to be subsidized both for the government to be able to provide the kits for free, and in the private sector to ensure they are affordable. Out of the current pipeline for HIVST kits on the regulatory pathway (under review by NARI), there are three domestically manufactured kit, the rest are imports. Some respondents were of the view that India developing indigenous manufactures will help to lower the price and will lead to an overall price reduction across the market. PATH India recognized this as an important consideration.

Finding 14. The inclusion of virtual populations via online access to HIVST kits has been well received, but there are concerns around the maintenance of the infrastructure. The convenience of online access has been seen as advantageous, especially

for specific KPs (MSM and FSW) and younger populations. In addition, beyond the distribution of test kits, the project has also provided a helpline, peer educators, links to counselling, IEC and community health services. A consideration raised by CSO-implementing partners is how the digital infrastructure and linkages to services will be integrated and sustained in a national programme.

Finding 15. CSOs have found HIVST to be more accessible than Community Based Screening (CBS) and believe STAR 3 has increased coverage reaching previously untested PLHIV. CSOs commented that they believe HIVST is reaching previously untested, or not tested in the past year PLHIV and their partners. However, concern has been raised that the demonstration project is limited (112,000 kits), and more consideration is needed as to whether the models are replicable/adaptable to be scaled-up nation wide, for example in the North East, where there have been logistic challenges due to difficult terrain. Anecdotally, the CSOs have found HIVST kits to be more accessible than CBS, as they require no referral, and the tests are anonymous, confidential, convenient and reliable.

Finding 16. STAR 3 will have to demonstrate that the kits and the service models are cost-effective within the India context. To be sustainable, the overall cost associated with the yield of positive tests, and the number of PLHIV previously untested, must be advantageous and competitive compared with existing diagnostic services, such as CBS. At present, facility- testing and treatment is free in India, with no user fee. Therefore consideration needs to be given to the financing of HIVST, and how this compares where there are out-of-pocket payment and a requirement of further confirmatory testing at a facility.

Finding 17. To support a sustainable transition, consideration needs to be given to how the infrastructure and systems of the five different service models could be maintained.

Consultees particularly mentioned: i) Virtual service - maintenance and support for continuation of the HIVST access website, the virtual counsellors, health helplines and continued demand generation activities; ii) transition of project elements supported by the ILO that support HIVST in the workplace; iii) community follow-up with navigators

and peer educators, has been an important component for capturing results and linkages to treatment and counselling. It is unclear whether a national programme, or unassisted model, would sustain the same levels of community mobilization, and the implications this would have on the effectiveness of the service.

Finding 18. The government of India is engaged with STAR 3, however unless HIVST is integrated into national policy, the government will not implement and scale-up the program. NACO are a technical partner of the demonstration project, and have shown interest, however without a national policy, transition and scale-up will be limited. Once the findings of the project on demand, risk of harm, and linkages to treatment and counselling are available, strong advocacy for a budgeted national policy and programme will be required for effective scale-up.

Finding 19. The relevant scale-up partners –Global Fund and PEPFAR - are actively participating in discussions to provide HIVST kits to India. The scale-up partners have continued to engage in STAR 3 India.

The Global Fund is in active discussion with STAR 3 to enable availability of HIVST kits as part of their comprehensive package of sexually transmitted infection (STI) screening and prevention services for at-risk individuals. PATH will provide insight and support to the HIV self-testing elements of the strategy (STAR, annual report).⁹ To date, India was the only STAR country where HIVST quantification and forecasting did not take place to help inform the Global Fund procured test kits.⁹

STAR 3 India is a PEPFAR approved programme and implemented by PEPFAR partners. As such, WHO are of the view that scale-up of HIVST is likely to start in districts where PEPFAR is working but national-level scale-up will be slower. Some of the implementing partners commented that there is some risk in PEPFAR's position on the scale-up of HIVST given their prioritization of index testing in their 2020 Country Operational Plans, leading to ambiguity whether HIVST would count within PEPFAR testing targets.

Best Practice

PATH has led with effective convening authority to coordinate multi-sector partners, government and given a platform to HIV champions in India.

- PATH have worked closely with implementing partners and engaged with NACO at various levels, including the Drug Controller General of India (DCGI). This required a lot of coordination, which PATH has managed well, and within a few months.
- Early engagement of the government as technical partners to the project, has assisted in integrating HIVST with national public services and facilitated open dialogue with national policymakers.
- The inclusion of 14 states, five different service models, including digital innovations, and community engagement with over 250 CSOs/CBO was highly commended for good geographical representation and innovative service models (e.g. virtual populations, community networks and workplace distribution); helping improve the reach of the project to KPs and build demand generation.

Lessons Learnt

STAR 3 India is a comprehensive and well-designed study which involved communities and KPs, however challenges were met with delays, staff-training, engagement with partners, and approval processes.

- The large number of implementing partners and CSOs/CBOs (many conducting a research study for the first time), required more time (including periodic capacity building) and resources than budgeted and this had implication for the quality of the project.
- While recognizing the impact of COVID-19 in India, stakeholders were still of the view that the project needed a more realistic timeline for preparation, including the time needed for the regulatory approvals of both DCGI and ICMR as well as the complex process of importing kits into India.

Maintaining the linkage between HIVST, treatment and care remained a challenge for specific Key Population-groups and an unassisted model needs further evaluation.

- Through community engagement the HIVST project linked with public services for integrated counselling and confirmatory tests at facility-based centers. However this remained a challenge for some key groups, such as PWID, where follow-up with individuals has been hard to maintain.
- The project did not test a fully unassisted model. This was recognised as having huge reach potential, however would require consideration of linkage to services, especially where the only option is an unassisted HIVST and no health facilities are available.

The following recommendations would support the introduction of HIVST into the national HIV program of India and for consideration with future projects:

Recommendations

Dissemination of results and continued advocacy to NACO is required to integrate HIVST into national policy.

- Once STAR 3 results are available (scheduled for 30th June 2022) it is important that the evidence is widely disseminated with policy-makers, government representatives and key stakeholders, including CSOs/CBOs. The development of a comprehensive advocacy strategy will support in guiding a coordinated and sustained effort for HIVST to be integrated into national policy.

Manage the transition of the digital innovation and architecture of community engagement into the national programme.

- STAR 3 India has been commended for the network of community educators and navigators supporting the project implementation, as well as digital innovation reaching virtual populations, and the ILO-led model in workplaces. Consideration needs to be given to how these services can be continued and scaled-up to a national level, to maintain strong demand generation and access to services (e.g website maintenance, the virtual counsellors, health helplines etc.)

Engage early with national regulatory bodies, whilst supporting efforts to harmonize regulatory processes.

- The STAR project was introducing HIVST into India for the first time. There was not a clearly articulated regulatory pathway, and regulatory approval involved several national agencies. These challenges were not exclusive to HIVST but do point to the need for early engagement to expediate and overcome regulatory barriers, including import processes and clear agreement on processes and technical requirements for introduction and roll-out.

Unitaid should consider a broader approach within sexual and reproductive health and overlapping vulnerabilities.

- Other STIs are increasing in India, for example syphilis, as well as HIV co-infection with other infectious diseases including Hepatitis C. A broader system approach with combined self-tests would address these vulnerabilities more holistically.

Consultation list and References

Table A.2: India case-study stakeholder consultations

Category	Organisation	Name	Position
Grantees/ Sub-grantees	PATH	Kimberly Green	Director, Primary Health Care
	PATH	Asha Hegde	Deputy Director, HIV/ TB- STAR HIVST India Lead
	PATH	Kannan Mariyappan	PATH Senior programme officer
	PATH	Chinmay Laxmeshwar	HIVST programme officer
Civil Society Organisations	Humsafar Trust	Murgesh Subramaniam	Project Director
	ITECH (PEPFAR Partner)	Madhuri Mukherjee	Country Director
	SAATHII	Manish S. Mudaliar	Director of Operations
Government	National HIV Program, NACO	Chinmoyee Das	Assistant Director General
Technical partners	Fermish, Clinical Technologies	Dr Khalid Khan	CEO (regulatory consultant)
	WHO, India Country Office	Rajat Adhikary	National Program Officer, HIV Prevention, Strategy and Surveillance

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Appendix B

Cameroon

Case Study

Unitaid Grantees: PSI, implementation by Association Camerounaise pour le Marketing Social (ACMS)

Duration: Jan 2020 – June 2021 with NCE to March 2022

Geographies: Southern, Central, and Littoral Regions

HIV and testing context

UNAIDS estimates the prevalence of HIV in Cameroon is 3.1%¹ and that in 2019 there were 510,000 PLHIV.² The HIV epidemic is generalised, with a higher prevalence of HIV among certain key population groups and regions. The Comité National de Lutte Contre le SIDA (CNLS) reported that in 2019, HIV prevalence among FSWs and MSM was 24.3% and 20.6% respectively.³

The testing gap is significant in Cameroon where an estimated 55.7% of all adults reported knowing their HIV status and 20.7% of young people 15-24 years.⁴ Testing is particularly low among youth where 43% of females and 62% of males aged 15-24 years have never been tested.⁵ Although awareness of HIV status is higher among FSWs and MSM (at 97% and 67.3%) these groups report avoiding health care structures for fear of stigma and discrimination.⁴ HIV testing is in all hospitals, and while not free everywhere, widely available. There are pockets of the population who are unaware of their status, in part due to risk of stigma at testing sites, and also distance to testing sites.

Prior to STAR 3, Cameroon did not have valid guidelines in place for the implementation of HIVST and efforts to register the OraSure HIVST were not yet successful.⁶

STAR 3 objectives and activities

STAR 3 provided support for efforts to catalyse the introduction and national adoption of the use of HIVST in Cameroon. Led by PSI and its affiliate the Cameroon Association for Social Marketing (ACMS), the objectives of the project were to:

- 1) establish an enabling environment by catalysing the validation of national guidelines for HIVST, integration of HIVST into Global Fund procurement, and facilitating registration of HIVST;
- 2) support implementation of differentiated HIVST distribution models and linkage to care in the Centre, South and Littoral Regions;
- 3) disseminate best practices from HIVST implementation to support transition and scale-up.

Key Findings

Finding 1. STAR 3 responded to a significant HIV testing gap in Cameroon and was suitably tailored to reach high-risk populations not accessing conventional HIV testing services. Prior to STAR 3 there were no valid national HIVST guidelines, or authorization for the distribution and use of HIVST in Cameroon. Conventional HIVST testing services were considered by stakeholders to be largely inadequate as there was poor uptake among high-risk youth and fear of accessing health facilities among KPs.

STAR 3 HIVST models prioritised partners of pregnant women and HIV index cases, workers in enterprises, and young people 18-24 years working in salons, barbershops, garages, etc. Three channels were designed to reach these groups (Table B.1): i) facility-based model for partner index testing through ANC clinics and individuals testing positive ii) community models (x3) and iii) workplace distribution.

Finding 2. STAR 3 was well-integrated within government structures in Cameroon and civil society and CBOs supporting local HIV responses. From project inception, PSI engaged directly with key government stakeholders, notably the National AIDS Control Committee (NACC) the government Global Fund Principal Recipient (PR) and the main coordinating body within the Ministry of Health (MoH) for all HIV response activities. PSI also engaged with the Department of Disease Control, Epidemics and Pandemics, the Department of Laboratory and Pharmacy, and the Department of Operational Research. STAR 3 also worked with the 3 Regional delegations

and 8 health district offices. In regions covered by the HIVST demonstration projects, STAR 3 also partnered with CAMNAFAW, the lead Global Fund PR for civil society and 7 community-based organizations (CBOs), with existing sub-recipient (SR) relationships with CAMNAFAW. These CBOs, including the network of associations of youth living with HIV (Recaj+), Renata, and Youth Development Foundation (YDF) were already playing an important role in promotion of conventional HIV testing services in Cameroon and were engaged directly with at-risk communities through their network of peer educators. They were therefore trusted by communities and end-users of HIVST, and already sensitized to issues around stigma in key populations and linkage to care.

Table B.1. Cameroon HIVST distribution models

Model	Population	Partners (The CNLS and CAMNAFAW engaged in coordination and distribution of all models)	States
Public sector facility based distribution: Secondary distribution for partners of ANC and HIV+ clients	High risk sexually active men, exposed sexual partners of HIV positive index clients	Healthcare facilities/ workers	Central South Littoral
Community distribution: fixed point/ hotspot distribution, door-to-door distribution, and targeted distribution	Vulnerable youth (18-24 years)	CBOs such as RECAJ+ (Association of PLHIV), RENATA (Réseau National des Associations de Tantines), and YDF (Youth Development Foundation)	
Workplace	Employees of enterprises	Multiple companies including ENEO, G4 Security, Ferme Suisse, Chantier Naval	

Finding 3. STAR 3 was highly coherent with global partners in Cameroon in that it intentionally sought to establish alignment with the Global Fund lead Principal Recipients (PR) but was less successful in engaging the employers' organisation (GICAM) for the workplace model. An important element in the design of the project was the approach to work through the CNLS and CAMNAFAW, lead Global Fund PRs, as stated previously. This was intended to pave the way for Global Fund transition and scale-up.

Through interviews, grantees reported challenges for the workplace model in engaging the Groupement Interpatronal du Cameroun (GICAM), the employers' organisation. This stood apart from other STAR 3 countries which were regarded as having strong relationships at country level with ILO country partners. Partnership with GICAM was ultimately not productive and was discontinued (discussed further in the Efficiency EQ).

Finding 4. STAR 3 was internally coherent with other Unitaid HIVST grants, as well as Unitaid's self-care portfolio more broadly. STAR 3 in Cameroon benefitted from input from the STAR core team as well as support from Solthis which had experience in building local and national capacity for HIVST in West Africa. Conversely, the Solthis team have reported learning from Cameroon's workplace model (which was not a model in the ATLAS grant design). COVID-19 international travel restrictions hindered planned supervision by international experts/global PSI team, resulting in the adoption of virtual forums to hold meetings.

PSI/ ACMS are also currently elaborating on strategies for the Unitaid supported HepC self-testing grant in Cameroon, which will target similar populations to HIVST and make use of existing partners and systems. ACMS have stated that the government relationships established for introducing HIVST have aided the HepC project.

Finding 5. The design of HIVST models included linkage to treatment but not PrEP services. Importantly, the 'assisted HIVST' model to support linkage to services was critiqued for undermining HIVST confidentiality. The HIVST project design adopted an 'assisted HIVST' strategy and a coordinated process that ensured linkage to treatment services. Peer educators, mentors and focal points mobilized beneficiaries to use tests, assisted them, and accompanied them for confirmatory testing as needed. Follow-up through telephone calls and site visits was also implemented. Interviews with implementers surfaced concerns around the potential risk to confidentiality of the assisted HIVST strategy which while promoting linkage to care, may be inappropriate for KP and undermine efforts to reach certain groups (this issue was not identified in the program document review).

At the time of the STAR 3 projects, PrEP pilots were completed in project regions and so no referral was possible. Implementing partners stated that individuals who tested negative had access to counselling on safe sex practices but not PrEP, VMMC, or condoms.

Finding 6. STAR 3 established a well-functioning framework of collaboration among stakeholders, with leadership by the CNLS. A

CNLS-led steering committee organized meetings with all implementing stakeholders on a quarterly basis with support from STAR 3. Evidence generated on HIVST performance from the DHIS2 dashboards was shared with the MoH and CNLS and other stakeholders in late 2021 following start of the distribution projects.

There was also strong coordination and communication of the STAR 3 project through the other MoH departments described earlier. An indication of the strong buy-in for the HIVST projects was the CNLS's leadership in stepping in as lead technical partner for the workplace model (described in the following section).

Finding 7. Implementation delays at project inception in Cameroon were strongly linked to challenges in establishing civil society and CBO partnerships. This was in part attributed to a lack of shared understanding of STAR 3 objectives amongst partners. STAR 3 HIVST

projects had a delayed start in Cameroon where facility-based distribution of HIVST kits began in mid-2021 and the workplace distribution model did not begin until quarter 3, 2021.

Reasons for the delayed start were investigated with the STAR country team and focused on the following: i) inadequate sensitization of country partners on the intent of STAR 3 to work alongside NFM3, and poor understanding by implementing partners on distribution and linkage models; ii) the switch to virtual working during the COVID-19 pandemic also challenged effective communication, and stakeholder meetings had to be postponed multiple times.

There were also partner challenges, in that as STAR 3 partnerships were guided by existing Global Fund PR/SR relationships, STAR 3 was working with some grantees with more limited

capacity and weaker buy-in. Partnership with two CBOs, Press Jeune Development (PJID) intended to distribute to high-risk youth, and GICAM which was leading workplace distribution, were discontinued. To fill the gap in technical support for the workplace model, the CNLS assumed responsibility for coordinating this model through HIV Regional Technical Working Groups (the decentralized technical units of the CNLS which supervise HIV activities regionally).

Grantees were also concerned about CAMNAFAW's capacity to deliver activities in a timely way. For example, in 2021, CAMNAFAW initially erroneously procured a blood-based HIVST kit not approved for use in Cameroon, which had to be transferred to the Uganda STAR 3 project. However, the relationship and capacity-building within STAR 3 of CAMNAFAW was viewed as crucial for preparing for transition to Global Fund scale-up.

These challenges had a significant impact on activities progress. This is reflected by low budget expenditure in STAR 3's first year (2020), at 35.6%.

Finding 8. STAR 3 catalyzed an enabling HIVST policy environment in Cameroon, although evidence generation through the project was limited. STAR 3 provided technical support to update HIVST guidelines and catalysed the validation process and adoption of guidelines by the MoH. STAR 3 also supported the creation and validation of the training modules for HIVST in Cameroon and conducted TOT and cascade training of health workers and implementers on the guidelines, and established and harmonized DHIS2 indicators. STAR 3 also supported communication materials and strategies for HIVST in Cameroon.

While programmatic data through the DHIS2 dashboard was regarded by stakeholders as useful, they regarded overall evidence generation and dissemination as slow during the grant due to delays in distribution channels.

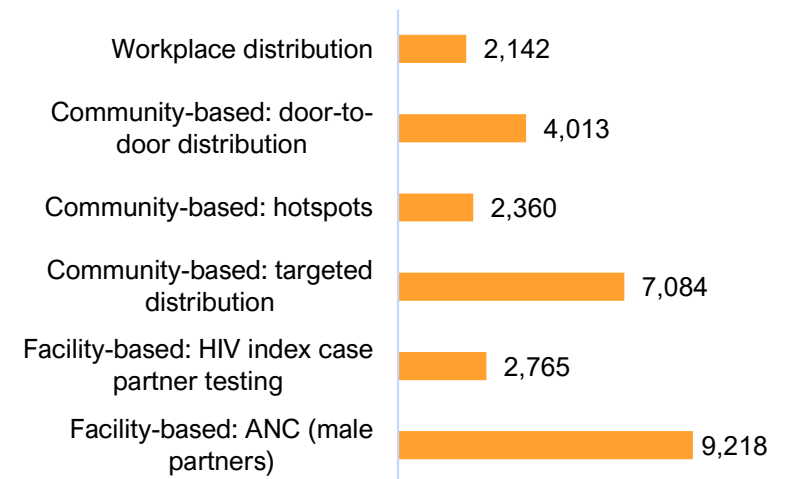
Across the 3 HIVST channels piloted, STAR 3 supported training of 153 health care workers within 80 health facilities, 7 CBOs and 68 community health workers, and 29 focal points for workplaces, with a capacity refresher for 81 peer educators and teenage mentors.

Finding 9. STAR 3 filled an identified testing gap among youth and KP through diverse distribution channels. Nearly 30k HIVST kits were distributed by the end 2021 and 95% of people testing positive were linked to care. In total by the end of 2021, the grant supported distribution of 27,538 HIVST kits from which 157 HIV cases were confirmed positive and 154 PLHIV were linked to treatment (95%) (See Figure B.1 of HIVST by channel).

The latest reported quarterly data (Q4 2021) showed that the highest number of first-time testers was reached through community-based testing (29% at hotspots), and that facility-based index partner testing showed the highest yield (8.3%) and link to confirmatory testing (86.2%). Linkage to treatment was close to 100% across all models except community distribution at hotspots (66.7%).

Of note, the grant was successful in reaching male partners of pregnant women which has been a longstanding challenge. Of 9,218 HIVST kits distributed by pregnant women to their male partners, 105 HIV positive cases were identified and 100% were linked to treatment.

Figure B.1: Kits distributed Q2-Q4 2021¹



Finding 10. Stakeholders believe that the registration of multiple kits in Cameroon will keep prices low through competition, and that the strategy of keeping HIVST free for end-users is crucial for use by target populations. In 2020 OraSure was registered in Cameroon, with the US\$2 price point negotiated by Unitaid. ACMS reports that price of HIVST is regarded by the government as acceptable, provided HIVST remains free for end-users and costs are borne by donors rather than the health system. In the transition from STAR 3 to Global Fund NFM3 recipients (CNLS and CAMNAFAW) the expectation is that HIVST will remain free for end-users.

¹Data for Figure B.1 obtained from ACMS quarterly reports and do not fully align with figures in the STAR 2021 Annual Report

Finding 11. STAR 3 facilitated registration of the OraQuick HIVST in Cameroon and supported integration of HIVST PSM into national systems. Openness of the CNLS to blood-based products is unique in West and Central Africa and a feasibility study is planned.

Prior to STAR 3, registration for the OraQuick HIVST had been stalled. Grantees reported that STAR 3 collaborated with the CNLS to identify bottlenecks and OraQuick was successfully registered in 2020. STAR 3 and WHO PQ CRP* also conducted trainings on the approval and registration of HIVST products.

During STAR 3, the PSM capacity of the CNLS and CAMNAFAW was significantly strengthened, including quantification and forecasting, procurement and distribution systems and STAR 3 trained CAMNAFAW in the Global Fund Wambo procurement mechanism.

However, challenges have persisted in PSM capacity and during the HIVST distribution projects, the STAR core team ultimately decided to directly procure and deliver 70,250 kits to project sites rather than engaging CNLS and CAMNAFAW to do so.

* Collaborative Registration Procedure

A Feasibility Study will inform the government's decision on inclusion of BBT in national guidelines

From interviews and program materials, the government were initially reluctant to introduce blood-based HIVST products, similar to views held in other WCA countries. Partners report Cameroon's interest in considering BBT was instigated by data on cost-effectiveness, as well as evidence provided by WHO and PSI from earlier STAR phases. Additionally, there is evidence that PrEP users prefer blood-based HIVST because of added assurance around accuracy, however government considerations around waste management and environmental effects remain.

The feasibility study planned for 2022 will include BBT from Viatrix/Mylan, Abbot, and Chembio which have been ordered by STAR 3 for the purpose of the acceptability study. Further, STAR 3 materials also report registration of 2 BBT are in progress in Cameroon (Insti and Chembio).

According to program reports, printing of national guidelines has been delayed pending the inclusion of BBT following the feasibility study.

Finding 12. STAR 3 has significantly contributed to national readiness for scale-up, including an enabling policy environment and support for expansion of HIVST under Global Fund NFM3 as well as PEPFAR.

STAR 3 contributed to the validation and endorsement of national HIVST guidelines, developed training materials, integrated HIVST within the national M&E system, and provided support in assessing needs, quantification, and developed a distribution plan for the Global Fund NFM3 proposal. Additionally, implementers felt that there was sufficient support at the operational level from districts and authorities to support distribution models.

HIVST procurement estimates through the Global Fund NFM3 are 245k (2022) and 303k(2023), representing a significant increase from the ~30k distributed by the end of 2021 in the STAR 3 projects.

STAR 3 coordinated with PEPFAR grantees (EGPAF and Georgetown University) to identify health facilities each partner would support to avoid duplication of efforts and doubling counting. STAR 3 also included lead PEPFAR grantees, FHI360 and Care

within HIVST TOT to sensitize them on HIVST. Further, CAMNAFAW, the Global Fund, CNLS and many partners implementing HIVST participated in the PEPFAR COP21. According to HIVST partners, PEPFAR is providing HIVST support within its HIV investments with Georgetown University, EGPAF, and Cameroon Baptist Convention Health Services (CBCHS).

Finding 13. The transition of PSM to the lead Global Fund civil society PR CAMNAFAW is regarded as a risk for the longer-term sustainability of HIVST supply.

As noted earlier, STAR 3 has transitioned HIVST distribution to CAMNAFAW and the CNLS, with CAMNAFAW responsible for the supply chain. While this transition was regarded by partners as smooth, stakeholder concerns remain about the capacity of CAMNAFAW to lead the transition. While STAR 3 regards more might have been done during the project period to strengthen this organization, it was also felt this would be challenging to address as an external partner.

This risk is being mitigated by support and coordination from the CNLS and

Regional Technical Groups which the STAR 3 project engaged with significantly. Additionally, the Global Fund has provided funding to ACMS/PSI to maintain technical assistance in Cameroon to support transition to scale.

STAR 3 also reached a mutual agreement with CAMNAFAW, which was included in the NFM3 proposal, for ACMS to deliver some of the HIVST kits planned for national scale-up. Currently however, CAMNAFAW has no HIVST stock and still awaiting funds from the Global Fund to complete the purchase of kits.

Finding 14. HIVST models targeting young people, male partners of pregnant women, company workers and KP were viewed to have had a considerable impact on the HIV response needs in Cameroon and to expand access to testing for those not reached through conventional HTS. Stakeholders noted that STAR 3 had addressed a long-term inequity in testing access in Cameroon, and that vulnerable young people benefitted from and preferred HIVST. Informants expressed that the support was “an important project”, and desire for HIVST to be continued and scaled up to all regions of Cameroon.

Best Practice

Stakeholders shared a common assessment that STAR 3 had a positive impact on access to HIV services

STAR 3's effective advocacy and coordination with the MoH and CNLS was seen as a key value-add of the grant.

The inclusion of community leaders CAMNAFAW was central to the success of the project

Lessons Learnt

Participant confidentiality was a concern at the community level, and consideration of more anonymous linkages to services would have better supported uptake.

A co-creation workshop at the start of the project with CSO-partners would have built stronger buy-in and helped avoid unnecessary delays.

The project underestimated the time required to fully engage the government, which led to significant delays

- STAR 3 reports indicated a high level of linkage to HIV treatment following HIVST, suggesting that HIVST did lead to better clinical outcomes for PLHIV. In particular, HIVST is regarded as having potential to improve PMTCT coverage by engaging the male partners of pregnant women.
- Relationships with the MoH were strong and stakeholders appreciated involvement of the CNLS at the start of the grant. Success in Cameroon is attributed to having involved the government from the start and the key structure within the government, in this instance the CNLS.
- Despite initial delays and capacity challenges in working with CAMNAFAW it was viewed as crucial to develop a relationship with the Global Fund PR and build capacity in HIVST. CAMNAFAW and STAR 3 were able to jointly develop a sustainable transition plan now underway and technical support provided by the Global Fund through ACMS/PSI is continuing some of the technical support provided by STAR 3.
- Although HIVST was widely accepted at the community level it was felt that the assisted HIVST strategy posed a threat to confidentiality. Systems supporting more anonymous linkage to services (e.g. digital models) were suggested by some stakeholders, recognizing would likely not be a government priority.
- Having a co-conception workshop at the start of the grant with implementation partners to establish a shared understanding of the objectives of STAR 3 and delivery models would have been a good practice and helped to mitigate start up delay.
- The project could have taken a more realistic view of the pace for deeply engaging the government, particularly considering a context where no HIVST was registered. The 18 month original timeframe of STAR 3 was regarded as too short.

The following recommendations are made to support the introduction of HIVST into the national HIV program of Cameroon and for consideration with future projects:

Recommendations

As STAR 3 transitions into the scale-up phase, PEPFAR and their implementing partners need to be more closely engaged. This will be an important step in expanding the enabling environment where Global Fund NFM3 support has already been successfully secured.

Given the success of STAR 3 in advocating for the use of blood-based products within Cameroon, this also provides an opportunity for open dialogue and potential introduction within the wider WCA region.

- STAR 3 successfully helped to secure Global Fund NFM3 support in Cameroon, with significant expansion of HIVST planned for 2022-2023. Given common grantees between the Global Fund and PEPFAR, and PEPFAR's inclusion of HIVST within COP21 (and anticipated in COP22) it is advisable that during the scale-up of HIVST, PEPFAR and its implementing partners should be more closely engaged.
- PSI/ACMS attribute the openness of the government to explore feasibility of BBT to a desire to bring efficiencies in procurement of HIVST and to PSI/ACMS's high responsiveness in relation to government concerns (e.g. waste disposal), which also built on the established ACMS government relationships prior to STAR 3. Pending the results of the study, this experience would be valuable for advocacy to other countries hesitant to adopt BBT, particularly in WCA.

Consultation list and References

Table B.2: Cameroon case-study stakeholder consultations

Category	Organisation	Name	Position
Grantees/ Sub-grantees	ACMS	Annie Michelle Salla Mabally	Deputy Executive Director
	ACMS	Lily Claire Ekobika	STAR Coordinator
	PSI	Karin Hatzold	Project Director, STAR
Civil Society Organisations	RECAJ+	Lonsi Sonwa	Promotion of human rights and community engagement, Supervisor
	Youth Development Fund	Mooh Alexandre	Supervisor
	Enterprise Ferme Suisse	Yanou Christian	Support Staff at Edea Regional Hospital
Government	CNLS (National AIDS Control Committee, Global Fund PR)	Billong Serge	Deputy Permanent Secretary
	DLMEP (Ministry of Health)	Bouba Haman	Deputy Director HIV/ STI/TB/ Hepatitis,
Technical partners	CAMNAFAW	Armel Nyadjio	Program Director
	CAMNAFAW	Ndomo Yannick	Focal Point

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- PEPFAR (May 10, 2021), Cameroon Country Operational Plan (strategic direction summary).

Appendix C

Côte d'Ivoire

Case Study

Grantees: *Solthis, MTVSAF*

Duration

*ATLAS: June 2018 – Nov 2021
with NCE to June 2022*

*MTV Shuga: April 2018 – June
2021 with NCE to June 2022*

Geographies: *7 regions of
southern Côte d'Ivoire plus
national MTV Shuga
broadcast*

HIV Funding landscape:

*Domestic (7%); PEPFAR
(77%); Global Fund (16 %).*

Background

At project start, Côte d'Ivoire had approximately 460,000 PLHIV, the highest (2.6%) prevalence in the West and Central Africa region, with a higher burden among women (3.5% vs 1.7% for men). The impact of the epidemic is greatest among KP, with prevalence rates of 12.2% among female sex workers (FSW) and 12.3% among men having sex with men (MSM).

The testing gap is significant, and only 63% of PLHIV were aware of their status. Reaching the first -95 UN target was regarded as a priority, in particular developing strategies to reach KP, men over 35 years and AGYW.

HIV Self-testing Policy and Registration Landscape

The political enabling environment was advantageous for the introduction of HIVST. Prior to the start of ATLAS, HIVST was already in national policy. There was a keen interest by the Programme National de Lutte contre le Sida (PNLS), as well as the Global Fund and PEPFAR to introduce HIVST, with PEPFAR funding a small pilot in 2018. The Global Fund NFM2 had allocated a small volume of HIVST to the national CSO Alliance CI, though these had not been distributed.

Unitaid's HIVST portfolio in Côte d'Ivoire

Program materials describe Côte d'Ivoire was selected for the ATLAS project due to a diverse epidemiological and operational context. Further as an influential country in the sub-region, there was a catalytic opportunity to influence other countries to integrate HIVST within their national HIV policy. According to interviews with Unitaid, support for MTV Shuga was directed to Côte d'Ivoire to complement the ATLAS initiative.

ATLAS Project Objectives

- i) Establish the environment for introduction and scale-up of HIVST
- ii) establish functioning delivery channels for HIVST kits to reach target populations, with links to confirmatory testing and treatment
- iii) Generate and disseminate evidence among key national, regional and international stakeholders

MTV Shuga objectives

To develop demand-generation campaigns to increase the number of young people who know their HIV status and are linked to prevention, care and treatment.

Key Findings

Finding 1. ATLAS and MTV Shuga investments were each highly relevant in responding to the HIV-testing gap and lower access to services amongst KP and young people. ATLAS focused predominantly on reaching KPs (FSW, MSM, PWIDs) and their sexual partners, peers and clients; sexually transmitted infection (STI) patients and their partners; and the partners of PLHIV.

MTV Shuga in Côte d'Ivoire planned a 2-part series (MTV Shuga Babi, series 1 and 2), the first to strengthen basic knowledge on HIV prevention, transmission, conventional testing and linkage to ART, and a second series to introduce HIVST. MTV SAF did not have a presence in WCA and therefore developed new French language materials and content responsive to the context.

ATLAS delivery models focused in HIV 'hotspot' regions: Gbokle-Nawa-San Pedro region has the highest number of new HIV cases per year among all regions: HIV prevalence is estimated to be 4.3% and only 19% of PLHIV know

their HIV status. Abidjan city constitutes the second HIV hotspot within the country, with a prevalence of 5.1%, but with better access to HIV testing, and nearby Sud-Comoé.²

HIVST channels and implementing partners are listed in Table C.1. An innovation in ATLAS was testing of STI+ patients and their partners given the increased susceptibility to HIV among people infected with an STI, and prior evidence in ATLAS countries only 28% of STI counselling sessions were found to offer HIV testing.

Finding 2. ATLAS was well timed, as HIVST was included in the National Strategy since 2016 without any concrete implementation and donor funding was increasingly focused on health facilities to maximise case finding. As described previously, there was a strong interest in HIVST amongst the government and donors. PEPFAR was funding Jhpiego in 2018 for a small HIVST pilot, and the Global Fund NFM2 had included 4,500 HIVST for Alliance CI, the Principal Recipient (PR) for civil society. However, progress since adopting an HIVST permissive policy was stalled and the Global Fund HIVST had not been distributed.

Table C.1: Côte d'Ivoire HIVST distribution models

Model	Population	Partners
Community - Direct and secondary distribution	FSW and their sexual partners and clients, MSM and their sexual partners, PWUD et their sexual partners	Espace Confiance
Health Facility – secondary distribution	Sexual partners of HIV+ clients and STI+ clients	Ariel Glaser
Community - Direct and secondary distribution	FSW and their sexual partners and clients, MSM and their sexual partners	Aprosam, Eloé, Heartland Alliance
Community - Direct and secondary distribution	FSW and their sexual partners and clients	Blety
Community - Direct and secondary distribution	MSM and their sexual partners	Arc-en-Ciel, Ruban Rouge (Blety sub)

In terms of priorities in HIV testing services (HTS), stakeholders report that ATLAS was introduced in the context of significant reduction in donor funding for Voluntary Counselling and Testing Centres (VCT) in communities, and redirection of VCT to CDIP (Conseil et Dépistage Initié par le Prestataire) – thus testing in health facilities. The intent of this shift was to increase the proportion of case findings (and improve yield).

Given high levels of stigma, this shift in HTS was regarded as reducing access by KP to testing and ultimately, other HIV services. As a result, stakeholders interviewed felt ATLAS was launched at the right moment and was instrumental to reach targeted KP with community distribution via civil society organisations.

Finding 3. ATLAS and MTV Shuga were strongly aligned with the overall national priorities in terms of HIV testing and worked closely with the government and community stakeholders involved in the HIV response. In the lead up to the ATLAS project initiation, the PNLS hosted a meeting in January 2018 with key stakeholders to agree on joint working amongst partners for introduction of HIVST.

According to the ATLAS project plans, Solthis participated and presented the proposed ATLAS strategy.² The PNLS priorities for HIVST were reaching KP and working with community partners. The ATLAS project was 'co-designed' with the PNLS and was approved and signed by the MoH.

In regards to MTV Shuga, documentary evidence describes that the PNLS attended storyline meetings and feedback over email on key content (messages, scripts and unedited episodes). Interviews with MTV SAF report WHO also provided valuable technical inputs into scripts and content. One limitation was that MTV Shuga storylines featuring issues concerning KP (e.g. MSM) on mass-media were restricted limiting the potential for demand generation.

Finding 4. ATLAS partnered with Global Fund and PEPFAR partners, leveraging the existing sub-granting system already in place and existing KP-focused initiatives. MTV Shuga had greater difficulty establishing new country relationships. ATLAS partnered with CBOs implementing existing Global Fund and PEPFAR projects supporting KPs. These organisations were all well established and active in the country providing HIV prevention, treatment and care and support services through a large network of community health worker and peer educators. Partners were deeply familiar with the ATLAS target geographies and KP networks within these communities (Table C.1).

For MTV Shuga's radio series, reports describe MTV SAF could initially not find a qualified or interested country partner and as a result wrote the series in house and produced in France (the second radio series was produced in Côte d'Ivoire). For the second TV series MPM Film and Boucan production were hired to produce it jointly. All the authors and directors working on the TV series were Ivorian.

Finding 5. Internal coherence within Unitaïd's country investments was limited by weakly aligned priority populations in grant design. While the first MTV Shuga Babi series was synergistic with ATLAS in its foundational messages on HIV prevention and attitudes, the second series that introduced HIVST did not closely link to HIVST supply channels, given the differences in target populations between the MTV Shuga and ATLAS grants.

Interviews with Solthis point to collaborative working relationships between the two projects at key early moments, including inputs from Solthis on the HIVST scenarios for the scripts of MTV Shuga Babi series 1 and 2.

Finding 6. There were significant delays in establishing the enabling environment for HIVST at the start of ATLAS, however this was regarded as crucial for buy-in and operational readiness. MTV Shuga activities were also challenged by the need to establish new partnerships and Covid-19 to a lesser extent. The ATLAS team reports distribution of HIVST was 6 months behind the planned timeline, owing to significant efforts by the project team to prepare implementing partners to operationalize the HIVST models. ATLAS worked nearly from 'scratch' to newly establish HIVST training materials, complete ToTs and socialize key actors on the program. Implementation of HIVST models began in late 2019.

While the inception period took significant time, there were also efficiencies in terms of cost savings by working with the same networks of community health workers and peer educators financed through Global Fund and PEPFAR programs, as reported in program materials.

MTV Shuga also experienced delays, including the comic book and in finding a partner for the MTV Shuga radio show as described earlier.

The COVID-19 pandemic in 2020 disrupted program activities to an extent, however ATLAS community-based distribution of HIVST continued, with Unitaïd supporting procurement of PPE for sub-grantees working in communities.

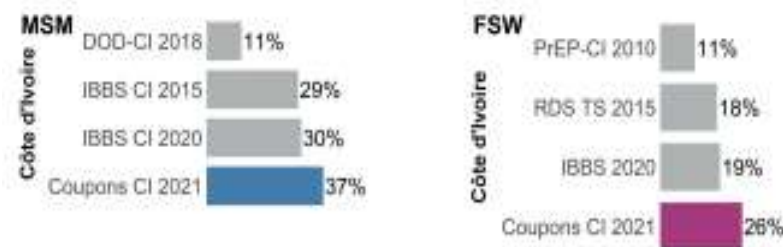
Equally, MTV Shuga, were able to move ahead with filming the shows during the pandemic, though program reports indicate screenings in educational settings of the first series of MTV Shuga Babi were limited given the restrictions related to COVID-19 in 2020. Filming of MTV's Shuga Babi series 2, which introduce HIVST, was done under strict Covid-19 protocols and had a digital-only launch that featured messages from Ivorian celebrities, from Unitaïd and MTV SAF. MTV Shuga Alone Together, a mini-series on COVID-19, was added by Unitaïd to the MTV SAF grant (covering Côte d'Ivoire, South Africa, Kenya, Nigeria, Botswana and the USA series) and followed the lives of MTV Shuga characters as they navigated their lives during the pandemic.

Finding 7. Through working with the PNLs and country stakeholders, ATLAS has significantly contributed to building an enabling environment for HIVST in Côte d'Ivoire. HIVST has been firmly embedded in key government HIV strategies, plans and governance/TWG structures. Interviews and program materials report the following key achievements: 2018 HIVST national guidelines were revised with WHO and ATLAS support in 2021 (still to be printed). The 8 ATLAS delivery channels implemented have been endorsed by national stakeholders, and HIVST target populations are included in the National Strategic Plan (NSP). A sub-HIVST TWG within the national HTS TWG has been established and is used on an ad-hoc basis. Training materials developed by ATLAS have been adopted nationally and a pool of trainers established alongside a supervision guide that was agreed with the PNLs to be integrated in the next HIV testing tool revision. Four DHIS2 indicators have been agreed, with the intent to integrate the ATLAS DHIS2 platform within the national DHIS2 in support of scale.

Finding 8. ATLAS's approach to focus on reaching peripheral and "hidden" populations through social network-based HIVST distribution successfully reached 1st time testers. A cumulative 196,609 HIVST were distributed to the end of January 2022. Over 80% of HIVST were distributed through secondary distribution with the FSW channel contributing to 54 % of HIVST distributed while the MSM channel contributed to 27%.

Research conducted by IRD to assess the extent the FSW and MSM channels were reaching first time testers reported that 37% of people reached through the MSM-channel were 1st time testers, and 26% of people reached through FSW-channel were 1st time testers (Figure C.1).

Figure C.1: Proportion of first-time testers in Coupons survey compared with other surveys conducted among MSM and FSW*



Finding 9. Despite promising research that ATLAS models are reaching new groups, different monitoring requirements for PEPFAR grantees was a challenge for country partners. Monitoring within the KP-models established through the PNLs-ATLAS project did not track individual HIVST and results and linkage to services. This was aligned with WHO guidance, and further was regarded by Solthis as crucial for anonymity and confidentiality within priority populations. According to research materials, a national hotline for HIVST and distribution through social networks and existing CBOs working with KP offers numerous options for support for people testing positive to link them with confirmatory testing and services.

PEPFAR implementing partners engaged in the PNLs-ATLAS HIVST distribution regard the lack of harmonisation in monitoring a significant challenge. Research to 'triangulate' routine HIV indicators and HIVST distribution to attribute changes in prevention and treatment to HIVST has been presented to PEPFAR and remains unresolved.

Finding 10. ATLAS has worked closely with scale-up partners (Global Fund and PEPFAR) to facilitate an effective transition and secure procurement, however there remain significant investment gaps.

As noted in the ATLAS annual 2021 review, transition has started in Côte d'Ivoire: HIVST has been fully integrated into the revised National Supply and Procurement (NSP) plans with an objective of procuring 602k kits (2021-2023) and 1,025k kits (2024-2025). For 2021-23, approximately 442k have been distributed/committed (this figure includes 30k HIVST to be confirmed by Global Fund) It is anticipated that some reprogramming of available funds from UNICEF and Global Fund NFM3, as well as PEPFAR COP 22 development will provide an opportunity to fill remaining gaps.

Advocacy has been initiated at the local level under the leadership of the PNLs, albeit to date with limited impact. Greater emphasis is now being placed on global dialogue mediated by the WHO and based on the upcoming impact results of the ATLAS initiative, with the aim to influence COP22 and Global Fund investment in the country.

Finding 11. The ATLAS operational model has built a comprehensive approach to reach KPs and high-risk groups through CSO/CBOs.

However, concerns have been raised about maintaining services after transition. ATLAS research on impact is still underway, however stakeholders are of the preliminary view that the initiative has had significant impact in reaching hard to reach, poor and underserved populations (MSM, FSW, PWID) and their clients and partners. ATLAS has also strengthened the capacity of the health services and procurement mechanisms, to enable KPs to know their HIV status and seek treatment in a comprehensive continuum of care.

ATLAS HIVST distribution completed at the end of February 2022. To assist with the end of project, coordination with national authorities has been set-up to make available 4 months of transition stocks (~30k kits) in the 52 delivery sites and ensure smooth transition from ATLAS to other donor support (Global Fund, PEPFAR, UNICEF). Despite these efforts, some implementing partners have raised concerns about the sustainability and of the project services after the ATLAS funding ends. For example, during the

stakeholder consultations it was noted that the remaining stock of HIVST kits available at some facilities had not been distributed following the announcement of the project end in February 2022. This suggests that while transition plans have been developed, there is ambiguity around operationalisation and clear communication with all stakeholders on the plans for HIVST distribution as the ATLAS support ends.

Finding 12. MTV Shuga successfully aired two series of Shuga Babi TV on RTI2 in Côte d'Ivoire as well as expanded reach into wider African francophone markets.

Alongside RTI2, the series aired on several Ivorian and pan-African channels including NCI, Edan TV Network, Life TV, and BET France. MTV Shuga also reported a positive externality of their partnership with the Ruban Rouge HIV helpline, in that it led to an increased volume of helpline calls. Discussions are ongoing with distribution company Côte Ouest Audiovisuel, to also show the series on several other regional channels. Overall, MTV Shuga has developed sustainable products which will remain freely-available to third-party broadcasters and NGOs on the MTV Shuga website. At present, no further series are planned in the country.

Best Practice	<p>Working with existing CSOs and CBOs leveraged the social network-based HIVST distribution which had a positive impact on access to HIV testing, including first time testers.</p> <p>The project had strong leadership and successfully built a constructive enabling environment for HIVST</p>	<ul style="list-style-type: none"> • Civil Society has been a core partner of the ATLAS initiative from the inception through to the delivery, transition and advocacy to influence national strategies. Notably the social network-based approach has been highly successful at reaching 1st time testers (see Slide 58) and hidden populations via secondary distribution channels. Successes gained by HIVST could also be instrumental for new projects, such as STI self-testing. • The ATLAS initiative fully integrated into national systems by building strong partnerships, including establishing an MoU with the National HIV Programme and working through existing technical working groups and HIV programme departments on all project aspects. The implementation model taken by Solthis successfully integrated HIVST into HIV services, aiding uptake and adoption.
Lessons Learnt	<p>The project underestimated the time needed to develop relationships with country partners to set-up of the distribution channels and build community engagement.</p> <p>Weak alignment between the ATLAS initiative and MTV Shuga demand generation led to a missed opportunity to address the HIV epidemic in AGYW</p>	<ul style="list-style-type: none"> • The ATLAS project had a comprehensive and well-structured approach to building strong partner buy-in to the project (see bullet above). However, this approach took longer than estimated and has led to delays in the results, with implications for influencing funding cycles. • Stakeholders view country investments missed an opportunity to reach young people with HIVST (where the HIV prevalence is 1.1%). Evidence on the effect of the MTV Shuga project on young people's HIV-related knowledge and attitudes will be available once the evaluation by LSHTM is completed.

The following recommendations are made to support the introduction of HIVST into the national HIV program of Cote d'Ivoire and for consideration with future projects:

Recommendations

As the project closes, a clear scale up plan must be established and communicated to all stakeholders to ensure consistent and expanded provision of services.

Targeted dissemination of the final project results and advocacy to influence scale-up and gap filling.

- Implementation of the existing transition plan, with a focus now on a clear plan for scale requires strong and visible government leadership and clear communication with all stakeholders. In the near term, to support effective transition and planning for scale stakeholders recommended; i) a strong and visible leadership of PNLs to harmonize the HIVST practices among all the donors supported projects (PEPFAR, UNITAID, Global Fund); ii) dissemination of the National Operational HIVST Guidelines; iii) The rapid issuance of a decree or a circular note from the MOH on WHO's recommendations regarding the ethical requirements of HIVST monitoring.
- Although there have been delays in the final set of IRD research results due to the COVID-19 pandemic, once these are available, continued dissemination and advocacy would contribute to effective scale up planning, and support efforts to close remaining gaps in HIVST commitments.

Consultation list and References

Table C.2: Côte d'Ivoire case-study stakeholder consultations

Organisation	Name	Position
Grantees/ Sub-grantees		
Solthis	Olivier Geoffroy	Project Manager, ATLAS
Solthis	N'Guessan Kouassi Noel	Technical Officer, ATLAS
Technical Partners		
Alliance CI (GFATM PR)	Gueu Alexis	Program Director
UNAIDS	Dr Quenum	Contry Director
UNAIDS	Dr Jean Marie Massumboko	Consultant
Government		
PNLS*	Prof Ehui Eboi	Coordinating Director
Civil Society Organisations		
Espace Confiance	Dr. Camille Anoma	Executive Director
Blety	N'Drin Tety Josiane	Executive Director
Ariel Glaser	Dr Abokon	Executive Director
Ariel Glaser	Dr Ndraman	Technical Director
Heartland Alliance International	Dr Venance Kouakou	Country Director

*The case study planned to interview key informants from PNLS. The recommended stakeholder Prof. Eboi, or alternate KI, have not been available.

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Appendix D Unitaid HIVST Portfolio Theory of Change

Theory of Change: Expediting access to HIV self-testing in low and middle-income countries

Problem	Public Health Need	<ul style="list-style-type: none"> Inadequate testing coverage perpetuates gaps in treatment and prevention coverage causing high levels of HIV morbidity and mortality among PLHIV, ongoing transmission and increase in new infections Need for innovative, cost-effective testing approaches targeting the unreached populations 		
	Access barriers	<p>Limited uptake largely due the barriers:</p> <ul style="list-style-type: none"> Affordability: High price of HIVST & perceived lack of cost-effectiveness; Demand and adoption: Lack of country level guidance on distribution as well as demand of QA products; Supply and delivery: Lack of effective supply chain systems including quantifications, clarity of storage and distribution to end users 		
Pathway to impact	Input	Outputs	Outcomes	Impact
	<ul style="list-style-type: none"> UNITAID funding Leveraged funds from other donors and governments 	<ol style="list-style-type: none"> Enabling environment: Supportive environment for introduction and integration of HIVST is created Effective delivery: Delivery models are developed and tested including linkage to care Evidence generation on acceptability, feasibility and effectiveness is provided to support policy, guidelines and scale up Demand creation: Innovating engagement of the communities, target population for increased awareness and demand of HIVST Market intervention: Intervention that will promote price reduction and diversity of products are implemented 	<p>Improved access to and uptake of HIVST in LMIC: and propel countries to reach first-two of the UN's 90-90-90 targets by 2020 and 95-95-95 by 2030</p> <ul style="list-style-type: none"> Rigorous evidence available on acceptability, feasibility and effectiveness of existing and upcoming tools, use cases and delivery models to inform global and national guidance Strengthened national level policies, guidance and strategies accessible to sub-national levels Delivery models and linkage integrated within existing systems to support cost-effective delivery and funding secured for transition and scale-up Price reduction and increase affordability 	<p>Public health impact:</p> <ul style="list-style-type: none"> Reduced morbidity and mortality among PLHIV; <p>Economic impact:</p> <ul style="list-style-type: none"> Increased economic impact. <p>Equitable access to diagnosis and treatment</p>
Key Risks	<ul style="list-style-type: none"> Strategic: Duplication of efforts leading to HIVST reaching those already being reached by the standard of care resulting in limited value add Implementation: Weak health system limiting the potential for integration of the proven effective models Scalability & transition: Lack of sustainable funding, delays in adoption into country policies and guidelines, low acceptability; limited capacity of governments to expand recommended approaches beyond project areas 			

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Appendix F Consultation list

Table F.1: Global level stakeholder consultations

Organisation	Name	Position
Unitaid Secretariat	Anisa Ghadrshenas	Technical Officer, Strategy Team
	Dale Halliday	Technical Officer, Strategy Team
	Heather Ingold	Programme Manager
	Anna Hellstrom	Programme Officer for HIVST and PrEP
	Ombeni Mwerinde	Monitoring and Evaluation Manager, Results Team
	Loveena Dookhony	Monitoring and Evaluation Manager, Results Team
	Priyanka Soni	Results Officer, Results Team
	Ademola Osigbesan	Technical Manager, Procurement and Supply Chain Management
	Kehinde Onasanya	Technical Manager, Strategic Sourcing and Supply
	Matthieu Vittot	Grant Finance Officer, Finance & Administration team
	Mailys Bobin	Grant Finance Officer, Finance & Administration team
Kristen Dorman	Legal Officer	
Grantees/ Sub-grantees		
PSI	Karin Hatzold	STAR Project Director
PSI	Aayush Solanki	STAR Senior Market Advisor
Solthis	Anthony Vautier	ATLAS Technical Director
Solthis	Clémence Doumenc-Aïdara	ATLAS Project Director
IRD	Joseph Larmarange	ATLAS Scientific Coordinator
MTV SAF	Sara Piot	Deputy Executive Director
Imperial College	Marie-Claude Boily	ATLAS, Modelling Work Package Lead
LSHTM	Liz Corbett	STAR HIVST, Research Lead
LSTM	Frances Cowan	STAR HIVST, Deputy Research Lead
LSHTM	Isolde Birdthistle	MTV Shuga Down South, Evaluation Research Lead

Table F.1 (cont.) : Global level stakeholder consultations

Organisation	Name	Position
Donors		
CIFF	Taryn Baker	Director, Sexual and Reproductive Health and Rights, Choices
Bill and Melinda Gates Foundation	Tanya Shewchuk	Senior Program Officer, Vaccines & Disease Control Programs
The Global Fund	Obinna Onyekwena	HIV Disease Advisor
The Global Fund	David Maman	HIV Advisor
The Global Fund	Susana Lorente	HIV Advisor
PEPFAR/ USAID	Vincent Wong	Branch Chief, Behavioral and Structural Interventions, Office of HIV/AIDS
Technical partners		
WHO	Cheryl Johnson	Technical Officer, HIV Testing Services
WHO	Anna Bekelynck	Consultant, West and Central Africa Support on HIV Testing
WHO/UNAIDS	Muhammad Shahid Jamil	Technical Officer, Global HIV, Hepatitis and STI Programme
UNAIDS	Mach-Houd Kouton	West and Central Africa, Regional Senior Advisor
UNAIDS	Purvi Shah	Asia-Pacific, Regional Consultant, Innovative Testing and Virtual Interventions/ HIVST Portfolio Focal Point
ILO	Syed Mohammad Afsar	Senior Technical Specialist, ILO Programme on HIV/AIDS
ILO	Dirkje (Diddie) Schaaf	Technical Officer
Manufacturers		
bioLytical	Hans Croukamp	COO
bioLytical	David Weaver	Commercial Director
Mylan/ Viartis	Srinivas Sivareddypeta	Senior Manager, Strategic Projects
Mylan/ Viartis	Kedar Madheka	Diagnostic and Strategic Initiatives Lead
OraSure Technologies Inc.	Brian Reid	Vice President, International Sales

Table F.2: Country level stakeholder consultations (non-case studies)

Organisation	Name	Position
Mozambique		
Grantees/ Sub-grantees		
PSI	Páscoa Wate	Technical Diretor
PSI	Meghan Butler	Director of Business Operations
PSI	Tina Vilanculo	HIVST Technical Advisor
Elos/ Jhpiego	Vânia Coutinho	Executive Director
Government		
Ministry of Health	Alény Couto	Head of HIV National Program, MoH
Donor		
PEPFAR/ USAID	Ana Paula Simbine	USAID HTC Focal Point
Mali		
Grantees/ Sub-grantees		
Solthis	Odé Kanku Kabemba	Country Director, Mali
Solthis	Sandra Ouegang	Project Manager, ATLAS Mali
Grantees/ Sub-grantees		
SOUTOURA	Sidibe Fadiala	Executive Director
Technical Partner		
FHI360	Tall Madani Moctar Saidou	
Government		
CSLS	Diallo Youssouf	Coordinator
Senegal		
Grantees/ Sub-grantees		
Solthis	Géraldine Colin	Country Director, Senegal
Solthis	Papa Alioune Gueye	Project Director, ATLAS Senegal
Enda Santé	Nguissali Turpin	Deputy Director

Table F.2 (cont.): Country level stakeholder consultations (non-case studies)

Organisation	Name	Position
Senegal		
Technical Partner		
ANCS	Massogui Thiandoum	Technical Director
Government		
DLSI	Cheikh Tidiane Ndour	Division Chief
South Africa		
Grantees/ Sub-grantees		
MTV SAF	Yvonne Diogo	South Africa Country Director
Tanzania		
Grantees/ Sub-grantees		
PSI	Edwin Mtei	Program Director
PSI	Aron Mugabiro	Operations Director
VIBINDO	Gaston Kikuwi	Chairperson
Technical partners		
ILO	Getrude Sima	Officer
Uganda		
Grantees/ Sub-grantees		
PATH	Edson Tweisigye	Senior Program Officer/ Project Manager
MARPI	Peter Kyambadde	Executive Director
MARPI	Kinalwa Patrick	
Lady Mermaid Empowerment Centre	Dorothy Nakayenga	Programs Coordinator
Government		
Ministry of Health	Géraldine Colin	Country Director, Senegal
	Geoffrey Taasi	HTS Program Officer

Appendix G Acronyms

Acronym	Full description
Afi	Area for Intervention
AGYW	Adolescent girls and young women
ANC	Antenatal Care
BBT	Blood Based Tests
CBO	Community-Based Organisation
CEPA	Cambridge Economic Policy Associates
CIFF	Children's Investment Fund Foundation
CNLS	Centre National de lutte contre le Sida (Cameroon)
COP	Country Operational Plan (PEPFAR)
CSO	Civil Society Organisations
EMAV	Early Market Access Vehicle
ERPD	Expert Review Panel for Diagnostics
FSW	Female Sex Workers
HIVST	HIV Self-Testing
HTS	HIV Testing Services
ILO	International Labour Organization
KII	Key Informant Interview
KP	Key Population
LMIC	Low- and Middle-Income Country
MoH	Ministry of Health
MOU	Memorandum of Understanding
MSM	Men who have sex with men
MTV SAF	MTV Staying Alive Foundation
NACO	National AIDS Control Organization (NACO)
NCE	No-Cost Extension
NFM	New Funding Model (for Global Fund grants)
PEPFAR	United States President's Emergency Plan For AIDS Relief
PLHIV	People living with HIV
PR	Principal Recipient (for Global Fund grants)
PrEP	Pre-Exposure Prophylaxis
PSI	Population Services International
PSM	Procurement and Supply Management
PWID	People who inject drugs
STI	Sexually-Transmitted Infections
TA	Technical Assistance
TAG	Technical Advisory Group
TG	Transgender
TOC	Theory of Change
TWG	Technical Working Group
UNAIDS	Joint United Nations Programme on HIV/AIDS
VMMC	Voluntary Medical Male Circumcision
WCA	Western and Central Africa
WHO	World Health Organization
WHO CRP	World Health Organization Collaborative Registration Procedure
WHO PQ	World Health Organization Prequalification

Important notice



UK

Queens House
55-56 Lincoln's Inn Fields
London WC2A 3LJ UK

T. **+44 (0)20 7269 0210**

E. info@cepa.co.uk

www.cepa.co.uk



Australia

Level 20, Tower 2 Darling Park
201 Sussex St
Sydney NSW2000

T. **+61 2 9006 1307**

E. info@cepa.net.au

www.cepa.net.au

