HIV Self-Testing Kit Market Development Workshop #2

Date: July 6, 2022

Location: Dar es Salaam, Tanzania – Slipway Hotel

Cooperative Agreement No:
7200AA21CA00027 (2021-2026)

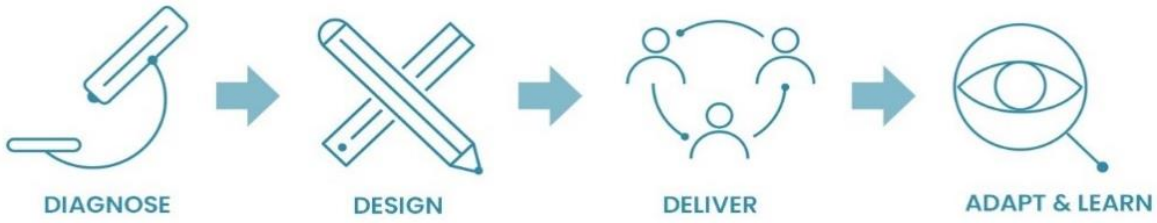
I. Background on the Activity and FHM Engage

FHM Engage is a global cooperative agreement providing technical assistance supporting strategic engagement of the private sector to advance health outcomes, in areas such as family planning, and maternal and child health, alongside other priority areas. Building on over 30 years of United States Agency for International Development (USAID) investment, FHM Engage focuses on strengthening local health markets by addressing the root causes of market underperformance in the core market functions[1] to create changes that catalyze supply and demand and support sustainable change. In line with this approach, FHM Engage seeks achievement towards two main results:

- Result 1: Improved market environment for greater private sector participation in the delivery of health products and services.
- Result 2: Improved equal access to and uptake of high-quality consumer driven health products, services, and information.

The FHM Engage approach, referred to as the Market Development Approach (MDA), draws on systems thinking to understand relationships between market actors and the incentives, accountabilities, and capacities driving their behaviors. The systematic process follows four steps to improve the operations and performance of a specific health market: (1) diagnose, (2) design, (3) deliver, and (4) adapt and learn (see Figure 1).

Figure 1: Pathway to Impact



Core to the MDA approach, is the idea that market actors lead the process based on the review of evidence. The market facilitator helps market actors throughout the process. During the DIAGNOSE Phase, the role of the market facilitator is to: (i) interact with market actors to understand which health problems are a priority in the country, (ii) gather data on the health problems identified by market actors and help market actors understand which health market they should focus on and what are the opportunities associated with these markets, (iii) understand the root causes of underperformance in the identified markets. During the DESIGN Phase, the market facilities can support market actors to understand (i) what can be done about the underperformance identified in the market, (ii) what are some global examples and good practices that market actors should be aware of, and (iii) to support market actors in identifying interventions to address underperformance in the market. The market facilitator can also help each market actor understand their role in addressing the various intervention areas. During the DELIVER and ADAPT and LEARN phases, the market facilitator continues to play a supporting function, helping market actors discuss the areas where things are going well, where things are not going well, and how to course correct. The market facilitator also plays a key role in helping market actors pull together learnings that can then to applied in the next iteration of market development.

In Year 1 of the project, both the FHM Engage Tanzania- and headquarters-based staff worked together to carry out the DIAGNOSE tasks for the HIV self-testing (HIV ST) market and started the DESIGN process. With a preliminary scoping of the HIV ST market, the team convened its second meeting of the HIV Self-Testing Market Development Group (HIV ST MDG) to deepen and validate the analysis. This report is a documentation of the public private dialogue to increase use of HIV products and services through private sector engagement

II. Introduction

This workshop is the second of several consultative workshops, meetings, and activities to co-create and collectively implement interventions that will introduce and encourage uptake of HIV self-testing kits (HIV STKs) through public and private channels.

The workshop was opened by the FHM Engage Technical Advisor who shared highlights of the FHM Engage project, the workshop objectives, and welcomed participants for introduction.

III. Workshop Proceedings

Workshop objectives: The meeting objectives included:

- A recap of the objectives of the HIV ST working group and the outcome of Workshop #1
- A focus on learnings from different HIV ST service delivery modalities to address some of the information gaps identified in Workshop #1
- Providing an opportunity for blood based HIV STK manufacturers/representatives to present their products to the group
- Summarizing and creating a plan to address the additional information gaps that were identified during the session to better understand current market performance

Workshop Participants: The workshop was attended by stakeholders from public, private, for-and not-for-profit providers, social/commercial importers and suppliers, and development partners. Representatives from the following organizations participated in the meeting: the Tanzania Commission for AIDS (TACAIDS), USAID, T-Marc, Sciex (representing Orasure), Synermed (representing Mylan HIV self-testing kit), Nebula Health Care (representing Bionnex), MyService, Tanzania Youth Alliance (TAYOA), Population Services International (PSI), FHI360, Amref, Pathfinder, and FHM Engage.

Presentation 1: Workshop #1 Recap

Prior to discussing the agenda for Workshop #2, FHM Engage shared the group's focus towards achieving the first of the 95-95-95 goals through expanding HIV self-testing (through various service delivery modalities, including through the private sector) to target populations not currently accessing other conventional HIV testing services. The facilitator shared a summary of Workshop #1, the identified information gaps, and the agreed action points so that new participants attending Workshop #2 would have a clear background of the group's focus and previous discussions.

Identified Actions from Workshop #1

- Continuous engagement with the group
- Expansion of the informal group - Tanzania Medicines and Medical Devices Authority (TMDA), Pharmacy Council, TACAIDS, and civil society organizations (CSOs)
- Advocacy with groups in collaboration with the Joint United Nations Program on HIV and AIDS (UNAIDS)
- Support of Private Facilities
- Address data challenges – FHM Engage will identify partners among the group to find solutions to these data gaps to:
    - Document learnings from other countries
    - Conduct rapid research on consumer preferences and willingness and ability to pay
    - Understand issues related to the import, distribution, and data capture of HIV STKs

Presentation II. World Health Organization (WHO)/ATLAS/STAR HIV ST Monitoring and Evaluation (M&E) Lessons from West and Central Africa

The purpose of the HIV ST Market Development Group is to co-create and collectively implement interventions that will introduce and encourage uptake of HIV STKs through public and private channels. Developing effective interventions requires an understanding of the key challenges and their root causes, as well as learning from the experience of others. M&E was cited in Workshop #1 as a challenge in various Tanzania delivery modalities, potentially posing as a barrier to scaling-up the Pharmacy Distribution Delivery model. As a result of this, FHM Engage decided to summarize an important webinar hosted on June 21, 2022, by the WHO/ATLAS/STAR Initiative on HIV ST M&E lessons learned from West and Central Africa. The webinar presentations summarized the WHO's guidance on i) HIV ST M&E, ii) best practices for data triangulation from the ALTAS program, and iii) emerging opportunities to implement technology (e.g., WhatsApp Chatbot) to collect information on the HIV ST process.

Webinar Link: WHO/STAR/ATLAS Webinar on HIV ST M&E lessons

WHO Presentation Key Takeaways:

- We need to be able to measure the impact of HIV ST access on the 95's goals; however, **it's important not to make M&E too onerous and complex**.
- We need pragmatic approaches. Developing and implementing M&E systems that monitor from the point in time when HIV ST is distributed to a user to the time when they are linked with treatment **is highly costly, difficult, and not feasible in a national scale-up.**
- **WHO General Principles on HIV ST M&E**:
  - Use multiple data sources
  - Data collection should not be intrusive or burdensome (we need to protect confidentiality and the privacy of individuals) and not make monitoring a deterrent from the use of HIV ST
  - We need to consider the human and financial cost of active monitoring
  - **Prioritization should be on the use of routine data + data triangulation** (look to the ATLAS project on the work they have done to measure the impact of HIV ST)
  - (Refer to: WHO HIV Self-Testing Strategic Framework: Guide for Planning, Introducing and Scaling-Up, 2018)

ATLAS Data Triangulation Method

- ATLAS is a project that introduced HIV ST in three countries: Ivory Coast, Mali, and Senegal
- **Lessons on M&E from the ATLAS Program**
  - Systematic data collection/report for HIV ST distribution is mandatory to monitor program implementation
  - **Systematic data collection on HIV ST use and results is not recommended nor realistic** (but voluntary feedback from users can be collected for analysis)
  - **Data triangulation should be considered to effectively monitor and evaluate HIV ST outcomes and indirect impact**
- Key variables required to replicate the ATLAS data triangulation methodology
  - Number of HIV STK distributed
  - Number of conventional HIV tests performed
  - Number of new diagnoses/positive tests
  - Number of new antiretroviral therapy (ART) initiates
  - Number of adults over the age of 15

  [The above variables were aggregated at the district level]

STAR Initiative: Digital Platforms to Facilitate HIV-Self Testing and Reporting Through Client Journey Experience

- PSI highlighted a special tool called the HIV ST Chatbot App or "virtual counselor" which can be used to:
  - Direct clients on where to access HIV ST

- Generate e-vouchers for HIV ST access and post-test services
- Privately access curated information about health issues, products, and services
- Integrate screening tools to assess risk profile, whether to test for HIV, and whether eligible for pre-exposure prophylaxis (PrEP)
- Automate follow-ups and reminders
- Receive feedback from a human
- **Share and collect data from the HIV ST process**

→ Takeaways

- Chatbot provides a good opportunity to educate about HIV prevention, care and testing, promote self-testing, and learn how to use self-test kits
- It is an efficient way to engage with large audience and retrieve information on health issues, services, and access points, especially for young people
- It uses multiple languages and can accommodate various nationalities and ethnicities
- It can accommodate multiple self-test kits and link to other self-care products, family planning (FP), PrEP
- Opportunity with human interface and helpline
- **Chatbot is being expanded in Tanzania**

Global Fund HIV ST M&E Approaches

Global Fund uses a mix of programmatic, budgetary, and procurement data for HIV ST M&E

→ **Programmatic data**

- HIV testing volumes, overall and stratified by key populations
- Self-testing distribution data will become available from New Funding Model 4 (2024)

→ **Budgetary data**

- New Funding Model 3 HIV Testing Budget (including self-testing)

→ **Procurement data**

- Procurement performance management (PPM) 2018-2021

→ Currently one supplier represents 84 percent of total HIV ST market orders placed through PPM.

→ The presenter posed a question about the potential price reductions on HIV ST in the future and getting closer to $1/ test, as Abbott's self-test kit is a new entrant to the market with an announced price of $1.40

Questions & Discussion:

→ USAID representative asked if there is a tool for regression analysis to be adapted. FHM Engage was urged to reach out to ATLAS/STAR for further information.

Presentation III. Private Pharmacy Distribution Model

PSI Shared their experience with the Pharmacy Distribution model.

- The project started in February 2021-August 2022 (implementation ended in March 2022).
- **Implementation regions:** Mwanza, Dodoma, and Dar es Salaam
- **STAR Pharmacy Distribution Model**
  - **Targeted Clients:** At risk men, adolescent girls and young women (AGYW), and key populations (KPs).
  - **Price:** It was noted that pharmacies were issued kits freely from PSI and they [the pharmacies] were instructed to sell at a price of a maximum Tsh 3,000. (Subsidized price).
  - **Partners:** The STAR project partnered with the Pharmacy Council Tanzania, Pharmaceutical Society of Tanzania (PST), and the National AIDS Control Program (NACP).
  - **Demand Creation:** PSI shared that the Pharmacy Distribution Model entailed demand creation for HIV STKs through information, education, and communication (IEC) materials; training pharmaceutical personnel to identify potential clients; and use of community health workers (CHW) from nearby health facilities to generate demand.
  - **Training:** Pharmacists were trained on screening clients eligible for HIV ST, counseling clients, registration and records keeping, and issuing the kits over the course of three days.
  - **Unassisted modality:** It was noted that HIV ST was conducted outside the pharmacies; Pharmaceutical personnel did NOT provide HIV testing service at the pharmacy.
  - PSI engaged 60 private pharmacies and supported them in the provision of HIV ST services.
- **Major achievements**
  - Oriented 13 national training of trainers (TOTs) who are available to facilitate scale-up.
  - Engaged 60 private pharmacies to implement HIV ST distribution.
  - Successfully trained 60 pharmaceutical personnel.
  - Distributed 18,550 HIV ST kits through private pharmacies.
  - Developed a HIV ST pharmacy reporting tool, which is in use.
  - Integrated HIV ST in the Pharmacy Council's unstructured supplementary service data (USSD) reporting platform.
  - Produced and distributed IEC materials and conducted IPC demand creation.
- **Implementation challenges**
  - Low return rate noted (out of 18,550 distributed tests, only 684 clients voluntarily self-reported using the kit).
  - Limited visibility of distribution data, developed District Health Information Software (DHIS2) dashboards were not published.
  - Trained pharmaceutical personnel turn over (some of the trained personnel who moved from other pharmacies were not supported by the STAR project).
- **Lessons learned and recommendations:**
  - Private pharmacy is a promising channel for HIV ST distribution, and scale-up should be considered.
  - Population-level HIV ST awareness raising is critical to maximize demand.
  - Training content and modality should be revised to minimize training days and increase efficiency to enhance scale-up.

- Commercial suppliers of HIV ST should be encouraged to stimulate private sector led HIV ST distribution and promotion.
- Consider going to the lower ADDOs will increase access to HIV ST.
- Consider deploying different product/packaging from the public used HIV ST to provide full range of options for clients.
- Use of population level survey/studies is better for private pharmacy M&E.

Questions & Discussion:

Participants had questions for the STAR team following the presentation. Below is a summary of the questions and responses.

Q: Was there hesitancy for customers at the pharmacies to register and share their results?
A: The PSI program manager emphasized that self-testing and results reporting is voluntary. To encourage clients to report results and get linked to care and treatment services, PSI trained the pharmacists to provide pre-HIV ST counseling and share information about where to receive confirmatory testing. Also, project staff collected information (voluntarily from clients) through the pharmacy registers and followed-up with them within 21 days.

Q: How logical is it to monitor a HIV positive client from pharmacies & how to manage linkage between pharmacies to ART? How do we follow up the self-tested?
A: WHO guidance is that M&E for HIV ST should not be "too onerous or complex" and instead should use routine data + data triangulation to measure indirect impact. It is not feasible to monitor and track patients from the point of HIV STK distribution to the point they initiate ART, as this is costly and not feasible in a national scale-up. That being said, data from pharmacies were captured through a register. Pharmacy Council has a USSD platform to interlink with DHIS2. (However, to date, these systems have not been integrated.)

Q. What is the current stock status of HIV ST kits in the pharmacies?
A: About 3,000 HIV ST kits remain at private pharmacies.

Q. What were the STAR targets for the Pharmacy Distribution Model?
A: STAR anticipated that 40 percent of the 120,000 HIV STKs they had would be distributed through the pharmacy model. They did not reach that target as there was higher demand through the workplace model and there was a delay in commencing the Pharmacy Distribution Model.

Q: Is the demand for HIV STK high or low?
A: Demand is there, although it is hard to say if it is low or high; the uptake was promising, but more demand creation activities are required.

Q: Did STAR capture any information on the clients wanting the product but could not afford?
A: STAR did not capture the affordability data but had benchmarked the price of 5,000 TZS from a SHOPS Plus assessment.

Q. What are the next steps on the Pharmacy Model Evaluation?
A: A detailed programmatic report on the Pharmacy Model is forthcoming at the end of July 2022. A formal evaluation will be done on the workplace HIV ST model; itis expected to start in August 2022 and be finalized by December 2022.

Next Steps for PSI/STAR:

- → PSI will support NACP on the launch of WhatsApp Chatbot. PSI will lead partners and the government in the development of the platform, which will offer virtual counselling and linkage to care and treatment services, etc.
- → The Ministry is interested to see if the system can do the delivery itself, i.e., Information and Communication Technology (ICT) model.

Presentation IV. Afya Kamilifu (Amref) HIV STK Implementation Experience

- Afya Kamilifu is implemented in the Tanga, Simiyu, and Mara Regions
- **Training:**
  - Health facilities in the targeted areas received a national HIV ST training package (five-day training)
  - Peers (community outreach volunteers) received a four-day training
  - Regional/Council Health Management Team (R/CHMT) sensitization meeting (one day)

The Afya Kamilifu project distributes HIV STK through the following models:

- **Community based**: This is integrated with daily outreach services targeting hotspots, door to door, fishing communities, and mining.
- **Facility based**: At outpatient departments (OPD), there is secondary distribution for antenatal, family planning clients and direct distribution during HIV testing services (HTS) optimization. Clients test on site, at the private area within the facility.
- **Secondary distribution**: Enhance index testing through a referral option, peer-to-peer social network testing (KPs, AGYM, vulnerable populations).
- **Distribution at workplace:** formal and non-formal
- **Demand creation and linkage to HIV Prevention:** Integration with PrEP service and integration with social and behavior change communication (SBCC) for KPs and AGYWM.
- The targeted population for HIV STK services is all persons aged 18 and above who provided verbal, informed consent as per the national HTS guidelines; clients aged 15-17 who are sexually active; and pregnant or otherwise, hard to reach populations at risk of HIV such as:
  - Female sex workers and their partners
  - Males having sex with males and their partners
  - People who inject drugs and their partners
  - Adolescent girls and young women and their partners
  - Adolescent boys and young men and their partners.
  - HIV negative of sero-discordant couples and partners of ANC clients
  - Males and young people
  - Partners and family testing of people living with HIV
  - Other vulnerable populations (e.g., people in fishing, mining, and migrant communities, and long-distance track drivers.)

Questions & Discussion

Q: Through what channel(s) does Amref receive HIV STK supply?
A: AMREF receives free HIV STKs through the public sector (Medical Stores Department) only.

Q. As all of the HIV STKs you [Amref] are distributing are the free ones from the public sector, from a sustainability perspective, have you considered working with the formal workplaces to encourage them to purchase and distribute HIV STKs (for a free or subsidized price to employees) through their HIV workplace programs?
A: We are currently only working with the informal sector but can think about this.

Q: Is there a notable difference between clients returning to the health facilities (HF) in the assisted vs. unassisted testing modalities?
A: There was a higher return rate of clients who were assisted with HIV ST than those not assisted.
Amref shared that a high rate of return clients (over 98%) was due to investments made to engage community outreach volunteers, CHW, and peer educators who create demand, conduct post follow ups, and link clients to HFs and outreaches for confirmatory tests

Presentation IV. Viatris/Mylan HIV Self-Testing Demonstration

The Mylan representative presented on their WHO-PQ & TMDA registered blood based HIV self-testing kits which are accurate, safe to use, and convenient, with easy to interpret results.

Link: Mylan HIV self-test demonstration

Next Steps (some continuing from Workshop #1)

1. FHM Engage will work with stakeholders to finalize the dates for Workshop #3
2. FHM Engage will follow-up with the ATLAS program on their regression model and share with the HIV ST working group
3. The group will continue to address data challenges (identified in Workshop #1)
    a. FHM Engage will share the draft HIV ST policy brief for review prior to Workshop #3, which is to be validated by NACP/TMDA.
    b. Document and share learnings from other countries
    c. Conduct rapid research on consumer preferences and willingness and ability to pay
    d. Understand issues around HIV STK import, distribution, and data capture
4. Engage NACP on how to best support the development of distribution guidelines
5. Work with UNAIDS to commence HIV ST advocacy with i) the Prime Minister, ii) NACP, iii) religious leaders, and iv) sports figures
6. Work with Christian Social Services Commission (CSSC) and the Association of Private Health Facilities in Tanzania (APFHTA) to expand supply in private facilities
7. Assist CSSC (and other faith based organizations) and APFHTA to document i) current supply, ii) experience to date, and iii) barriers to expansion
8. Develop a quick action plan to expand HIV STKs in private facilities