

# HIV Self-Testing Kit Market Development Workshop Report

**Date: May 25, 2022**

**Location: Dar Es Salaam, Tanzania – Coral Beach Hotel**

Cooperative Agreement No:  
7200AA21CA00027 (2021-2026)

## 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<sup>1</sup> 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, and (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 be applied in the next iteration of market development.

In Year I 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 first meeting of the HIV Self-Testing Market Development Group (HIV ST MDG) to deepen and validate the analysis. The purpose of the one-day workshop was to: (i) form the HIV ST MDG, (ii) validate the analysis of the current HIV ST market, (iii) co-create a vision of what a well-performing HIV ST market will look like, and (iv) reach a consensus on a way forward to design a market strategy to improve market performance. 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 first 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. There are several principles that guide a market development approach – of all which were in display during the workshop. They include:

- Inclusive – Include key market actors that have and perform a critical role in the core market and market system
- Dynamic – Although a first step, the collective group will interact and iterate on their diagnosis of the HIV STK market performance and design of the HIV STK market strategy as they gather more information and opportunities emerge (e.g., new technology in the pipeline)
- Adaptive – Be flexible and respond to market actors needs in “real time.”

***(See Annex One for the agenda.)***

## III. Workshop Proceedings

**Workshop objective** – the meeting objectives included:

- Reaching consensus on the current HIV STK market
- Co-creating a vision on what a future HIV STK market will look like
- Agreeing on market interventions to achieve this vision

- Identifying next steps to deepen analysis and further refine the market strategy for HIV STKs

As the workshop unfolded, it became clear to the workshop facilitators that they wanted to move slower to finalize the diagnosis of the market performance. Several questions emerged, for which there was no data, and they agreed on actions to address these data gaps. As a result, the participants got as far as agreeing on the parameters of a vision for expanding access to HIV STKs in Tanzania.

**Workshop participants:** Using the market actor landscape analysis (**See Annex Two**), the workshop organizers took measures to ensure representation of the key market groups: public, private, for- and not-for-profit providers, social/commercial importers and distributors, and development partners (**see Annex Three**). Although many remarked that everyone who needed to be at table was present, there were a few notable gaps: Global Funds (on a trip) and the consumer voice. As noted in the agreements, next steps include identifying and inviting two to three civil society groups and/or non-government organizations (NGOs) who can represent the different consumer groups for HIV STKs.

**Workshop key agreements:** The interactive sessions validated the preliminary analysis conducted by the team but also crystalized some consensus agreements on (**see Annex Four**):

### **Part I: Scope the problem related to HIV STKs**

In framing the health problem, the participants generally agreed on its scope and that expanding access to HIV STK is a priority requiring actions: (i) Reaching people who don't know their HIV status is a Tanzanian priority, (ii) Low testing and awareness of status among key populations remains a challenge to achieving 95/95/95 targets, (iii) HIV testing is critical in the linkage to initiate care and treatment services, (iv) HIV ST is a complementary HIV testing approach that has shown acceptance by consumers (e.g. offers privacy, confidentiality, and is time saving) and offers benefits that might encourage and empower unreached populations to test.

### **Part II: Understand the core market (supply and demand) for HIV STKs**

- *Product supply:* There are too few products (type and number) to build the market the HIV ST market. Only Oraquick and Mylan are registered by the Tanzania Medicines and Medical Devices Authority (TMDA) in Tanzania and two are in the pipeline.
  - The need is great, but it is unclear who will pay in the future. Quantities will have to triple in three years from 930,000 in 2021 to 4.2 million in 2023. The government will need to mobilize approximately \$1.8 - \$2.8 million in 2021 to approximately \$8.5 - \$12.7 million. Currently, HIV STK government supply is donated by Global Funds; there is some commercial supply (quantity unknown).
- *Product supply modalities:* Regulations permit all market actors to deliver HIV STKs in multiple settings - public and private (e.g., antenatal care (ANC)/ outpatient department (OPD)/Pharmacy). But there is government hesitance to allow private pharmacies due to concerns about counseling, technical capacity, and appropriate disposal of blood kits.
- *Product demand:* There is agreement that HIV STKs should be focused on target population groups. The HIV STK framework clearly details the consumer groups: persons above the age of 18 including men, youth boys, and girls; key vulnerable populations; partners with people living with HIV (PLHIV); mobile populations; and certain occupations. We know who they are, how many they are, and where they are. *But there is low motivation to get tested and low awareness of HIV STKs.*

### **Part III: Analyze market system constraints**

- *Market stewardship:* The National AIDS Control Program (NACP) leads the HIV Prevention Technical Working Group (TWG). HIV STK resides here, but it currently is not a focus and could use support to mobilize the market actors and raise its profile on NACP proceedings.
- *Skills:* There is limited private sector capacity due to a five-day training requirement and access to affordable products. There is greater public capacity. Referral system requires strengthening.
- *Technology:* Consumers accept and perform self-testing. They have indicated a preference for blood (based on rapid market studies done), yet only oral is available.
- *Regulations:* There are different interpretations of regulations. Although TMDA has registered two (oral and blood) products, NACP has only authorized the use of oral. Also, the President’s Emergency Plan for AIDS Relief (PEPFAR) does not support the use of blood kits (but this may be changing).
  - NACP and Pharmacy Council are currently awaiting results of a pilot done by Population Services International (PSI) and do not allow pharmacies, although the framework supports them to dispense HIV STKs.
  - The regulatory bar is too high for blood kits and newer technology (e.g. urine) to enter the Tanzanian market.
  - NACP’s five-day training requirement is a barrier to private providers.
- *Norms:* There are several cultural norms creating barriers for consumers to seek HIV testing, particularly among youth and high-risk population groups.
- *Financing:* Currently NACP is mainly donor reliant and there is limited opportunity for social and commercial supply.
- *Market intel:* There is high awareness among the general population on the need to know one’s HIV status, but low awareness on HIV self-testing and STKs.

### **Part IV: Co-create a vision for HIV STKs market**

The workshop participants agreed on the basic parameters of what a well performing HIV STK market would look like but wanted more information in key areas to further refine and develop this vision. The diagram illustrates an agreement on key components of the HIV STK market. Key areas of consensus included:

- Agreement that this is a new, emerging product in Tanzania that will require initially, donor funds to “prime” the market.
- NACP signaled its goal for this market to be sustainable in the medium-term, including facilitating private supply.
- NACP agreed on the need to clarify why blood based STKs are not allowed even though framework and guidelines are open to them.
- NACP also stated that the market should be segmented – public free price, social affordable prices, and a commercial price-creating space for different delivery channels.



## IV. Agreements

- The workshop participants agreed to use an “informal” mechanism to continue working together to design a market strategy for HIV STKs.
- They committed to meeting at least once a month to co-create a draft of the market strategy by September.
- The informal group needs to include representative organization that can bring consumer perspective to the deliberations. Also, other government agencies like Pharmacy Council should participate.
- Data challenges were a constant theme throughout the workshop and participants agreed to work together to address these data gaps (see next steps). PSI and Amref have agreed to present their learning to date on the two HIV STK pilots in the next two monthly meetings.
- Several participants proposed the group start to advocate for HIV STKs and mobilize influential champions who can assist the group to elevate this topic on the ministry’s agenda.

## V. Next Steps

The participants identified and agreed to the following actions:

1. FHM Engage will work with the stakeholders to finalize the dates for the next four meetings.
2. Expand the informal group to include key government agencies (e.g., TMDA, Pharmacy Council, and the Tanzania Commission for AIDS (TACAIDS)). FHM Engage will work with NACP to meet with each of these groups to integrate them into the market strategy design process in time to participate in the next meeting.
3. Expand the informal group to include NGOs and civil society organizations (CSOs) representing target consumer groups. FHM Engage will identify which groups and report back at the next meeting.
4. Address the data challenges – FHM Engage will identify partners among the group to find solutions to these data gaps to: (i) draft a synthesis, which NACP/TMDA will validate (1 to 2 pages), of key policies and regulations to develop a common interpretation of regulations and guidelines; (ii) document learnings from other countries; (iii) conduct rapid research on consumer preferences and willingness and ability to pay; and (iv) understand issues related to the import, distribution, and data capture of HIV STKs.
5. Support the development of distribution guidelines for HIV STKs (FHM Engage team).
6. Commence advocacy with (i) the Prime Minister, (ii) NACP regulators, (iii) religious leaders, and (iv) sports figures (FHM Engage to work with the Joint United Nations Program on HIV/AIDS (UNAIDS)).
7. Expand supply in private facilities (where it is currently allowed).
8. Assist Christian Social Services Commission (CSSC) (and other faith based organizations) and the Association of Private Health Facilities in Tanzania (APHFTA) to document (i) current supply, (ii) experience to date, and (iii) barriers to expansion.
9. Develop a quick action plan to expand HIV STKs in private facilities.

# Annex I. Workshop Agenda

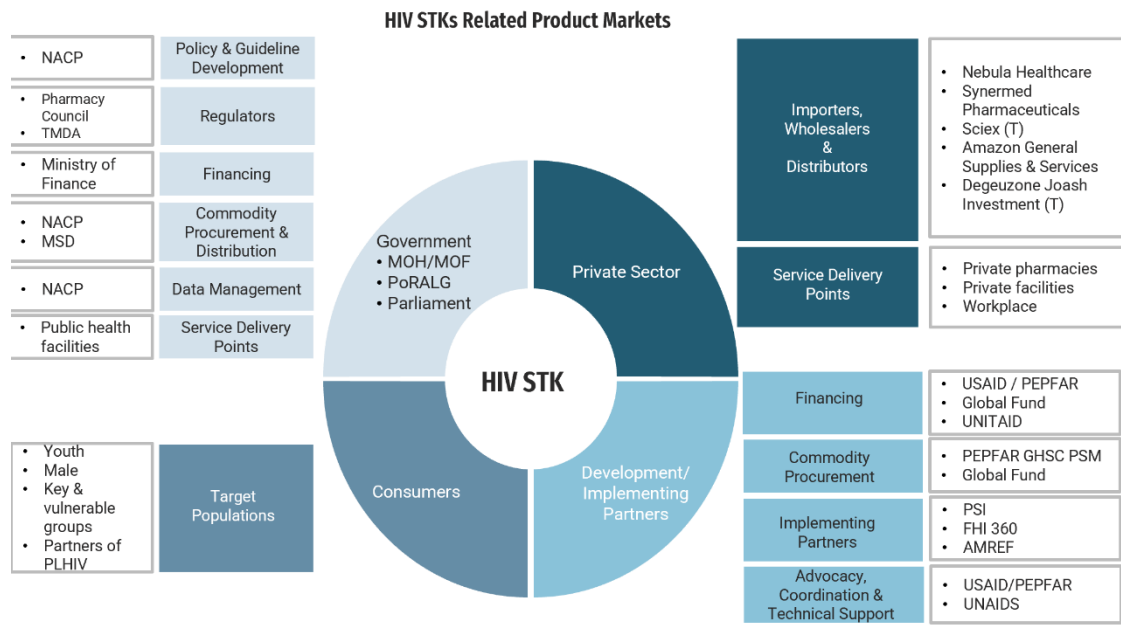
HIV STK Meeting Agenda  
 Coral Beach Hotel  
 Yacht Club Road  
 Wednesday, May 25

## Meeting Objectives:

- ➔ Reach consensus on the current HIV STK market
- ➔ Co-create a vision on what a future HIV STK market will look like
- ➔ Agree on market interventions to achieve this vision
- ➔ Identify next steps to deepen analysis and further refine the market strategy for HIV STKs

Time	Session	Facilitator
09:00-09:30	<b>Welcome</b> <ul style="list-style-type: none"> <li>• Opening remarks</li> <li>• Introduction to FHM Engage</li> <li>• Participant Introduction</li> </ul>	<ul style="list-style-type: none"> <li>• [Name Redacted], USAID</li> <li>• [Name Redacted], FHM Engage</li> <li>• [Name Redacted], FHM Engage</li> </ul>
09:30-09:45	<b>Market system framework and HIV STKs</b> <ul style="list-style-type: none"> <li>• Technical Presentation</li> </ul>	<ul style="list-style-type: none"> <li>• [Name Redacted], FHM Engage</li> </ul>
09:45-11:00	<b>Working Session #1</b> Understanding the current market for HIV STKs <ul style="list-style-type: none"> <li>• Facilitated discussion on core market operations</li> </ul>	<ul style="list-style-type: none"> <li>• [Name Redacted], FHM Engage</li> </ul>
11:00-11:30	Tea break	
11:30-01:00	<b>Working Session #2</b> Understanding the current market for HIV STKs <ul style="list-style-type: none"> <li>• Facilitated discussion on factors shaping market operations</li> </ul>	<ul style="list-style-type: none"> <li>• [Name Redacted], FHM Engage</li> </ul>
01:00-02:00	Lunch	
02:00-02:45	<b>Working Session #3</b> Co-creation of vision of a “well-performing” HIV STKs market <ul style="list-style-type: none"> <li>• Facilitated discussion on how the HIV STK market can work better</li> </ul>	<ul style="list-style-type: none"> <li>• [Name Redacted], FHM Engage</li> </ul>
02:45-04:15	<b>Working Session #4</b> Co-creation of market system changes <ul style="list-style-type: none"> <li>• Facilitated discussion on changes needed to make the market work better</li> </ul>	<ul style="list-style-type: none"> <li>• [Name Redacted], FHM Engage</li> <li>• [Name Redacted], FHM Engage</li> </ul>
04:15-04:30	<b>Next steps &amp; Closure</b>	<ul style="list-style-type: none"> <li>• [Name Redacted], FHM Engage</li> <li>• [Name Redacted], USAID</li> </ul>

# Annex 2. HIV STK Market Actor Landscape



## Annex 3. Participant Lists

HIV STK MDA WORKSHOP I, May 25, 2022

Table 1: Participant List

Name	Gender	Organization	Position	Workshop 1 (May 25, 2022)	Workshop 2 (July 6, 2022)	Workshop 3 (August 25, 2022)
[Name Redacted]	Male	TAYOA	Program Manager		x	x
[Name Redacted]	Male	Synermed	Regulatory	x	x	
[Name Redacted]	Male	T-MARC	Marketing Manager	x		x
[Name Redacted]	Female	FHI360			x	
[Name Redacted]	Female	FHM Engage	Consultant	x		x
[Name Redacted]	Female	APHFTA	Health Coordinator	x		
[Name Redacted]	Male	MyService	Managing Director		x	x
[Name Redacted]	Female	Pathfinder	Project Officer	x		
[Name Redacted]	Male	FHM Engage	Technical Director	x	x	
[Name Redacted]	Male	CSSC	QI Coordinator	x		
[Name Redacted]	Female	Tanzania Public Health Association	Consultant	x		
[Name Redacted]	Male	PSI	HIVST Technical Advisor	x	x	
[Name Redacted]	Male	FHM Engage	Consultant	x		
[Name Redacted]	Male	PSI			x	
[Name Redacted]	Female	AMREF	Technical Director	x	x	



[Name Redacted]	Male	FHM Engage	Chief of Party	x	x	x
[Name Redacted]	Male	USAID	Sr. PPP Advisor	x	x	x
[Name Redacted]	Male	R4D	Program Director		x	
[Name Redacted]	Male	MOH-NACP	Acting Head of Prevention Unit	x		
[Name Redacted]	Female	R4D	Operations Coordinator		x	
[Name Redacted]	Female	FHM Engage	Technical Advisor		x	x
[Name Redacted]	Male	Sciex	Sales Representative	x	x	x
[Name Redacted]	Male	USAID	PMS-HSS	x		
[Name Redacted]	Female	Pathfinder	Clinical Advisor	x		
[Name Redacted]	Male	Pathfinder	Country Director	x		
[Name Redacted]	Male	TACAIDS	KVP- Coordinator		x	
[Name Redacted]	Male	UNAIDS	Adviser	x		
[Name Redacted]	Female	T-MARC	M&E Manager		x	
[Name Redacted]	Male	Nebula Healthcare	FAS	x		
[Name Redacted]	Male	Pathfinder	Senior Advocacy Specialist	x		
[Name Redacted]	Male	Pathfinder	Director of Programs	x	x	
[Name Redacted]	Male	PSI			x	
[Name Redacted]	Male	USAID	Health Officer	x		
[Name Redacted]	Male	Nebula	Business Development Manager		x	x
[Name Redacted]	Female	FHM Engage	Fellow	x	x	x
[Name Redacted]	Male	Synermed	General Manager	x		

[Name Redacted]	Male	USAID	PMS-HSS	x	x	
[Name Redacted]	Male	R4D	Senior Program Officer	x		
[Name Redacted]	Female	USAID	Public Health Specialist	x		x

# Annex 4. Workshop Agreements

## Pre-workshop

### **Pre - Workshop**

- Conducted rapid market systems analysis
- Conducted market actor mapping and PPD ecosystem
  
- Team validated of market system analysis and market actor mapping/ PPD ecosystem
- Conducted additional meetings supplement missing information on market system analysis



## Workshop - Scope HIV STKs market

### Step 1: Define the problem

#### **THE PROBLEM**

- Reaching people who don't know their HIV status is a global health priority
- Low testing and awareness of status among key populations remains a challenge to achieving ambitious Joint United Nations Program goals of 95/95/95
- HIV testing is critical in the linkage to initiate care and treatment services
- HIV Self Tests is a complementary HIV testing approach have been shown to be well accepted, offer the privacy, confidentiality and time - saving benefits that might encourage and empower unreached populations to test

*General agreement on problem scope and it is a priority*



## Workshop-Scope HIV STKs market

Step 2: Scope Supply

### Supply



#### PRODUCT SELECTION

- HIVST can be conducted with either oral or blood -based test kits.
- Only the oral HIVST kits** allowed for use in Tanzania to minimize HIVST kits disposal complications

#### QUALITY STANDARDS

- All HIV ST must be approved and registered by the MOH through the TMDA
- Only HIVST kits approved by TMDA will be allowed in the market
- TMDA will ensure **that all HIVST kits for use in Tanzania**
  - have **WHO pre-qualification**.
  - have undergone in -country validation,
  - have been locally registered with a lot -to-lot validation

*Regulatory bar for entry is high*



## Workshop-Scope HIV STKs market

Step 2: Scope Supply

### Supply



#### Availability

- Only Oraquick and Mylan are allowed
- Two are in the pipeline – both are blood based

#### Projected Need

2021: 930,357                      2022: 3,457,250                      2023: 4,237,566

#### Financing

2021: ~\$1.8-\$2.8m                      2022: ~\$6.9-\$10.4m                      2023: ~\$8.5m-\$12.7m

*Too few products (type and number) to build the market  
Need is great.....who will pay now? Who will pay later?*



## Workshop-Scope HIV STKs market

Step 2: Scope Supply

### Supply



#### Suppliers

- Public                      ANC/OPD/Pharmacy
- PFP                              ANC/OPD/Pharmacy
- PNFP                            ANC/OPD/Pharmacy
- Community
- Pilots                            Workplace  
Private pharmacies

*Regulations permits all market actors to deliver HIV STKs in multiple settings but....  
Reluctance to allow private pharmacies*



## Workshop-Scope HIV STKs market

### Demand

Step 2: Scope Demand



#### Target Groups

Persons above age 18 including:

1. Men
2. Youth (Adolescent Girls and Young Women; Adolescent Boys and Young Men)
3. Key Populations (Men who have Sex with Men, Female Sex Workers, Persons Who Inject Drugs)
4. Partners of PLHIV who attend clinics
5. Mobile populations
6. Certain occupations (e.g., miners, drivers, construction, workers who work away from their homes, fishermen, etc.)

*We know who they are, how many they are, and where they are but.....  
target population not aware about HIVST*



## Workshop-Scope HIV STKs market

Step 2: Scope Supply & Demand

### Dive deeper – questions to answer

#### SUPPLY

##### AVAILABILITY

- Do we have enough HIVSTK to meet the demand in Tanzania? What do you think are the key barriers to availability?
- Do we need private importers to complement the existing public supply to meet targets? What are the challenges related to their entry?

##### ACCESSIBILITY

- Do the current delivery modalities reach the intended targets for HIV STK?

#### DEMAND

##### AWARENESS

- Are intended target groups aware of HIV STK in the public sector? in the private sector?

##### APPROPRIATENESS

- Do we have the right products available that address consumer preferences?

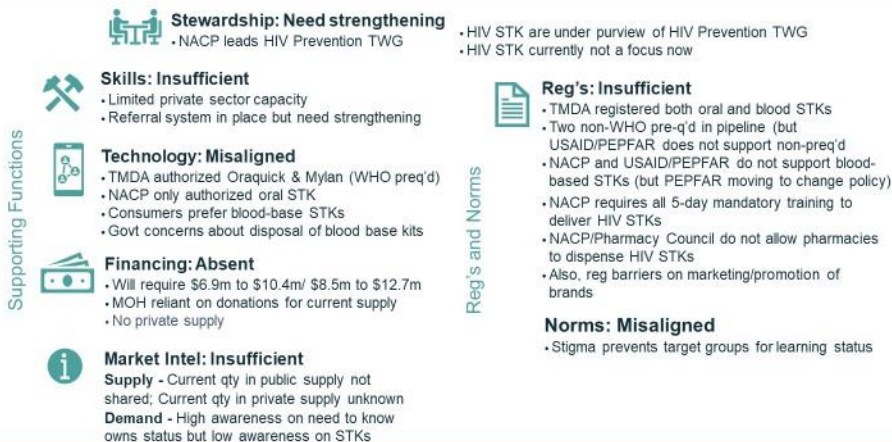
##### AFFORDABILITY

- Is free public supply sufficient to meet demand ?
- Will the private sector price be affordable?



## Workshop-Market Systems: Factors of Underperformance

Step 3: Analyze market systems



## Workshop: Co-create vision

### Step 4: Co-create vision

#### What

##### Products

- Both oral- and blood-based HIV STKs
- Allow for urine-based when available

#### Who

##### Target groups

- Target groups identified in HIV STK Framework

#### Where

##### Geographic areas

- HIV AIDS "hot spots"
- Geographic areas where target groups reside

#### How

##### Modalities

- Public and private supply
- Public and private delivery >>> all modalities

##### Modalities

- Facilities
- Communities
- Pharmacies
- Workplace
- ICT model (future)

} Linkages between all modalities

#### How much

##### Price

- Public free price
- Social affordable prices
- Commercial market price

