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Frontier Health Markets (FHM) Engage

MARKET FACILITATION GUIDE

Based on the application of rapid market scoping and design process for HIV Self-Test Kits - Tanzania

September 26, 2022

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Acronyms

ADDO	Accredited Drug Dispensing Outlet
ADPP	Asst. Director Policy and Planning
ANC	Antenatal Care
ART	Antiretroviral therapy
CDGEC	Community Development, Gender, Elderly and Children
CMO	Chief Medical Officer
CP	Chief Pharmacist
DAH	Development Assistance for Health
DHR	Director of Human Resources
DNMS	Director of Nursing & Midwifery Services
DPM	Director of Planning Management
DPP	Director of Policy and Planning
DPS	Director Preventive Services
FBO	Faith-Based Organization
FHM	Frontier Health Markets
FP	Family Planning
GF	Global Fund
GoT	Government of Tanzania
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HIVST	HIV Self-Testing
HIVSTK	HIV Self-Test Kit
HRH	Human Resources for Health
HSSP	Health Sector Strategic Plan
HTS	HIV Testing Services
ICT	Information, Communication and Technology
KVP	Key and Vulnerable Populations
M&E	Monitoring & Evaluation
MDA	Market Development Approach
MDG	Market Development Group
MEAL	Monitoring, Evaluation, and Adaptive Learning
MHS	Mixed Health Systems
MNCH	Maternal, Newborn, and Child Health
MNH	Muhimbili National Hospital
MOH	Ministry of Health
NACP	National AIDS Control Programme
NBS	National Bureau of Standards
NGO	Non-Governmental Organization

NIMR	National Institute of Medical Research
NIP	Network Implementing Partner
PEPFAR	President's Emergency Plan for AIDS Relief
PFP	Private For Profit
PLHIV	People Living with HIV
PMO	Prime Minister's Office
PNFP	Private Not For Profit
PORALG	President's Office Regional Administration and Local Government
POPSMGG	President's Office Public Services Management and Good Governance
PPD	Public Private Dialogue
PPHF	Public-Private Health Forum
PPP	Public Private Partnerships
PrEP	Pre-exposure Prophylaxis
PSE	Private Sector Engagement
PSI	Population Services International
SHOPS	Sustaining Health Outcomes through the Private Sector
SRA	Stringent Regulatory Authority
STK	Self-Test Kit
SWAp	Sector-Wide Approach
TA	Technical Assistance
TB	Tuberculosis
TMA	Total Market Approach
T-MARC	Tanzania Marketing and Communications for AIDS, Reproductive Health, Child Survival and Infectious Diseases
TMDA	Tanzania Medicines and Medical Devices Authority
TOC	Theory of Change
TPSF	Tanzania Private Sector Foundation
TWG	Technical Working Groups
USAID	United States Agency for International Development
WHO	World Health Organization
WHO-PQ	WHO Prequalification

Introduction and Purpose of the Market Facilitation Guide

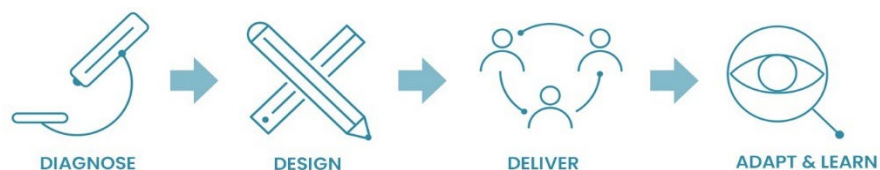
Frontier Health Markets (FHM) Engage is a global cooperative agreement funded by the United States Agency for International Development (USAID) to provide technical assistance (TA) supporting local actors to improve the ability of health markets to contribute to equitable provision of and access to high-quality family planning (FP) and other health product and services in mixed health systems (MHS). FHM Engage focuses on strengthening local health markets by addressing the root causes of market failures in core market function areas to create the necessary behavior changes that catalyze supply and demand and support sustainable change.

FHM Engage has adopted an intrinsically different approach to driving private sector engagement (PSE) at the country level. Through USAID and other donor support, countries have over the years developed many innovative approaches to private sector engagement, such as social marketing and social franchising. The local private sector in most low and middle-income countries is also growing rapidly and many innovations in health care are emerging in countries themselves. In the future, country-owned and country-driven approaches are needed both in terms of the core market functions of the demand and supply side. Moreover, the healthcare ecosystem within which these country-led approaches and innovations operate will also have to be strengthened. Therefore, supporting functions and rules and regulations are also needed.

Development Assistance for Health (DAH) through USAID and other donors is increasingly focused on supporting a localization agenda. The private sector is central to this localization agenda. To give all market actors (public and private) a voice and to create a level playing field for the public and private sectors to contribute to sustainable FP; maternal, newborn, and child health (MNCH); HIV/AIDS; tuberculosis (TB); and malaria outcomes, different approaches are needed.

The FHM Engage approach, which is 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 4 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 – as stated above – is 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 may be to conduct some or all of the following tasks: (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. The necessity of some of these tasks depends on whether any of the problems and root causes have been pre-identified through other investigation and data gathering. During the DESIGN Phase, the Market Facilitator can support market actors to understand: (i) what can be done about the underperformance identified in the market, (ii) what some global examples and good practices can market actors should be aware of, and (iii) support market actors identify 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 DELIVER and ADAPT AND LEARN, the Market Facilitator continues to play a supporting function, helping market actors discuss 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.

The purpose of the MDA is to work with market actors to achieve more optimally performing markets that better serve population health needs. One of the key early learnings from Year 1 is that the MDA process needs to be applied flexibly. In Year 1 of FHM Engage, we sought to apply MDA in specific country contexts to understand how the process works, what the key lessons learned and how the process could be refined for further use. Tanzania was one of the first countries to apply the MDA process. Therefore, in this document, we have captured what we learned from the process in Tanzania. In Year 2, based on our work in additional countries (India, Kenya, Madagascar, Nigeria, Pakistan, and other markets in Tanzania), we hope to continue to better understand how MDA can be applied, including the learnings from applying the full MDA process as well as rapid processes. Eventually, the application of MDA and its broader learnings are relevant for the global health community, including other donors as they drive PSE.

In Tanzania, the goal was to understand specific product markets under the broader HIV/AIDS market. FHM Engage applied this systematic MDA process/Pathway to Impact to three markets in the HIV prevention area: HIV self-test kit (HIVSTK), oral pre-exposure prophylaxis (PrEP) kit, and condoms for HIV prevention. Below is a summary of the activity's application of the market systems thinking and process to the HIVST kit market. In Year 1 of the Tanzanian activity, both the FHM Engage Tanzania- and headquarter-based staff worked together to carry out the DIAGNOSE tasks for the HIVSTK market and start the DESIGN process. The summary offers a brief description of the tasks, the tools and materials used, and actual analysis and inputs in the annexes.

Market Facilitation Steps

Diagnose

Jan

Step 1: Define the Health Problem and Select the “Right” Health Market

FHM Engage, in partnership with USAID/Tanzania, agreed to focus on HIVST kit, oral PrEP kit, and condoms markets. In the case of Tanzania, the previous USAID-supported Sustaining Health Outcomes through the Private Sector (SHOPs) Plus project had already been working on these areas and a lot of work had been done, including application of the Total Market Approach (TMA). This decision was fully aligned with the Tanzanian Ministry of Health’s (MOH) activities and goals, through its National AIDS Strategy to achieve the 95/95/95 targets: 95 percent of all HIV-positive individuals are diagnosed; 95 percent of those diagnosed receive antiretroviral therapy (ART), and 95 percent treated achieve viral suppression by 2030. The FHM Engage team started the HIVSTK market and conducted a rapid analysis of the health priorities in Tanzania to determine if HIV is a priority and that by developing the HIVSTK market FHM Engage will help achieve a health outcome. This was an important first step, since the MDA process focuses on joint decision-making by market actors so that even if a specific market actor (e.g., donor or government) identifies a specific health market, a due diligence is needed so that all market actors can understand why a specific health market was selected and that selection is backed by data. The rapid analysis confirmed that the MOH is struggling to reach its first goal of “95 percent diagnosed” and therefore, focused on expanding access to HIV tests is a relevant market (see Box 1).

Box 1: 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
 - There are currently ~1.74 million PLWH in Tanzania
 - Only 61% of people living with HIV (PLHIV) older than age 15 knew their HIV status (*THIS 2016/2017*)
 - 40.8% of males above age 15 have never had a HIV test
 - There is low HIV testing among adolescents aged 15-19 years 79% of males and 61.4% of females have never tested for HIV (*THIS 2016/2017*)
 - HIV prevalence among key populations is high (People who inject drugs: 36%; Sex workers: 26%; Men who have sex with men: 25%) (*Consensus estimates on Key Populations Size HIV Prevalence in Tanzania, July 2014*)
- 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

Feb

Step 2: Assess the Core Market

In February 2022, the FHM Engage Tanzanian team, with support from the global team and a network implementing partner (NIP), analyzed the core market operations, which entailed three tasks: (1) understanding the demand and supply dynamics in the current HIVSTK market, (2) landscaping the HIVST market actors, and (3) assessing mechanisms used to convene and interact with the key HIVSTK market actors.

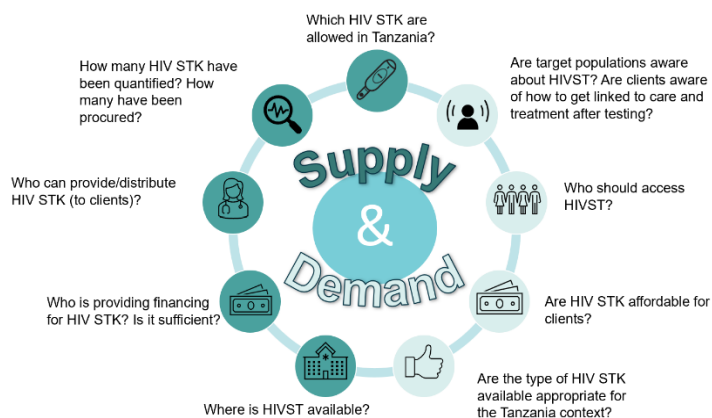
Landscaping market actors. The team first focused on identifying the actors active in the HIVSTK market. The landscape analysis was comprised of (i) scanning government documents related to HIVSTK, (ii) conducting key informant interviews using a standardized interview guide, and (iii) using worksheets to integrate and synthesize the information. The landscape exercise mapped the public, private, civil society, and development partner actors, and their roles and responsibilities in the current HIVSTK market (see Annex 2). The landscape analysis provided the basis for the FHM Engage team to identify and prioritize the number of market actors to create a small, manageable group with decision-making authority that could guide the market scoping and design the HIVSTK market strategy.

Mar *Assess public-private dialogue (PPD) platforms.* The team concurrently scanned and assessed the dialogue and coordination platforms in health to identify an existing mechanism to convene the HIVSTK market actors. This analysis drew on the same data sources as the market actor landscaping exercise. The team organized the data into worksheets to assess the strengths and weaknesses of each potential dialogue mechanism (see Annex 3). The PPD analysis recommended that all market development activities should be aligned to the MOH’s Sector Wide Approach (SWAp) and technical working groups (TWG) structure. The analysis also suggested that the most appropriate TWG to oversee the HIVSTK market scoping and subsequent market design would be the HIV/AIDS Prevention TWG. However, the assessment determined that this TWG does not have all the relevant HIVSTK market actors – particularly the commercial ones – and its mandate does not directly align to the market development objectives. Thus, the FHM Engage team decided to form a Market Development Group (MDG) that is directly linked to and supports the HIV/AIDS Prevention TWG.

Apr Based on the prior analyses, the FHM Engage team reached out, through one-on-one meetings, to each of the prospective market actors to gauge their interest in working together to improve the performance of the HIVSTK market. They agreed and the FHM Engage team starts to organize its first HIVSTK workshop planned for May.

Understand core market operations. During this period, the FHM Engage Headquarters and Tanzanian team analyzed how the HIVSTK core market is structured (see Figure 2). The analysis identified several supply- and demand-side constraints undermining the performance of the HIVSTK market. The team organized their analysis in a worksheet (see Annex 4).

FIGURE 2. FACTORS TO CONSIDER IN HIVSTK CORE MARKET

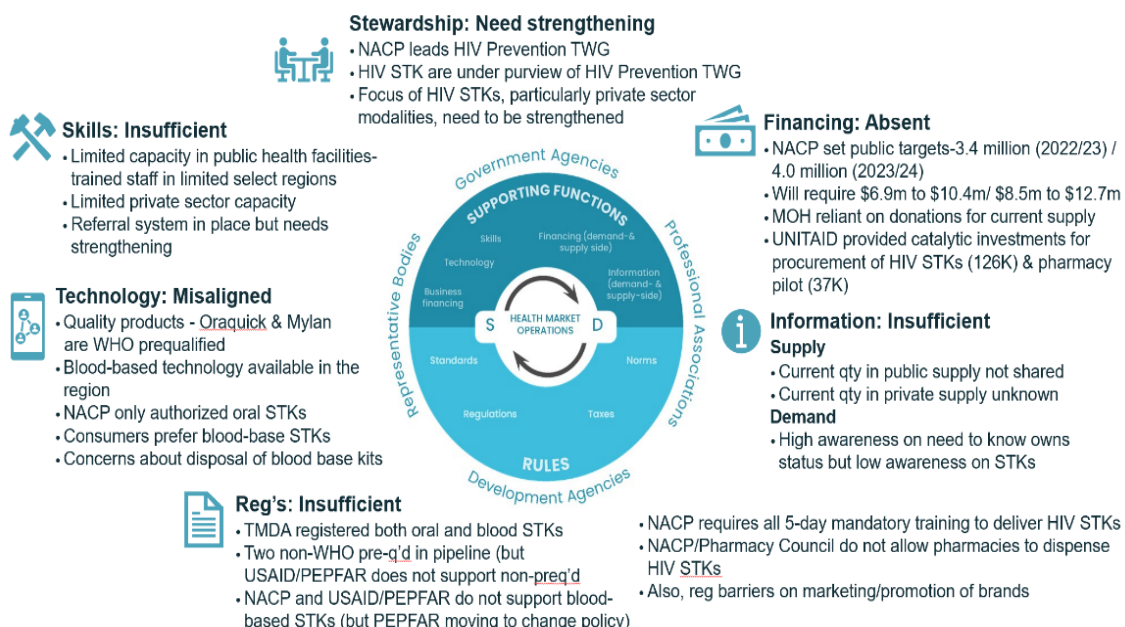


Apr

Step 3: Analyze Market Systems

With a better understanding of how the core market was (or was not) working, the team’s analysis moved beyond the core market to market systems to evaluate the root causes for why the HIVSTK market was underperforming. The team described the HIVSTK market system’s supporting functions, rules, and market actors to gain insights into the reasons for its (under)performance (see Annex 5). This analysis helped the team articulate the kinds of market system weaknesses that were negatively impacting the core market’s performance and the nature of its underperformance. Using the worksheet, the team deepened their analysis and understanding of (i) why such underperformance factors persist, and (ii) in what ways are important functions and rules in the market system absent, insufficient, and/or misaligned (see Figure 3). These insights gave the team ideas on where and how to intervene in the HIVSTK market and the preliminary ideas for the market strategy.

FIGURE 3. SUMMARY OF MARKET SYSTEM FACTORS



May

Workshop #1: Deepen and Validate the Analysis

With a preliminary scoping of the HIVSTK market, the team convened its first meeting of the HIVSTK MDG to deepen and validate the analysis. The workshop was the first of several consultative workshops, meetings, and activities to co-create and collectively implement interventions introduce and encourage the uptake of HIVSTKs through public and private channels. There are several principles that guide a MDA – all of which were on display during the workshop. The principles are: (i) be inclusive of all key market actors, (ii) be dynamic and iterative, and (iii) be adaptive and flexible to meet the needs of the market actors in “real-time.”

The purpose of the one-day workshop was to: (i) form the HIVSTK MDG, (ii) validate the analysis of the current HIVSTK market, (iii) co-create a vision of what a well-performing HIVSTK market would look like, and (iv) reach a consensus on a way forward to design a market strategy to improve market performance. To prepare for the workshop, the FHM

Engage team drafted a highly interactive agenda, conducted “dry runs” of each exercise, developed in-depth facilitation guidelines which are reflected in this brief as well, and prepared PowerPoint presentations summarizing the analysis conducted in DIAGNOSE Steps 1 – 3 (see Annex 6).

Additional Analyses

Additional questions and issues around supply and demand emerged during the workshop. They focused on (i) clarification of regulatory barriers to blood-based self-test kits, (ii) service modalities to deliver HIVSTK, and (iii) pricing strategies. The FHM Engage team took additional actions to address these information gaps:

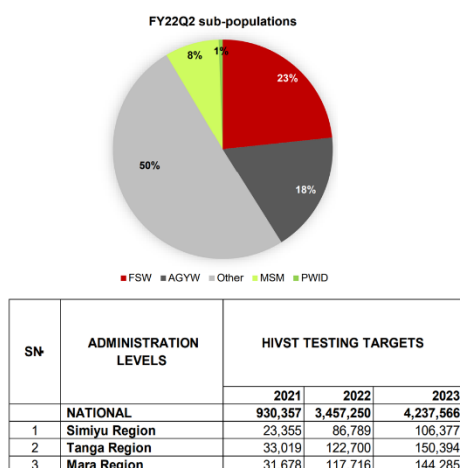
Jun

Legal/Regulatory Review. FHM Engage conducted a review of the Tanzanian policies and regulations on HIVSTK to benchmark them against WHO’s regulations (see Annex 7).

Jul

Workshop #2 to Discuss Service Delivery Modalities. The team invited Population Services International (PSI) and Amref to present the evaluation of the pharmacy model and description of the community-based model, respectively. PSI and Amref presented their service delivery models at a second workshop held on July 6th (see Annex 8). Both these presentations raised questions relevant to the market actor’s analysis of the current HIVSTK market conditions, including: With respect to the community-based model, can this service modality reach the target groups effectively? Is it cost-effective? And is it sustainable given its reliance on President’s Emergency Plan for AIDS Relief (PEPFAR) funds (see Figure 4)? The PSI presentation confirmed that the pharmacy service modality is also valid for Tanzania, but several barriers would have to be addressed for it to succeed. Also, the PSI evaluation indicated that the MDG should also consider workplace programs as another service modality (see Figure 5).

FIGURE 4. KEY MESSAGES ON AMREF COMMUNITY-BASED MODEL

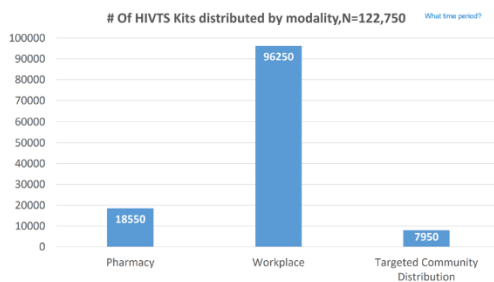


The model is working but some questions arise:

- Can ambitious targets be met? (Is there financing /supply)
- Does this modality reach the “right” groups effectively? (Which ones? At what cost? Is it sustainable?)

FIGURE 5. KEY MESSAGES ON PSI PHARMACY AND WORKPLAN MODELS

Pharmacy Distribution Performance



Workplace delivery of STKs

- Workplace appears to be an effective modality to distribute HIV ST
 - Need to address any obstacles identified in forthcoming evaluation (e.g., stigma)
 - Need to explore sustainable approaches to expand workplace approach (e.g. employer contribution, socially affordable price)

Pharmacy delivery of STKs

- If the pharmacy model is expanded, need to address important obstacles
 - Cumbersome reporting requirements
 - Demand generation needed
 - Training adapted to address staff turn over (e.g. virtual training, mandatory CPD, etc.)
 - Improved client instructions through adapted inserts / leaflets
 - To address sustainability, explore commercial supply of STKs only
 - Also need to better understand willingness / ability to pay to establish price ranges



Regional Benchmark. Lastly, FHM Engage global staff conducted a regional analysis that included information on (i) regulations governing the introduction of HIVSTK, (ii) product type, (iii) service modalities, (iv) product introduction strategies, and (v) pricing. The analysis covered Kenya, Thailand, South Africa, and Zambia. The market actors found the regional analysis helpful by confirming their initial ideas on how to introduce HIVSTKs in the Tanzanian market.

TABLE I. HIGHLIGHTS FROM REGIONAL BENCHMARKING EXERCISE

Topic	Kenya	South Africa	Thailand	Zambia
Introduction	2017	2016	2019	?
Delivery modalities	Physical pharmacies, online pharmacies, vending machines, roadside clinics	Physical pharmacies, online pharmacies, community pharmacies, vending machines, online website (NGO)	Physical pharmacies, online pharmacies, online website (NGO), retail outlets as OTC	Physical pharmacies, online pharmacies, vending machines, online website (NGO)
Pricing data	Blood kits \$2.10-\$8.40 USD Oral slightly higher price Commercial price, no subsidized price available	\$6.00 - \$18.00 USD Voucher to obtain free STKs	Blood kits \$15.00-19.00 USD Oral kits \$50.00 USD Willingness to pay from KVP is \$9.50 USD. Free in public sector.	Blood kits \$1.20-2.40 USD Oral kits \$6.10-\$15.20 USD Higher demand from young women
Product type	Blood and oral	Blood and oral	Blood and oral	Blood and oral
Promotion strategies	PSK maintains a website of pharmacies offering HIVSTK and instructional videos on HIVST Awareness campaigns through digital platforms, community and pharmacy to drive demand	Ensuring private market actors are only selling HIV STKs designed to be use by lay people	Provided OTC status for HIVST	Human-centered design to develop Zambia-specific instructions for HIVST
Reaching Target population	Sending SMS reminders to truckers and FSWs about availability of HIV STKs at all roadside clinics	Demand generation through digital marketing techniques using search engine optimization for specific keywords related to online behaviors of the key populations, as well as Google Banner advertising on dating applications	Online counseling and supervised HIV self-testing for MSM and transgender individuals	Limited innovations in private health market service delivery for HIVSTK

Alignment to HIV/AIDS Theory of Change

In July, the FHM Engage Monitoring, Evaluation, and Adaptive Learning (MEAL) team traveled to Dar to facilitate a one-day workshop with market actors involved in the three HIV target markets: HIVSTK, oral PrEP kit, and condoms for HIV prevention. The purpose of the workshop was to develop a theory of change (TOC) for the HIV health area to help align

strategies for the three markets. The team facilitated a highly interactive discussion to reach a consensus on a vision for private sector engagement in the HIV health area over the next five years. The group then worked backward from the vision to identify the intermediate outcomes that link the vision to the activities market actors are currently implementing. Through this process, the group also started to articulate some of the market system changes needed to achieve this vision. The HIV health area TOC served as the foundation for the August DESIGN workshop described below.

Design

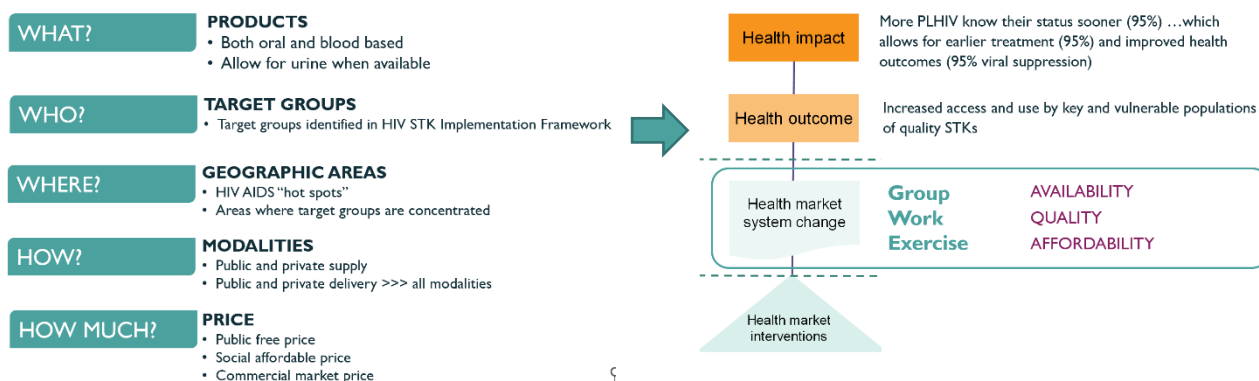


Workshop #3: Co-Create an HIVSTK-specific Theory of Change

The purpose of workshop #3 was to pivot from the current analysis of the root causes of the HIVSTK market underperformance toward visioning a well-performing market. The workshop objectives included: (1) Agreeing on and developing a framework (e.g., TOC) for an HIVSTK market strategy, and (2) Defining the next steps to further develop and finalize the HIVSTK market strategy.

Like Workshop #1, the FHM Engage team drafted a highly interactive agenda, conducted “dry runs” of each working group exercise, developed in-depth facilitation guidelines, and prepared PowerPoint presentations to facilitate the pivot from DIAGNOSE to DESIGN (see Annex 9). A critical element of the DESIGN workshop was creating a TOC for the HIVSTK market (see Figure 6).

FIGURE 6. PARAMETERS OF THEORY OF CHANGE FOR HIVSTK MARKET



Due to extenuating circumstances (e.g., census, torrential rain), the workshop as planned could only be held with a smaller group of market actors. However, the FHM Engage team adapted the agenda to discuss the implications of the additional analysis on the parameters of the TOC; share additional updates on NACP’s revised HIVSTK targets; and share updates on the Pharmacy Council’s activities to support pharmacy delivery of HIVSTK and its preliminary findings on a new service modality – vending machines. The group agreed to work together on developing the strategic framework for the HIVSTK market strategy through working meetings among a smaller number of market actors and to present the draft strategy in the fall.

Conclusion and Next Steps

Tanzania was the first country where the MDA approach was applied to specific products and services identified as a priority for the mission. In that sense, it was the first country where FHM Engage through its local and global teams led the market facilitation process and develop market facilitation guidelines to facilitate application in other countries.

The FHM Engage MEAL team is currently leading a pause and reflect on the application of MDA in Tanzania, including the role of the Market Facilitator. These learnings will be captured in this brief by the end of October.

It is planned to use this guide as we launch market facilitation with other NIPs and partners in Kenya, India, and Pakistan. The learnings from these countries will be included in this brief in Year 2, helping us develop a solid output from the core work program support for MDA application in multiple FHM Engage country contexts.

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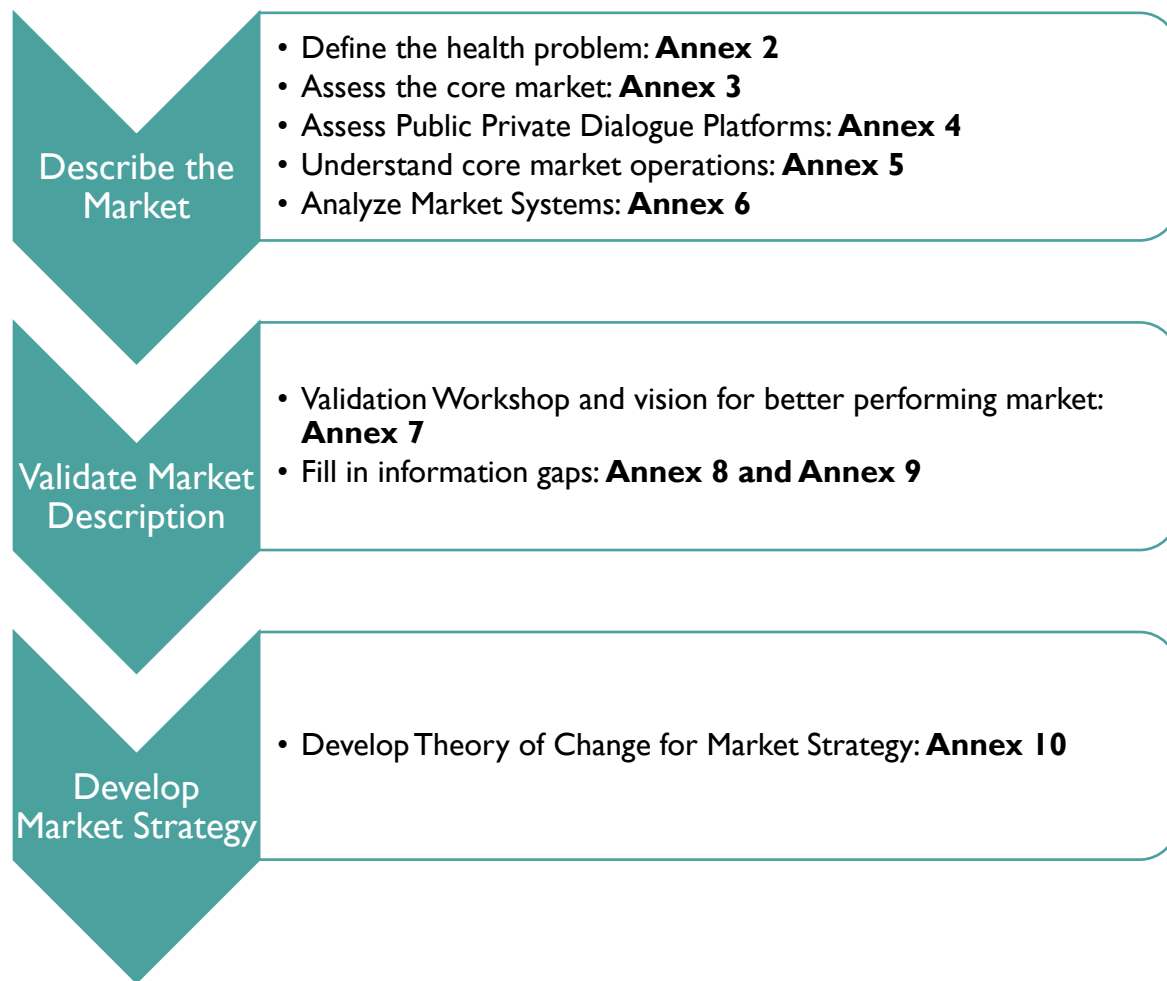
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Annex I. Summary of Annexes

The Annexes that follow serve to (1) Describe the HIVSTK Market, (2) Validate the Market Description, and (3) begin to Develop a Market Strategy. The Annexes associated with each step provide additional insight into the aspects of each step.



Annex 2. HIV Problem Statement and Health Problem Prioritization Worksheets

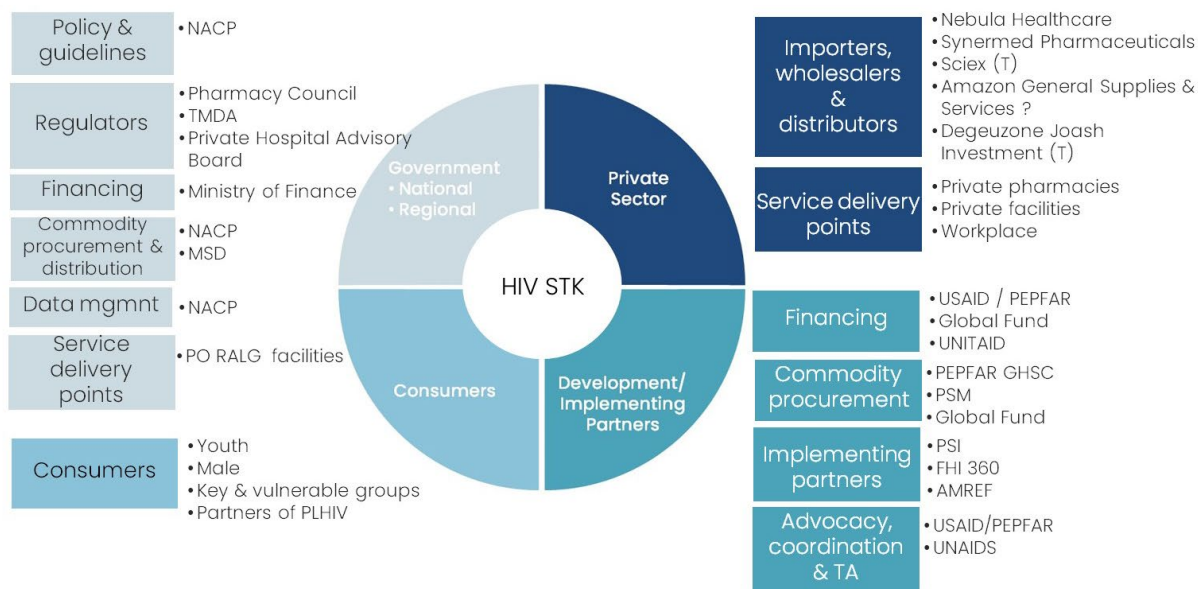
Problem Summary

Health Problem Statement	<ul style="list-style-type: none"> • HIV continues to be a significant health problem in Tanzania, with the 2019 adult (ages 15-64) prevalence rate of 4.8% among the general population (6.2% among females, 3.7% males) • Higher prevalence rates observed in high-risk groups (35% PWID, 2% SWs, 25% MSM). • Many people are unaware of their status and thus can't be referred to treatment. <ul style="list-style-type: none"> - 83% of PLHIV > age 15 know their HIV status (2019); the lowest in the 95-95-95 cascade - HIV testing rates are too low, particularly among key groups (40.8% of males > age 15 have never tested for HIV; 79% of males and 61.4% of females ages 15-29 have never tested for HIV).
Prioritization of health problem using UHC Lens	
Access	<ul style="list-style-type: none"> • It is not easy enough for those who want access to testing to get it. Why? Stockouts in public sector? Limited supply in private? Or is it a demand issue?
Quality	<ul style="list-style-type: none"> • Need to focus on quality of self-test kits • Quality seems to be less the issue as ART coverage and viral suppression is high for PLHIV <ul style="list-style-type: none"> - 90% ART coverage for the total population, although challenges persist in some key populations (e.g., only 66% ART coverage children) - 92% of people on ART achieved viral suppression, indicating no loss to follow up issue
Affordability	<ul style="list-style-type: none"> • HIV testing/treatment services in Tanzania are largely donor-subsidized in public facilities only (e.g., Global Fund (GF) and PEPFAR), affordability may not be significant barrier (need to check) • Although this presents sustainability challenges <ul style="list-style-type: none"> - PEPFAR contributed 67% of total HIV/AIDS budget in Tanzania in 2017/18; GF contributed 18% • What is price in private sector?

Problem Prioritization

Prioritization of health problem using selection criteria	
Relevance	<ul style="list-style-type: none"> • With 1.7 million PLHIV as of 2019, Tanzania has the 4th highest number of PLIV in the world and thus continues to be a global priority country in prevention and treatment of HIV. • Need to know status to better enable initiation on treatment.
Opportunity	<ul style="list-style-type: none"> • HIV continues to be a major government priority in Tanzania. In 2018, the GoT adopted the 4th generation of National Multisectoral Strategic Framework for HIV and AIDS 2018/19 – 2022/23 (NMSF IV) guides AIDS planning and mainstreaming by all sectors. NMSF IV pursues objectives of “zero new HIV infections, zero HIV-related deaths and zero stigma and discrimination.” • Donor priority as well so sufficient funds and technical resources.
Feasibility	<ul style="list-style-type: none"> • GoT, donors, and other market actors are committed and have been working for decades to address HIV in TZ, with significant progress achieved, with significant capacity built despite a complex operational environment (e.g., diverse geographies, public/private provision, challenges specific to certain population groups, etc.). • However, with the greatest achievements in Tanzania linked to treatment provision and adherence, attention could be most feasibly focused on addressed testing gaps. • Global evidence points to increased access to testing as the key link in improving prevention services towards a more effective treatment chain and HIV response overall.

Annex 3. HIVSTK Market Actor Landscape Worksheet and Analysis



- Accredited Drug Dispensing Outlets (ADDOs) or community pharmacies represent a feasible option for introduction through private sector retail (95 percent of Tanzania population lives within 5km of an ADDO), and have demonstrated interest in dispensing a suite of HIV products, but would require:
 - Significant oversight (stewardship)
 - Changes in protocols from the Tanzania Food & Drug Authority and Pharmacy Council (rules),
 - Capacity building (including efforts and linkages to strengthened referral systems), and
 - Extensive practical and logistical planning for rollout and ongoing regulation.

Annex 4. Analysis of Policy Dialogue Platforms for HIV/AIDS Markets

Acronyms

ADPP	Asst. Director Policy and Planning
CDGEC	Community Development, Gender, Elderly and Children
CMO	Chief Medical Officer
CP	Chief Pharmacist
DHR	Director of Human Resources
DNMS	Director of Nursing & Midwifery Services
DPM	Director of Planning Management
DPP	Director of Policy and Planning
DPS	Director Preventive Services
FBO	Faith-Based Organization
GoT	Government of Tanzania
HRH	Human Resources for Health
HIVST	HIV Self-Testing
HIVSTK	HIV Self-Test Kit
HSSP	Health Sector Strategic Plan
ICT	Information, Communication and Technology
MDA	Market Development Approach
MNH	Muhimbili National Hospital
MOH	Ministry of Health
NACP	National AIDS Control Programme
NBS	National Bureau of Standards
NGO	Non-Governmental Organization
NIMR	National Institute of Medical Research
PFP	Private For Profit
PLHIV	People Living with HIV
PMO	Prime Minister's Office
PNFP	Private Not For Profit
PORALG	President's Office Regional Administration and Local Government
POPSMGG	President's Office Public Services Management and Good Governance
PPD	Public Private Dialogue
PPHF	Public-Private Health Forum
PPP	Public Private Partnership
PrEP	Pre-Exposure Prophylaxis

PSE	Private Sector Engagement
TPSF	Tanzania Private Sector Foundation
T-MARC	Tanzania Marketing and Communications for AIDS, Reproductive Health, Child Survival and Infectious Diseases
TMA	Total Market Approach
TMDA	Tanzania Medicines and Medical Devices Authority
TWG	Technical Working Group
USAID	United States Agency for International Development
WHO	World Health Organization

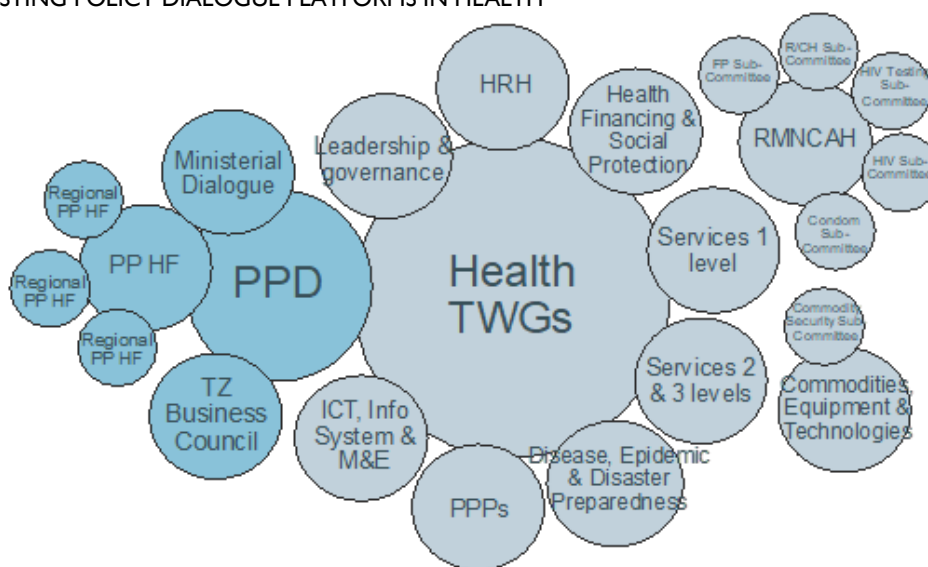
I. Policy Dialogue Platforms

Existing Dialogue Platforms

Policy dialogue is a reflective process that involves people from different interest groups who discuss an issue in which they have a mutual – but not necessarily common – interest. People in different positions will have different perspectives on, and possibly divergent interests in, the same problem. An open dialogue can reach a shared understanding of the problem and lead to agreed solutions to a policy-related problem (FAO, 2019).

Actors in the HIV/AIDS markets on HIV self-test kits (HIVSTK), condoms and pre-exposure prophylaxis (PrEP) whether technical or business-oriented, operate in a given institutional and policy context. In Tanzania, the range of policy dialogue platforms present in the health sector are: (i) public private dialogue (PPD) platforms that span economic and health sectors; and (ii) technical working groups (TWGs) and sub-committees specific to the health sector (see Figure 1).

FIGURE 1: EXISTING POLICY DIALOGUE PLATFORMS IN HEALTH



The SWAp Structure and Technical Working Groups

The Government of Tanzania (GoT) adopted a Sector-Wide Approach (SWAp) as a planning strategy for the health sector. SWAp provides a mechanism for policy and technical dialogue among key stakeholders in health. Principles guiding SWAp dialogue include (i) fostering national ownership, (ii) alignment to national priorities, (iii) use of country systems, and (iv) strengthening accountability (HSSP V, 2021-2026).

The SWAp structure is organized at the national and sub-national levels and the MOH has plans to further decentralize this structure to regional and council levels to ensure that inputs from local council and regional stakeholders are incorporated as outlined in the Health Sector Strategic Plan (HSSP) V 2021 – 2026.

All the work is conducted through TWGs.

The TWGs have the mandate to coordinate the delivery of specific strategic priorities and strategic outcomes in the health sector within the SWAp implementation framework. The TWG's main function is to provide a forum for (i) consultation, deliberation, and consensus-building, (ii) information-sharing and networking, and (iii) advice and recommendations for the way forward on specific technical issues. The HSSP V in 2022 detailed the number, thematic areas, and scopes. Currently there are 10 TWGs (see Box 1). According to the HSSP V, SWAp partners (GoT, Directors, and NSAs) nominate the Chair of each TWGs, and they, in turn, are appointed by the MOH. The TWGs report to the Joint MOH-PORALG Management Team of Chief Medical Officer (MOH), DPP (MOH & PORALG), and DPS-Health (PORALG). As can be observed, these TWGs are very formal, bureaucratic in nature and may not be agile enough to address the demands of market development.

Mostly importantly, several of TWGs have created sub-structures called by different names – “sub-TWG,” “sub-committee,” or “task force” – that have a more specific purpose. Some of **these entities are more aligned and relevant to the HIV/AIDS markets under consideration**. Moreover, several of these entities meet more frequently and share updates more regularly than the TWG quarterly meetings. Those that are relevant to the FHM Engage priority health commodities and service markets are listed in Box 2.

Upon further examination of the relevant TWGs and sub-structures, there are challenges that need to be addressed so that they can perform market stewardship roles. First, **TWG attendance and participation of private-for-profit actors has been low and in some cases absent** (see Table 1). Previously, these entities had very little to no

Box 1: SWAp Technical Working Groups

1. Leadership and Governance
2. Human Resources for Health
3. Health Financing and Social protection
4. Public-Private Partnership
5. Reproductive, Maternal, New-born, Child and Adolescent Health
6. Service Delivery (1) Primary Health Care
7. Service Delivery (2) Secondary and Tertiary
8. Disease, Epidemics and Disaster Preparedness and Response
9. Health Commodities, Equipment and Technologies
10. Information Communication Technology, Information system & ME

Box 2: Relevant Programmatic Sub-Groups

- Condom Sub-Committee
- Family Planning Sub-Committee
- HIV Testing Sub-Committee
- HIV Prevention Sub-Committee
- Youth and Adolescent Sub-Committee
- Reproductive Child Health Sub-Committee
- Commodity Security Sub-Committee

representation of private for profit (PFP) organizations in their meetings. The private sector was represented by private not for profit (PNFP) organizations (e.g., faith-based organizations (FBOs) and some non-governmental organizations (NGOs)). Issues cited by PFP stakeholders include (i) they are not invited to participate as evidenced by the membership list in almost all of the sub-structures except for the Public Private Partnership (PPP) TWG, (ii) if they are included, they feel that the engagement is one-sided as the government sets the agenda without any consultation or input from non-state actors, and (iii) they see little value proposition in participating in the TWGs as the government does not engage the private sector to co-create solutions. Only the PPP TWG has officially designated a private sector Co-Chair and representatives while some of the TWGs and Sub-Committees, like the Condom Sub-Committee and Commodity Security TWG, have informally invited private sector members.

Second, **many of the relevant TWGs and/or sub-structures are not fully functional** (e.g., defined as regular meetings, consistent and regular communications, and active participation of its members). For example, prior to COVID, the PPP TWG had a small group of champions actively promoting public private partnerships and met on a regular (almost monthly) basis. In recent years, this TWG has become dormant. Of the sub-structures, the Family Planning TWG, the Commodity Security TWG, and the Condom Sub-Committee are most functional.

Third, the majority of TWGs and sub-structures **are not focused on private sector and have not explicitly expressed interest in collaborating with the private sector**. They include the HRH TWG, the Health Financing and Social Protection TWG, and the Disease, Epidemics and Disaster Preparedness and Response TWG.

TABLE 1: STATUS OF TWG PLATFORMS IN TANZANIA

Name	Focus Areas	Membership	Selection Criteria*				PPD potential
			A	B	C	D	
TWG I Leadership and Governance	Ensure achievement of HSSP V outcomes (big picture) <ul style="list-style-type: none"> • Coordination – TWGs and Cooperating Partners • Health Sector Structures and Systems • Decentralization of SWAp • Strengthening of Social Accountability • Inter-sectoral coordination • Health in All Policies 	<ul style="list-style-type: none"> • Chair: DPP-HSRS • Co-Chair: DHSWN & PORALG • Secretariat: DAHRM & DPP • Members: CMO, PORALG, MOF, POPSMGG, PMO (HiAP), Regulatory Bodies, Agencies, and Development Partners 	1	3	2	1	LOW

<p>TWG 2 Human Resource for Health</p>	<p>Ensure human capital, competence, and skills to deliver quality health services</p> <ul style="list-style-type: none"> Improvement training institutions Innovations in services and technology Innovative training and (online) learning platforms HRH Planning & HRH Deployment HRH retention, Performance assessment, and Motivation Continuing professional development Nurses and midwives 	<ul style="list-style-type: none"> Chair: DHR Co-Chair: DHSWN & PORALG Secretariat: DNMS Members: DHR, DAHRM, PORALG, DNMS, ICT, Professional Councils, and Development Partners 	2	3	3	3	MEDIUM
<p>TWG 3 Health Financing and Social Protection</p>	<p>Ensure sustainable financing of health care delivery system with social protection</p> <ul style="list-style-type: none"> Resource mobilization from Public and Private Public Financial Management Universal Health Insurance Identification and addressing needs of the Poor Cross subsidization and pooling of risks and resources 	<ul style="list-style-type: none"> Chair: DPP MOH Co-Chair: DHSWN & PORALG Secretariat: ADPP Members: DPP, PORALG, ICT, DPP, DPM, NHIF, MOFP, CDGEC, and Development Partners 	1	3	3	2	LOW to MEDIUM
<p>TWG 4 Public Private Partnership</p>	<ul style="list-style-type: none"> Promote compliance with the policy guidelines and legal arrangements for PPP in service delivery Operationalize and implement PPPs through effective innovative models of private sector engagement at all levels Increase collaboration and participation between public and private health sectors to deliver quality health services equitably 	<ul style="list-style-type: none"> Chair: DPP Policy and Planning Co-Chair: DHSWN & PORALG Secretariat: P&P (MOH & PORALG) Members: DCS, CP, DPS, DE PRU, DHQA, MSD, TM DA, TPSF, TAPI, APHTA, TNBC, and Development Partners 	4	2	4	4	MEDIUM to HIGH

	<ul style="list-style-type: none"> Strengthen functioning and feedback mechanism for PPPs 						
TWG 5 RMNCAH	<p>Responsible for all activities related to RMNCAH including:</p> <ul style="list-style-type: none"> ANC Peri-natal care Child health, Adolescence, Young Adults, AGTW Sexual and Reproductive Health, Family Planning GBV & VAC 	<ul style="list-style-type: none"> Chair: DPS Co-Chair: DHSWN & PORALG Secretariat: DNMS Members: DPS, DCS, DNMS, HQAU, CP, CDGEC PORALG, Professional Associations, and Development Partners 	2	3	4	3	MEDIUM to HIGH
TWG 6 Service Delivery (1) Primary Health Care	<p>Ensure quality provision of primary health care services</p> <ul style="list-style-type: none"> Infrastructure Health Promotion Communicable diseases and non-communicable diseases Quality of Services Non-Communicable diseases Disease Epidemics and Emergency Preparedness and Response Traditional and Alternative Medicine 	<ul style="list-style-type: none"> Chair: CMO Co-Chair: DHSWN & PORALG Secretariat: DHSWN, DPS Members: PORALG, DCS, DPS, DNMS, HQAU, EPRU, CDGEC Institutions under MOH, and Development Partners 	2	3	3	3	LOW to MEDIUM
TWG 7 Service Delivery (2) Secondary and Tertiary Care	<p>Ensure quality provision of 2nd & 3rd health services</p> <ul style="list-style-type: none"> Specialized and super specialist services Palliative and Rehabilitative Care Quality of Services Referral System Medical tourism Urban Health Disease Epidemics and Emergency Preparedness and Response Health Research and Research translation 	<ul style="list-style-type: none"> Chair: DCS Co-Chair: DHSWN & PORALG Secretariat: HQAU, MNH & NIMR Members: PORALG, DCS, DPS, CD, DS, OHR, and Development Partners 	2	3	2	3	LOW

<p>TWG 8 Disease, Epidemics and Disaster Preparedness and Response</p>	<ul style="list-style-type: none"> • Prepare, Detect, Response, and Recovery • Epidemics, particularly new epidemics due to globalization • Emerging and Re-Emerging Diseases. • Antimicrobial resistance, and prudent use of medicines • Disasters with health impact, e.g., as result of climate change or urbanization • Monitoring and reporting outbreaks and health events in the country in accordance with international health regulations 	<ul style="list-style-type: none"> • Chair DPS • Co-Chair: DHSWN PORALG Secretariat: EPRU • Members: DHSWN, PMO, DPS, DCS, HRH, CP, and Development Partners 	1	2	1	2	LOW
<p>TWG 9 Health Commodities, Equipment and Technologies</p>	<p>Ensuring availability of medicines, vaccines, diagnostic reagents, other health commodities, equipment and medical devices for service delivery at all levels</p> <ul style="list-style-type: none"> • Rationalization & harmonization of supply chains, Quantification, lead time, and pipeline management • Inventory management and control • Alignment of health commodities with package of interventions • Health equipment and medical devices • Local production of health Commodities 	<ul style="list-style-type: none"> • Chair: CP • Co-Chair: DCS • Secretariat: Diagnostic Services, CP, Members: ICT, DPP, DPM, EPRU, DPS, DCS, DNMS, HQAU, CP, PORALG, MDAs, Research Institutions, and Development Partners 	2	3	4	4	HIGH
<p>TWG 10 ICT, Information System and ME&L</p>	<p>Provides support for health service delivery, monitoring and evaluation</p> <ul style="list-style-type: none"> • Expand use of ICT, the privacy of patients/workers, data protection, integrated ICT systems, operationalize 	<ul style="list-style-type: none"> • Chair: DPP M&E • Co-Chair: DICT – MOH & PORALG • Secretariat: M&E (MOH) ICT (MOH & PORALG) 	1	2	2	2	LOW

	<p>interoperability to align applications,</p> <ul style="list-style-type: none"> • Develop long term plan for health infrastructure investments • Manage health Information systems for monitoring service delivery • Develop Annual Profile Health Sector Report • Conduct evaluation, process evaluation and end line evaluation 	<ul style="list-style-type: none"> • Members: PORALG, ICT, DPP, DPM, MOFP, e-GOV, NBS, and Development Partners 					
<p>Selection Criteria: A: Private sector participation B: Level of functionality C: Relevance to target health market D: Interest in private sector collaboration Source: <i>Common Management Arrangement for the 5th HSSP Plan 2021-2026</i></p>		<p>Ranking: 4-High 3-Medium 2-Low 1-Absent 0-Unknown</p>					

Public Private Dialogue Platforms

PPD platforms are structured mechanisms, anchored at the highest practical level, coordinated by a light secretariat, and aimed at facilitating the discovery process by involving a balanced range of public and private sector actors in identifying, filtering, accelerating, implementing, and measuring actions and reforms that tend to improve issues of matter to the stakeholders (Benjamin, H. 2018).

Since the change in government administration in Tanzania, there is growing support within the MOH and the private sector to expand public-private engagement and collaboration to achieve national health goals. Despite the genuine interest from public and private stakeholders, some key challenges in establishing successful health PPD include:

- Absence of a core group of public and private policy champions advocating for greater public and private cooperation.
- Existing PPD platforms meet infrequently, on an ad hoc and irregular basis leading to perpetual mistrust. The main reason for this is lack of regular funding to support strong secretariats and roll out of PPD activities. Most of the PPD forums are heavily donor dependent in running their secretariats, meetings, and activities.
- Composition of the PPD membership is not representative of the complete private sector (PFP and PNFP) leading to limited input from the wider private sector actors.
- Limited skills – communication, active listening, negotiation and persuasion, conflict resolution, and adaptive learning – among both public and private sector leaders to foster collaboration and build trust.
- In the absence of a mechanism and/or platform for inclusive planning, private sector interviewees expressed their difficulty accessing MOH’s plans and strategies and were unclear on what the ministry’s health priorities were.

- Wavering political support and political good will for private sector engagement (PSE). The success of PPD forums fluctuates with the prevailing political context and environment with regards to PSE and government views on the role of the private sector as evidenced by the last government administration.

Of the four identified in the PPD assessment, two are related to the health markets: Ministerial Dialogue (led by the Tanzania Private Sector Foundation (TPSF) on the private sector) and Public-Private Health Forum (PPHF) (see Table 2). However, their purpose and sphere of influence are not relevant for dialogue and stewardship of a health market. That being said, the PPHF platform could be leveraged to advocate for needed policy and regulatory reforms to improve market operations and promote greater private sector participation in these (and other) health markets.

TABLE 2. STATUS OF PPD PLATFORMS IN TANZANIA

Name	Focus Areas	Membership	Selection Criteria*				PPD potential
			A	B	C	D	
Ministerial Dialogue	<ul style="list-style-type: none"> • Engagement between private sector and policy makers in development of policies, regulations, strategies, and implementation plans that promote delivery of quality healthcare services. • Forum structure, processes, systems, and membership not anchored in any specific health objective or area. • Ad hoc meetings only when there are major issues within the health sector. 	<ul style="list-style-type: none"> • Chair: Health Minister • Secretariat: TPSF • Members: MOH Heads of Department, TPSF, APHFTA CSSC 	4	1	3	3	MEDIUM to HIGH
Public-Private Health Forum	<ul style="list-style-type: none"> • Participatory mechanism for PSE. • Consensus TOR focused on promoting collaboration and partnerships. • Balance representation from public and private sector (all segments) and civil society. • Small group of champions. 	<ul style="list-style-type: none"> • Chair: MOH Director Policy and Planning • Co-Chair: TPHA • Secretariat: TPSF • Members: MOHSW, PORALG, MOF, PMO/TIC, NHIF, APHFTA, PRINMAT, TPAI/TPM, CSSC, BAKWATA, TPHA, 	4	2	3	4	HIGH

	<ul style="list-style-type: none"> • Convene annual forum to share experiences, identify issues, and jointly propose solutions for public-private collaboration. • Annual forum expected to be in September 2022. Last forum was in 2020 and postponed due to COVID-19 pandemic. • Limited resources prevent PPHF from fulfilling scope. 	MAT, ATE, API, PMTI, CSO					
Tanzania National Business Council	<ul style="list-style-type: none"> • The platform provides a strategic forum for public and private sector leaders to deliberate issues of promoting economic growth at the national level. • Also have regional and district level councils. • Meet ad hoc with health agenda not prominent. 	<ul style="list-style-type: none"> • Chair: President, Tanzania • Secretariat: TNBC • Members: National government ministers and department heads of all ministries, private sector umbrella associations, and federations of all sectors. 	4	3	1	2	LOW
Parliamentary Committee on Health Matters	<ul style="list-style-type: none"> • Draft new legislation, review, amend, and improve other government legislation and regulations related to health. • Committee meets regularly when parliament is in session. • Select private sector actors as needed to draft or amend various health legislation. • Focuses exclusively on legislative process. 	<ul style="list-style-type: none"> • Chair: Member of Parliament • Secretariat: Social Services and Community Development Committee • Members: All private health sector organizations (?) 	2	3	3	2	MEDIUM to HIGH
Selection Criteria: A: Private sector participation B: Level of functionality C: Relevance to target health market		Ranking: 4-High 3-Medium 2-Low 1-Absent					

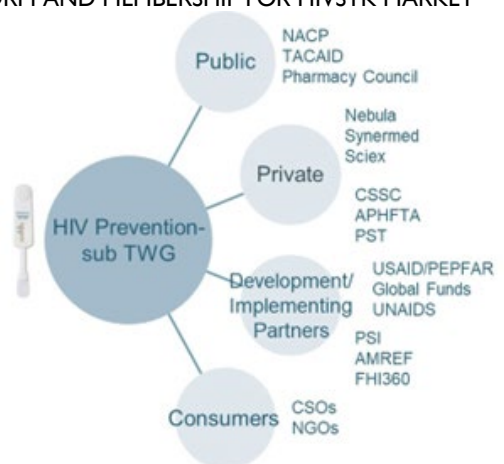
<p>D: Interest in private sector collaboration in health Source: <i>Common Management Arrangement for the 5th HSSP Plan 2021-2026</i></p>	<p>0-Unknown</p>
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2. RECOMMENDATIONS FOR DIALOGUE PLATFORMS FOR MARKETS IN HIV/AIDS

Synthesizing the market actor landscape exercise and the assessment of dialogue and coordination mechanisms, the FHM Engage team recommends where to anchor the dialogue and stewardship functions for each of the priority markets supporting HIV/AIDS. Of the two types of dialogue platform and coordination mechanisms, the SWAp structure and its supporting TWG and sub-TWGs were identified to be the most relevant to the priority health markets as well as aligned with a dialogue and stewardship function. Below is a summary of the proposed platform mechanism, membership, and steps needed to strengthen its role as market steward.

HIVSTK Dialogue Platforms

FIGURE 2. PROPOSED PPD PLATFORM AND MEMBERSHIP FOR HIVSTK MARKET



Based on the FHM Engage team’s analysis, we propose “housing” the PPD initiatives and stewardship activities of the HIVSTK market in the **HIV Prevention sub-TWG**. Although HIVSTKs is not a high MOH priority, it is responsible for this activity. In addition, we have identified the most critical market actors to participate in the market leadership (see Figure 2).

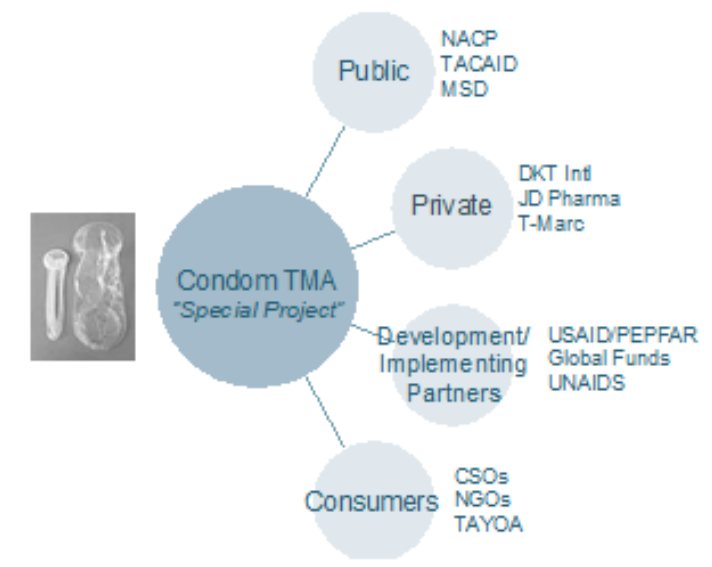
The May 2022 HIVSTK market development workshop created commitment and momentum to work in this market. Participants committed to meet monthly to raise the profile and priority of HIVSTKs and shape the market for both public and private sector actors.

Actions to facilitate the HIV Prevention sub-TWG to facilitate PPD and steward the HIVSTK market include:

- **Ensuring balanced representation.** Most members are public and there are limited private sector – particularly commercial sector – members. And additional scoping is required to identify the appropriate civil society organizations and NGOs representing the consumer groups for this product.
- **Leveraging FHM Engage to serve as the “honest broker.”** This group of actors will require logistical and technical support (see below) to meet its objectives. It will meet every month to draft a market strategy by the end of September.
- **Gathering evidence to advocate for HIV required regulatory changes.** HIVSTKs market actors identified several knowledge gaps (e.g., regional benchmarking on regulations and waste disposal strategies) to help advocate for regulatory change to allow for blood-based kits and expand scopes to allow pharmacists to dispense the kits.
- **Providing data needed to complete market scoping.** In addition, the market actors’ data gaps (e.g., regional benchmarking on pricing and product introduction strategies) will be critical to inform the market strategy.

Condom Dialogue Platform

FIGURE 3. PROPOSED CONDOM DIALOGUE PLATFORM AND MEMBERSHIP



Addressing the overstock of 100 million public condoms is a high priority area for the MOH. The MOH is committed to a private sector in this market as outlined in HIV prevention and FP related policies and strategies. The challenge now is how to move public supply without displacing private supply.

We propose the **Condom Sub-Committee** as the PPD mechanism to engage on the condom market. The Sub-Committee is active and meets quarterly but may not be agile enough to respond to the immediate crisis in supply.

Actions to support the Condom Sub-Committee to address the immediate condom crisis include:

- **Proposing a “special project.”** The MOH/MSD is ready to distribute the public condoms as soon as possible. Given the urgency, FHM Engage proposes forming a small group of critical

market actors to carry out a “special project” focused on assessing the impact of flooding the market with free condoms and developing strategies on how to build the condom market with other stakeholders in the condom market. Figure 3 guides the selection of a limited number of Condom Sub-Committee members to work on this special project (also see Box 3).

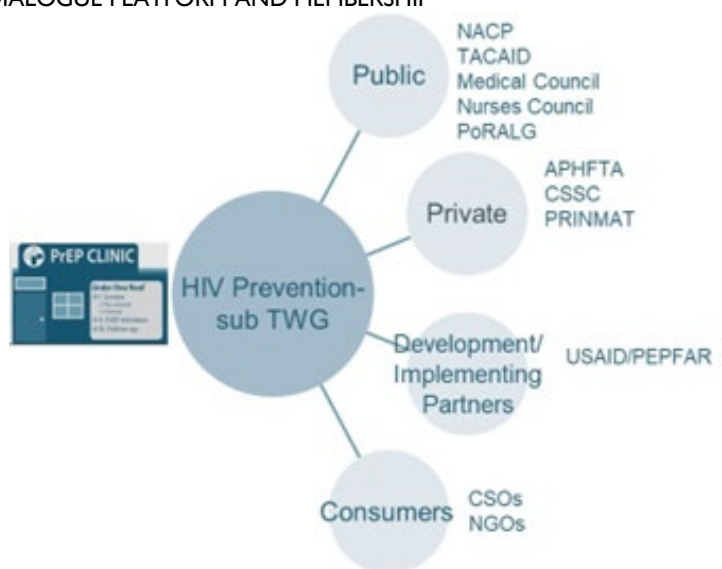
- **Ensuring balanced representation.** The Condom Sub-Committee has limited private sector representation – mainly social marketing brands. It would be important to include private sector entities representing commercial brands as well.
- **Leveraging FHM Engage** to serve as the “honest broker.” Like the HIVSTKs market actors, the special project first, and then the Condom Sub-Committee second, will require logistical and technical support to convene this small group, facilitate scenario planning to develop a plan to distribute the public condom supply with minimum displacement of private, and mobilize public and private resources and expertise to assist MSD to move the product.
- **Gathering evidence.** As part of the scenario planning, FHM Engage can scan other countries to explore how they were to stave off commercial market supply with flooding of public condom supply.

Box 3: Condom Market Primary Actors	
Govt	Private
MoH-NACP	T-Marc
MoH-TACAID	DKT Intl
MoH-MSD	JD Pharma
DP/IP	Consumers
USAID/PEPFAR	TAYOA
Global Fund	
UNAIDs	

PrEP Dialogue Platform

Based on the FHM Engage team’s analysis, we propose “housing” the PPD initiatives and stewardship activities of the PrEP market in the **HIV Prevention sub-TWG**. Figure 4 illustrates the key market actors. Given the immediate need in the condom market and the momentum in HIVSTK market, the FHM Engage team proposes convening this group and conducting a market scoping in August.

FIGURE 4. PROPOSED DIALOGUE PLATFORM AND MEMBERSHIP



This group of market actors will require the same type of support proposed for other market platforms: (i) convening and agreeing on purpose and direction like the HIVSTKs group, (ii) logistical support to facilitate the PrEP group's activities, (iii) gathering evidence to inform the PrEP activities and decisions, and (iv) supporting the group to develop a market strategy.

PPP TWG

As noted in the introduction, FHM Engage will be working in multiple health markets at the same time. As the different market TMA groups get up and running, it will be important for a leadership group comprised of senior public officials and private sector leaders to monitor progress and synergies between these health markets. In essence, this group can become the “steward of stewards.” In examining all the possible platforms and mechanisms, the FHM Engage team proposes exploring with the PPP TWG adding this function to their scope. This activity can be placed in the context of support to the PPP TWG to develop a new five-year private sector engagement strategy. Like the other market groups, the PPP TWG will require support as well, particularly to revitalize the members and start up the monthly meetings. In addition, they will need data and report – like a “dashboard.”

Annex 5. Core Market Analysis Worksheet

Core Health Market – HIV Self-Testing Kits (HIVSTKs)

Supply

- Bottom line – only 1 product in the marketplace
- HIVSTK are an emerging option to address the testing gap– of 5 WHO PQ'ed, only 2 currently are registered for use (1 oral – OraQuick; 1 blood-based – Mylan)
- But only type of product – OraQuick – legally available (Only oral tests are allowed. QUESTION: Gov't willing to change regs to allow for blood base?)
- Gov't reluctant for change, will say that they want to figure out oral before introducing blood
- Supply-side preference for oral-based HIVSTK technologies given concerns regarding safe disposal of blood-based tests and infection control risks
- Mainly dispensed in clinical settings, seeking expansion to other delivery points
- Limited supply
 - Currently HIVSTKs are free if administered through public sector. Administered thru NC clinic, outpatient, pharmacy, and through community outreach with peer volunteers. 100% reliance on donors
 - There's been limited authorization since 2018 of discrete, NACP authorized donor-implemented pilot HIVSTKs projects in public and private sector (e.g., PSI – pharmacies, XXX – CHW)
 - DATA GAP: Need more info on private supply.
 - Implications on price in terms of sustainability and feasibility aligned to customer WTP
 - Objective does not include offering HIVSTKs for all (too expensive) >>> should be a targeted approach
 - QUESTION: need to understand targets (geographic scope >>> only HIV hot spots? Or by consumer groups (See below).

Demand

- Pilot study results show general favor for HIVSTK option in ANC/PMTCT respondents
 - Some evidence that consumers prefer blood-based tests (more accurate) and can be conducted in private
 - Also trust blood over oral based on trust/familiarity with other blood-based tests (6)
 - Finally, don't trust oral based on years of campaign saying that cannot transmit HIV through saliva >>> fearful of saliva and HIV; also consumers believe oral test (6)
 - Consumers also prefer community pharmacies and pre-test counseling support (written/in-person)
- Gov't concerned over consumer ability to administer and interpret tests
- Gov't is also concerned about emotional consequences of being alone (fearful that consumer with positive test will commit suicide)
- Average WTP between \$1-\$2, posing challenges with intro in private markets if kits are at a higher unit price
- Insufficient demand to motivate greater private sector supply
- Youth a potentially large group (e.g., 60% under age 20; vulnerable group)
- Youth historically use private sector (access/confidentiality private sector but ability to pay)
- Men also an important group (data indicates they under test). Have experimented with workplace programs.
- DATA GAP: Insufficient data on current generation of youth health seeking behavior (e.g., prior administration suspended all youth-oriented projects); also latest generation have access to mobile phones and other forms of social media

Annex 6. Market System Analysis Worksheet

The Market System Analysis worksheet (or AIMS worksheet) helps to organize preliminary insights on barriers/key challenges that are highlighted through literature review and key stakeholder consultations. The key steps to completing this worksheet include:

1. Listing and describing the barriers that emerged from literature review and key stakeholder consultations according to its characteristic (e.g., core—supply/demand or supporting market function—rules/regs, financing, etc.).
2. Assigning each barrier a classification: Absent, Inadequate, or Mismatched and analysing how this barrier is affecting market operations and market actors' capacity and willingness to perform their respective roles.
 - **Absent:** A function or rule/regulation is missing because capacities and incentives are not in place, or do not exist, for any player(s) to perform it (e.g., demand-side financing does not exist to remove economic barriers for women who want to delivery in a facility or MOH cannot perform 'whole-system' planning because they lack accurate information on the private sector). If there is a missing market function (e.g., regulations are out-of-date and inconsistent with best practice on task shifting for injectables) or it exists but is not in practice (e.g., requirement to renew facility license every year but not implemented due to staffing constraints).
 - **Inadequate:** A systems function or rule/regulation has attracted the 'right' player(s), but they do not have adequate capacities or incentives to improve their performance of it (e.g., quality guidelines are in place, but MOH does not have enough staff to supervise private sector quality, or National Drug Administration may lack the capacity or power to adequately enforce standards designed to restrict the import of counterfeit or substandard pharmaceuticals).
 - **Mismatched:** A function or rule/regulation is ineffective because the player(s) performing it is 'wrong' for the role, and unlikely to have the capacities or incentives to perform a function/rule more effectively in the future (e.g., injectables may be restricted to qualified nurses/clinical officers too few in number to meet demand, or regulations require monthly allotments which creates a disincentive to continue use).
3. Prioritizing the barriers. The purpose of this exercise is not to be exhaustive but instead strategic. Select those barriers that: (i) have the most impact (e.g., can't improve performance without addressing it), (ii) are feasible (e.g., can address in the short-term (next 6 – 12 months) or medium-term (next 2 to 3 years)), and (iii) are aligned to the goals of the project.

Below is an example of how this worksheet was filled for HIVSTK in Tanzania.

Market characteristics		A	I	M	Observations
Core Market	Supply			M	<p>PRODUCT</p> <ul style="list-style-type: none"> Globally there are 5 WHO Prequalified HIVSTK In Tanzania, there are only 2 registered HIVSTK (1 oral-based – OraQuick; 1 blood-based – Mylan) a possible 3rd in the pipeline (blood-based – INSTI HIV self-Test); only the 1 oral-based product is “allowed” in Tanzania UNITAID provided a catalytic donation of HIVSTK in Tanzania (PSI led workplace and pharmacy pilot to test introduction through private channels) <ul style="list-style-type: none"> DATA GAP: What is uptake of public sector HIVSTKs?; do private providers (e.g. health facilities) offer HIVSTKs? If yes, it what quantity? INADEQUATE: Having only one product in the market makes it challenging for product differentiation when they are provided for free in public channels and for sale in the private; SHOP Plus studies showed that there was a preference for blood-based HIVSTKs which are currently not allowed in Tanzania.
					<p>WHOLESALE (5,6)</p> <ul style="list-style-type: none"> Sciex (a local importer/distributor) represents Oraquick (oral-based HIVSTK) Nebula (a local importer/distributor) is in the process of registering a blood-based product (though not WHO prequalified) Abbott is registering a blood-based HIVSTK Synermed has helped Mylan register their blood-based HIVSTK All suppliers have capacity (e.g., importer, wholesaler & distributor, licensed and quality recognized and interest (e.g., strong client base, suppliers believe there is private sector demand) <p>• QUESTION: Does TMDA allow the import of non preq’d products? Do suppliers have sufficient capital for inventory?</p> <p>• MISMATCHED: TMDA has allowed the registration of blood-based HIVSTK but the HIVST implementation framework does not allow for use of blood-based products in Tanzania. Unclear if TMDA would allow the import of non-WHO prequalified HIVSTK which is also counter to the HIVST Implementation framework.</p>
					<p>POINT OF CARE</p> <ul style="list-style-type: none"> Two delivery modes for HIVSTKs Directly Assisted: Clients receive in-person demonstration from a trained provider or peer before or during test. Settings: OPD, ANC in public (private?) facilities; pharmacy and community w/trained CHW. Unassisted: Individuals self-test using mfg. instructions for use. Users may be provided with links or contact (confirm) to access additional support (e.g., telephone hotlines or instructional videos). Settings: Pharmacy walk-in; Community thru peer, volunteer & CHW distribution. <ul style="list-style-type: none"> Currently, HIVSTKs are only available through public facilities and CHW programs. Public sector is delivering in limited # of regions DATA GAP: Where/which public health facilities? There is no mechanism to purchase from private distributors during stock-outs. Only private supply was through community, workplace and pharmacy-based pilots (60 in Mwanza, Dodoma, Dar es Salaam) Perception that HIVSTKs are available in private hospitals and pharmacies though this is not the case.

Supporting Function			<ul style="list-style-type: none"> • INADEQUATE: HIVSTKs are currently only available through public channels though there is private sector demand.
	Demand	A	<ul style="list-style-type: none"> • According to Ntl AIDS Strategy, target groups (i) men, (ii) youth, (iii) key and vulnerable populations, (iv) partners of PLHIV in clinics, (v) mobile populations, and (vi) certain occupations (3) • Given targeted approach, most likely groups are (i) men, (ii) youth, and (iii) vulnerable population groups • Both youth and men prefer alternative sources for testing. Private delivery channels can address the health seeking preferences for males and youth: convenience/less time lost at work; confidentiality; less stigma, etc. • Low awareness of HIVSTKs (most SBCC was suspended under prior administration) • Back of the envelop estimate of annual need + ~ 550 (5) yet TACAIDS expects MOH to dispense 3.2M this year and another 4M next year • Potential clients indicate familiarity with and willingness to purchase test kits from private retail outlets • ABSENT- DATA GAPS: Need to (i) quantify affected population (#, location, gender, education, etc.), (ii) identify access barriers & utilization rates, (iii) determine provider preference (e.g., public vs private), (iv) understand capacity and willingness to pay
	Financing (S)	A	<ul style="list-style-type: none"> • All products in public supply are donated by Global Fund, PEPFAR, & UNITAID • UNITAID provided catalytic donations to private sector (126,400 HIVSTKs under the STAR Initiative: 37,900 HIVSTKs through PSI pharmacy model by March 2022) • ABSENT: No plan to ensure sustainable supply for the public sector and to allow private supply.
	Financing (D)	A	<ul style="list-style-type: none"> • SHOPS+ estimates 11.16% import cost + 10-20% wholesale mark-up + 20-30% pharmacy mark-up (5). Confirm if possible to reduce margins. • Prices range from \$4.50 POS (Insti) to \$12.00 (Bio-Sure) (5). Confirm if out of date. • Sarah presented following price range: \$2, \$1.99-\$3.28 (EXW, accessories incl), \$0.8-\$1.5 (sales price to TZ retailer) and not more than \$2.5 to client. Confirm if current. • All tests are free through public sector. • ABSENT- DATA GAP: Do not currently understand willingness to pay
	Subsidies	A	<ul style="list-style-type: none"> • UNITAID provided catalytic donations to private sector (126,400 HIVSTKs under the STAR Initiative; 37,920 HIVSTKs to be distributed through PSI's pharmacy model by March 2022) (5) • Subsidized products – particularly in Dar, Arusha, and Kilimanjaro – will dampen private sector market • ABSENT- Donation has ended for the private sector pilots.
Information (S & D)	A	<ul style="list-style-type: none"> • Barriers to accessing HIVSTKs (include low knowledge on benefits of knowing status; unwillingness/fear to know status) • Need to replace the demand for Rapid Test Kit (used in HFs) for new STKs (6) • Limited self-test kits in market >>>> resulting in low consumer awareness on benefits of STKs • STKs, by law, required to have product inserts translated. But do not know if instructions are clear and understandable for self-administration. • Against the regs to advertise products, particularly to certain target groups. • DATA GAPS: Need to better understand info needs by target group 	

			<ul style="list-style-type: none"> • ABSENT: No public campaigns and information on benefits of knowing status, of availability of STKs
Technology		I	<ul style="list-style-type: none"> • New products represent latest technology in STK • Quality product as evidenced by WHO preq'd status • INADEQUATE - DATA GAPS: (i) Unclear if design is culturally appropriate and feasible given wide range of clinical and non-clinical settings, (ii) Unclear if package instruction are culturally appropriate
Regulations - Product registration (5)		I	<ul style="list-style-type: none"> • Tanzania law must be changed to allow for self-testing (need to verify). • Is there a need to replace RTKs sold and used as self-tests is critical to ensuring safety and the inclusion of commercial outlets in policy considerations • Products must be registered with Tanzania Food & Drug Authority • Should be registered as a “D” class screening product (<\$\$\$ to register, less time). Also since WHO pre-qual'd should be fast tracked (?) • National AIDS Control Program (NACP) will need to support commercial sale of self-test at pharmacies • INADEQUATE (Policy if first bottleneck – mis-matched>>>>most painful pinch point>>>policy to scale in pharmacies & private facilities) • Regulatory barriers on promoting health products
Regulations - Clinical (5)			<ul style="list-style-type: none"> • HIVSTKs policy published (5) • Regulatory pathways approved • Guidelines and operational plans published • Approved clinical sites and testing protocols. Additional work needed to clarify linkages to health system for confirmatory testing, initiating care (5)
Taxes		I	<ul style="list-style-type: none"> • SHOPS+ cost / price analysis assumes 18% VAT waiver. Confirm if possible to obtain VAT waiver. • Tanzania Import Costs: 5% Logistics, 2% Tanzania Food & Drug Authority Fee, 3% Port Levy, 1.16% Railway and Infrastructure Levy. • INADEQUATE: DATA GAP: Are taxes prohibiting availability/access to affordable HIVSTKs or will they in the future when private supply is allowed?

Annex 7. HIVSTK Market Development Workshop #1

HIVSTK MDA Workshop #1 Meeting Agenda

Coral Beach Hotel
Yacht Club Road
Wednesday, May 25

Meeting Objectives:

- Reach consensus on the current HIVSTK market
- Co-create a vision on what a future HIVSTK market will look like
- Agree on market interventions to achieve this vision
- Next steps to deepen analysis and further refine the market strategy for HIVSTKs

Time	Session	Facilitator
09:00-09:30	Welcome <ul style="list-style-type: none"> • Opening remarks • Introduction to FHM Engage • Participant Introduction 	<ul style="list-style-type: none"> • Gene Peuse, USAID • Dr. Amit Bhanot, FHM Engage • Farhan Yusef, FHM Engage
09:30-09:45	Market system framework and HIVSTKs <ul style="list-style-type: none"> • Technical Presentation 	<ul style="list-style-type: none"> • Barbara O'Hanlon, FHM Engage
09:45-11:00	Working Session #1 Understanding the current market for HIVSTKs <ul style="list-style-type: none"> • Facilitated discussion on core market operations 	<ul style="list-style-type: none"> • Sarah Alphs, FHM Engage
11:00-11:30	Tea break	
11:30-01:00	Working Session #2 Understanding the current market for HIVSTKs <ul style="list-style-type: none"> • Facilitated discussion on factors shaping market operations 	<ul style="list-style-type: none"> • Barbara O'Hanlon, FHM Engage
01:00-02:00	Lunch	
02:00-02:45	Working Session #3 Co-creation of vision of a “well-performing” HIVSTKs market <ul style="list-style-type: none"> • Facilitated discussion on how HIVSTK market can work better 	<ul style="list-style-type: none"> • Farhan Yusef, FHM Engage
02:45-04:15	Working Session #4 Co-creation of market system changes <ul style="list-style-type: none"> • Facilitated discussion on changes needed to make the market work better 	<ul style="list-style-type: none"> • Barbara O'Hanlon, FHM Engage • Sarah Alphs, FHM Engage
04:15-04:30	Next steps & Closure	<ul style="list-style-type: none"> • Farhan Yusef, FHM Engage • Gene Peuse, USAID

HIVSTK MDA WORKSHOP #1, May 25, 2022

Participant List

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HIVSTK MDA Workshop #1 Report

May 25, 2022, Coral Beach Hotel

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 HIVSTKs 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 a role 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 HIVSTK market performance and design of the HIVSTK 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”

Workshop Proceedings

Workshop objective: The meeting objectives included:

- Reaching consensus on the current HIVSTK market
- Co-creating a vision on what a future HIVSTK 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 HIVSTKs

As the workshop unfolded, it became clear to the workshop facilitators that they wanted to move more slowly to finalize the diagnosis of the market performance. Several questions emerged, for which there was no data, and they agreed to 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 HIVSTKs in Tanzania.

Workshop participants: Using the market actor landscape analysis (See *Annex A*), 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. 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 who can represent the different consumer groups for HIVSTKs.

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

Part I: Scope the problem related to HIVSTKs

In framing the health problem, the participants generally agreed on its scope and that expanding access to HIVSTKs 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 self-tests is a complementary HIV testing approach and has shown acceptance by consumers (e.g., offers privacy, confidentiality, and time saving) and offers benefits that might encourage and empower unreached populations to test.

Part II: Understand the core market (supply and demand) for HIVSTKs

- *Product supply:* There are too few products (type and number) to build the HIVSTK market. Only Oraquick and Mylan are registered by 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 930K in 2021 to 4.2M in 2023. Government will need to mobilize ~\$1.8-\$2.8M in 2021 to ~\$8.5-\$12.7M. Currently, HIVSTK government supply is donated by Global Fund; there is some commercial supply (quantity unknown).

- *Product supply modalities:* Regulations permit all market actors to deliver HIVSTKs in multiple settings: public and private (e.g., ANC/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 TKs should be focused on target population groups. HIVSTK framework clearly details the consumer groups: persons above age 18 including: men, youth boys and girls, key vulnerable populations, partners with 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 HIVSTKs.*

Part III: Analyze market system constraints

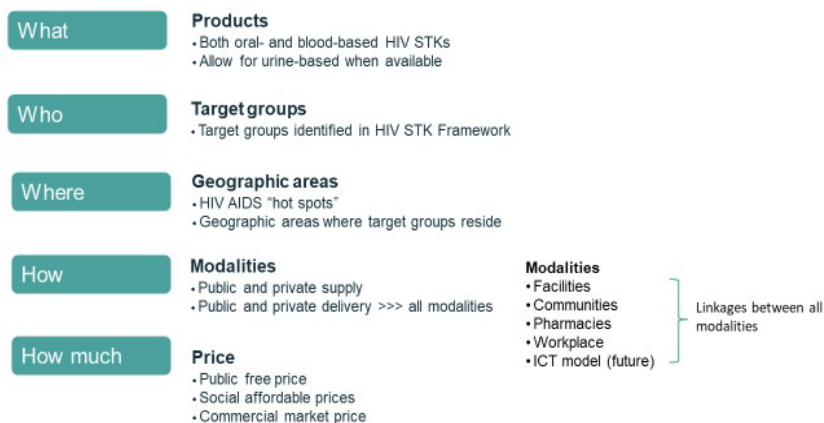
- *Market stewardship:* NACP leads the HIV Prevention TWG, here HIVSTK resides. But it currently is not a focus and could use support to mobilize the market actors and raise its profile on NACP proceedings.
- *Skills:* Limited private sector capacity due to 5-day training requirement and access to affordable products. Greater public capacity. Referral system requires strengthening.
- *Technology:* Consumers accept and perform self-testing. They indicate preference for blood (based on rapid market studies done). Yet only oral is available.
- *Regulations:* Different interpretations of regulations. Although TMDA has registered two (oral and blood) products, NACP has only authorized use of oral.
 - PEPFAR does not support use of blood kits (but this may be changing).
 - NACP and Pharmacy Council currently are awaiting results of a pilot done by PSI and do not allow pharmacies although the framework supports them to dispense HIVSTKs.
 - Regulatory bar is too high for blood kits and newer technology (e.g., urine) to enter to the Tanzanian market.

- NACP 5-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 HIVSTK market

The workshop participants agreed on the basic parameters of what a well performing HIVSTK market would look like but wanted more information in key areas to further refined and develop this vision. Diagram illustrates agreement on key components of the HIVSTK 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 HIVSTKs 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.



Agreements

- The workshop participants agreed to use an “informal” mechanism to continue working together to design a market strategy for HIVSTKs.
- 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 organizations that can bring consumer perspective to the deliberations. Also other government agencies, like Pharmacy Council should participate.

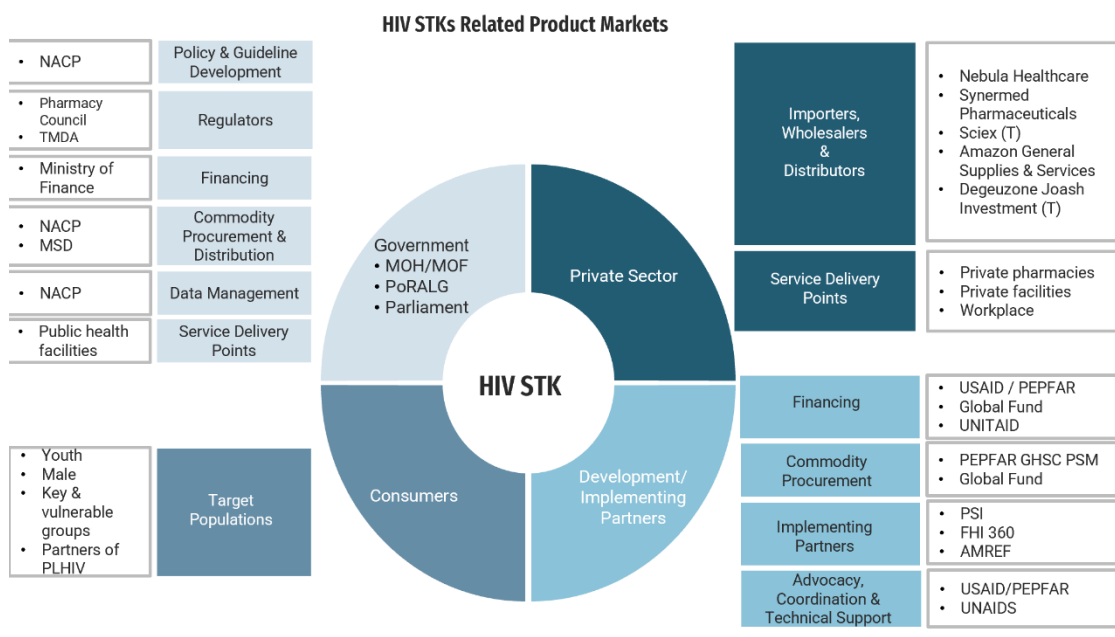
- Data challenges were a constant theme throughout the workshop and participants agreed to work together to address these data gaps (see next steps). PSI and Amref have agreed to present their learning to date on the two HIVSTK pilots in the next two monthly meetings.
- Several participants proposed the group start to advocate for HIVSTKs and mobilize influential who can assist the group to elevate this topic on ministry’s agenda.

Next Steps

The participants identified and agreed to following actions:

1. Support the development of distribution guidelines for HIVSTKs (FHM Engage team)
2. Commence advocacy with (i) Prime Minister, (ii) NACP regulators, (iii) religious leaders and (iv) sports figures (FHM Engage to work with UNAIDS)
3. Expand supply in private facilities (where it is currently allowed)
4. Assist CSSC (and other FBOs) and APHFTA to document (i) current supply, (ii) experience to date, and (iii) barriers to expansion
5. Develop quick action plan to expand HIVSTKs in private facilities

ANNEX A. HIVSTK Market Actor Landscape



ANNEX B. 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**
 - 1) have **WHO pre-qualification**,
 - 2) have undergone in -country validation,
 - 3) 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
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Financing

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

Step 2: Scope Demand

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

<div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">SUPPLY</div> <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">AVAILABILITY</div> <ul style="list-style-type: none"> 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? <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">ACCESSIBILITY</div> <ul style="list-style-type: none"> Do the current delivery modalities reach the intended targets for HIV STK? 	<div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">DEMAND</div> <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">AWARENESS</div> <ul style="list-style-type: none"> Are intended target groups aware of HIV STK in the public sector? In the private sector? <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">APPROPRIATENESS</div> <ul style="list-style-type: none"> Do we have the right products available that address consumer preferences? <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">AFFORDABILITY</div> <ul style="list-style-type: none"> Is free public supply sufficient to meet demand ? Will the private sector price be affordable?
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Workshop-Market Systems: Factors of Underperformance

Step 3: Analyze market systems

<p style="writing-mode: vertical-rl; transform: rotate(180deg); font-size: small;">Supporting Functions</p>	<div style="margin-bottom: 10px;"> <p>Stewardship: Need strengthening</p> <ul style="list-style-type: none"> NACP leads HIV Prevention TWG </div> <div style="margin-bottom: 10px;"> <p>Skills: Insufficient</p> <ul style="list-style-type: none"> Limited private sector capacity Referral system in place but need strengthening </div> <div style="margin-bottom: 10px;"> <p>Technology: Misaligned</p> <ul style="list-style-type: none"> TMDA authorized Oraquick & Mylan (WHO preq'd) NACP only authorized oral STK Consumers prefer blood-base STKs Govt concerns about disposal of blood base kits </div> <div style="margin-bottom: 10px;"> <p>Financing: Absent</p> <ul style="list-style-type: none"> Will require \$6.9m to \$10.4m/ \$8.5m to \$12.7m MOH reliant on donations for current supply No private supply </div> <div style="margin-bottom: 10px;"> <p>Market Intel: Insufficient</p> <p>Supply - Current qty in public supply not shared; Current qty in private supply unknown</p> <p>Demand - High awareness on need to know owns status but low awareness on STKs</p> </div>	<p style="writing-mode: vertical-rl; transform: rotate(180deg); font-size: small;">Reg's and Norms</p> <ul style="list-style-type: none"> HIV STK are under purview of HIV Prevention TWG HIV STK currently not a focus now <div style="margin-top: 10px;"> <p>Reg's: Insufficient</p> <ul style="list-style-type: none"> TMDA registered both oral and blood STKs Two non-WHO pre-q'd in pipeline (but USAID/PEPFAR does not support non-preq'd) USAID/PEPFAR does not support blood-based STKs (but PEPFAR moving to change policy) NACP and USAID/PEPFAR do not support blood-based STKs (but PEPFAR moving to change policy) NACP requires all 5-day mandatory training to deliver HIV STKs NACP/Pharmacy Council do not allow pharmacies to dispense HIV STKs Also, reg barriers on marketing/promotion of brands </div> <div style="margin-top: 10px;"> <p>Norms: Misaligned</p> <ul style="list-style-type: none"> Stigma prevents target groups for learning status </div>
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Workshop: Co-create vision

Step 4: Co-create vision

<div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">What</div> <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">Who</div> <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">Where</div> <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center; margin-bottom: 5px;">How</div> <div style="background-color: #1a3d4d; color: white; padding: 2px; text-align: center;">How much</div>	<div style="margin-bottom: 10px;"> <p>Products</p> <ul style="list-style-type: none"> Both oral- and blood-based HIV STKs Allow for urine-based when available </div> <div style="margin-bottom: 10px;"> <p>Target groups</p> <ul style="list-style-type: none"> Target groups identified in HIV STK Framework </div> <div style="margin-bottom: 10px;"> <p>Geographic areas</p> <ul style="list-style-type: none"> HIV AIDS "hot spots" Geographic areas where target groups reside </div> <div style="margin-bottom: 10px;"> <p>Modalities</p> <ul style="list-style-type: none"> Public and private supply Public and private delivery >>> all modalities </div> <div style="margin-bottom: 10px;"> <p>Price</p> <ul style="list-style-type: none"> Public free price Social affordable prices Commercial market price </div> <div style="margin-top: 10px;"> <p>Modalities</p> <ul style="list-style-type: none"> Facilities Communities Pharmacies Workplace ICT model (future) </div> <div style="margin-top: 10px;"> <p style="font-size: small;">} Linkages between all modalities</p> </div>
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Annex 8. Tanzania HIV Self-Testing Policy Synthesis

Published August 2022

Acronyms

ADDO	Accredited Drug Dispensing Outlet
ANC	Antenatal Care
FP	Family Planning
HIVST	HIV Self-Testing
HIVSTK	HIV Self-Test Kit
HTS	HIV Testing Services
KVP	Key and Vulnerable Populations
MNCH	Maternal Newborn Child Health
MOH	Ministry of Health
NACP	National AIDS Control Program
PLHIV	Persons Living with HIV
PrEP	Pre-Exposure Prophylaxis
SRA	Stringent Regulatory Authority
TMDA	Tanzania Medicines and Medical Device Authority
WHO	World Health Organization
WHO-PQ	WHO Prequalification

Background

Low testing and awareness of HIV status among key populations in Tanzania remains a challenge to accelerating progress towards the first of the ambitious Joint United Nations 95-95-95 goals – for 95 percent of all people with HIV to know their status by 2030.¹ Estimates suggest that ~1.74 million people are living with HIV in Tanzania, yet only 61 percent of this population over the age of 15 years know their status.² Additionally, prevalence among key and vulnerable populations is high. Testing remains particularly low in Tanzania among men and adolescents aged 15-19.³ Because HIV testing is critical in the linkage to initiate HIV care and treatment services, reaching people who don't know their HIV status is a global and national priority.

¹ UNAIDS. Understanding Fast-Track: accelerating action to end the AIDS epidemic by 2030. 2015.

² Tanzania Commission for AIDS (TACAIDS), Zanzibar AIDS Commission (ZAC). Tanzania HIV Impact Survey (THIS) 2016-2017: Final Report. Dar es Salaam, Tanzania. December 2018.

³ According to the Tanzania HIV Impact Survey 2016/2017 only 40.8% of males above 15 years have never had a HIV test; according to the Tanzania HIV Impact Survey 2016/2017 only 79% of males and 61.4% of females have never tested for HIV.

In 2016, the World Health Organization (WHO) recommended HIV self-testing (HIVST) as a testing approach that could expand access to HIV testing services (HTS) particularly to at-risk persons who may not otherwise test, or those at ongoing risk who need to test frequently. HIVST has been shown to be well accepted and offers the privacy, confidentiality, and time-saving benefits that might encourage and empower unreached populations to test.⁴

Ensuring access to HIVST relies on a number of factors including clear, supportive, and aligned regulations and policies. In November 2019, Tanzania’s HIV and AIDS (Prevention and Control) Act was amended to allow HIV self-testing in persons over the age of 18.⁵ Subsequently, the Tanzania Ministry of Health (MOH), National AIDS Control Program (NACP), together with other partners, developed the Tanzania HIV self-testing Implementation Framework to guide the implementation of HIVST in the country. The enactment of these policies were important steps towards broadening access to HTS; however, access to HIVST remains limited.

Objectives

This HIVST policy brief synthesizes current regulations and policies related to HIVST in Tanzania and compares them with global guidance and recommendations from the WHO. Additionally, it highlights areas where global and national policies are not aligned, potentially posing barriers to HIVST access in the country.

The objectives of this policy brief are:

1. To highlight alignment and misalignment of global and national policies around HIVST and
2. To serve as a starting point for discussions among key stakeholders on where policy alignment is necessary, now or in the future, to ensure continued and expanded access to HIVST to the identified populations in need.

A. What is HIV Self-Testing?

A consistent, harmonized definition of HIVST is required to achieve a common understanding among stakeholders at all levels. The table below summarizes how HIVST is defined in key global and national regulations and policy documents.

<p>World Health Organization⁶</p> <p><i>“HIV self-testing is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts.”</i></p>
<p>Tanzania Amendment of the HIV and AIDS (Prevention and Control) Act, (Cap. 431)</p> <p>Section 3 <i>“HIV self-testing means the process of a person collecting his own specimen, oral fluid or blood, performing a test and interpreting the results in a private setting, either alone or with someone he trusts.”</i></p>

⁴ Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2016.

⁵ Amendment of the HIV and AIDS (Prevention and Control) Act, Cap. 431. 2019.

⁶ Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2015.

Tanzania National Comprehensive Guidelines on HIV Testing Services, 2019

Definition of Terms: “HIV self-testing is a process in which an individual collects his or her specimen (oral fluid or blood) and then performs a test and interprets the test result often in private. Both reactive and non-reactive test results must be followed by additional HIV testing services.”

Tanzania HIV Self-Testing Implementation Framework, 2020

“HIV self-testing is defined as a process in which a person collects their specimen, either oral or blood, using a simple, rapid HIV test and performs the test and interprets their result, often in private settings, either alone or with someone else to provide any necessary support.”

Discussion

WHO and Tanzania’s relevant national policies define HIVST using similar language but these definitions are not completely aligned.

Tanzania’s HIV and AIDS (Prevention and Control) Act has dropped the pronoun “she” from the HIVST definition; however, practice does not exclude adult women from accessing HIV self-tests.

Tanzania’s National Comprehensive Guidelines on HTS adds additional language to the HIVST definition specifying “both reactive and non-reactive test results must be followed by additional HTSs.” This statement is not aligned with WHO guidance on re-testing (see Section F. *How to interpret HIVST results below*)

The specifications of bodily fluids that can be tested using HIVST may need to be expanded to allow for the market entry of innovative HIVST products in the future. HIVST is defined both by the WHO and Tanzania’s relevant policies as the “process of a person collecting his or her own specimen (oral fluid or blood)...” Currently, there is a urine-based HIV self-test product under WHO PQ review.

B. Who are the Target Populations for HIV Self-Testing?

In order for the HIVST approach to be both impactful and cost-effective, the World Health Organization recommends HIVST to be implemented as a complementary testing approach, not replacing conventional HTS, but rather targeting and prioritizing key populations who do not access other forms of HTS. The key priority populations for HIVST defined in global and national policy are summarized in the table below.

World Health Organization⁷**Section 2.3.1 Strategic planning for HIVST service delivery**

“HIVST is particularly appropriate for reaching people at high risk of HIV who are unable to access or have difficulty accessing existing services. In **low prevalence settings**, this may include **partners of people with HIV** and key populations. In **high prevalence settings**, this may include **men, serodiscordant couples** and partners, **adolescents** and **young people, key populations** and other **vulnerable groups** – as defined by country context.”

Tanzania Amendment of the HIV and AIDS (Prevention and Control) Act, (Cap. 431)

The HIV and AIDS Act was amended in 2019 to remove barriers to conventional HTS by removing consent requires for youth ages 15 to 18 years.

⁷ Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2016.

15.2 “A child or a person with inability to comprehend the result may undergo HIV testing after a written consent of a parent or recognized guardian. “Child” for the purposes of HIV testing under this Act, means a person below the age of fifteen.”

The HIV and AIDS Act is clear that HIVST should be restricted to those above the age of 18 years.

16A.3 “A person below the age of eighteen years shall not undertake self-testing or be provided with self-testing kits.”

Tanzania HIV Self-Testing Implementation Framework, 2020

2.2. “All persons aged 18 and above can undertake an HIV self-test on their own volition. Populations that are less likely to be reached with the routine provider and client-initiated HTS strategies, for one reason or the other, are expected to benefit from HIVST. These include:

- a. Men
- b. Youth
- c. Key and vulnerable populations
- d. Partners of PLHIV in clinics
- e. Mobile populations
- f. Certain occupations—miners, fisherfolk, drivers, and those working in construction industries, those separated from their families because of work.”

Discussion

WHO and Tanzania’s national policy are aligned in defining youth as one of the priority populations for HIVST, though their definitions of youth differ--Tanzania defines youth as those aged 15-35 years⁸ and the United Nations defines youth as those persons between the ages of 15 and 24 years.⁹

The THIS 2016/2017 revealed that HIV Testing remains low among youth ages 15-19 years. In an effort to reduce barriers impeding youth access to conventional HTS, the amendment of the HIV and AIDS (prevention and control) Act in 2019 removed consent requirements from a parent or guardian for individuals 15 years up to 18 years. Despite this achievement, barriers to HIVST access remain for a key segment of the population that could benefit from HIVST (youth ages 15-18 years) as the HIV and AIDS Act and HIVST Implementation Framework clearly limit HIVST to persons above 18 years.

C. Which HIV Self-Testing Kits are Recommended?

The WHO promotes the use of quality-assured HIVSKs. The table below summarizes key characteristics of HIVSTKs to be used in program implementation.

World Health Organization

As of June 2022, there are five quality-assured HIVST products that have achieved WHO prequalification (one oral and four blood-based). The details of these products are below:

- OraQuick HIV Self-Test (OraSure Technologies, USA); oral fluid
- INSTI HIV Self-Test (Bioanalytical, Canada); blood-based
- Mylan HIV Self-Test (Mylan, Atomo Diagnostics, Australia); blood-based
- SURE CHECK HIV 1/2 Assay (Chembio, USA); blood-based
- CheckNOW HIV SELF TEST (Abbott, Germany); **blood-based**

⁸ National Bureau of Statistics. (2013). 2012 Population and Housing Census (PHC). Population Distribution by Age and Sex.

⁹ Secretary-General’s Report to the General Assembly, A/36/215, 1981.

Amendment of the HIV and AIDS (Prevention and Control) Act, (Cap. 431)

Section 16C. “A person shall not use or supply self-testing kits unless the kits are approved and registered by the authority responsible for quality and standards control.”

Tanzania HIV Self-Testing Implementation Framework, 2020 Section 2.1 “HIVST can be conducted by either oral or blood-based test kits”

Section 6.1.1 “HIVSTKs procured and used for HIVST will be approved and registered by the MOH through the TMDA. Only HIVSTK approved by the TMDA will be allowed in the market. As part of a continuous process of guaranteeing the HIVSK, TMDA will ensure that all HIVSTK for use in Tanzania:

- Have WHO pre-qualification
- Have undergone in-country validation
- Have been locally registered with a lot-to-lot validation”

Section 6.1.6 “**Only the oral HIVSTK** will be allowed for use in Tanzania to minimize HIVSTK disposal complications. Disposal of used HIVSTK will follow manufacturers’ disposal guidance.”

Discussion

Global and national policies support the use of quality-assured HIVSTKs that have WHO pre-qualification.

List of HIVSTKs with approved registration at TMDA as of June 2022:

- OraQuick HIV Self-Test (OraSure Technologies, USA); oral fluid
- Mylan HIV Self-Test (Mylan, Atomo Diagnostics, Australia); blood-based
- CheckNOW HIV SELF TEST (Abbott, Germany); blood-based

Tanzania’s national policies on the use of oral vs. blood-based self-test kits are not aligned.

Tanzania’s HIVST Implementation Framework is more restrictive than Tanzania’s HIV and AIDS (Prevention and Control) Act. The HIV and AIDS Act does not prohibit the use of a specific type of HIVST kit. However, section 6.1.6 of the HIVST Implementation Framework clearly states that “only oral HIVST will be allowed for use...” This statement is confusing and contradictory to Section 6.1.1 of the same Implementation Framework, which states that “HIVST kits procured and used for HIV self-testing will be approved and registered by the MOH through the TMDA.” As of June 2022, two blood-based HIVSTK (and one oral-based) HIVSTK have been registered in the country through the TMDA. Currently, only the oral-based HIVSTK (from one manufacturer) is available for use in the country. Having a supply base of only **one manufacturer is a risk to having an uninterrupted supply of HIVSTKs** and will also pose other challenges when access to HIVSTK opens up through additional service delivery modalities (e.g., through private sector channels) where the tests may not be offered for free. As such, product differentiation discussions are necessary.

D. Where Should HIV Self-Test Kits be Available?

Various HIVST delivery approaches should be considered to broaden access points for the target populations. The table below summarizes some of the options for consideration.

World Health Organization¹⁰

2.3.1 Strategic planning for HIVST service delivery

“A continuum of different HIVST service delivery approaches can be considered, depending on the context, setting and population that the program is trying to reach. Approaches can be largely facility-based or community-based, implemented through secondary distribution (for example, delivered by sexual partners), integrated with other related health programs and interventions, or provided through pharmacies, vending machines, the Internet or other public and private sector channels.”

Figure 2.5 Different HIVST service delivery approaches

Different service delivery modalities include: community based; partner-delivered; facility based (pick up/self-administered on site); pharmacy-based; work-place programs; internet-based; PrEP programs; vending machines and kiosks.

Amendment of the HIV and AIDS (Prevention and Control) Act, (Cap. 431)

Section 13.4 *“Except for HIV self-testing, HIV testing shall be undergone or conducted in a health center or center recognized by NACP.”*

Tanzania HIV Self-Testing Implementation Framework, 2020

Section 3.2 HIVST Delivery Channels *“Various channels will be utilized for public and private sector settings to reach different populations in Tanzania.”*

3.2.1 Public Sector Settings

“(I) Public health facilities channel will involve provide self-testing kits by health providers within the facilities at selected points such as: ANC clinics, outpatient, pharmacies and outreach...”

“(II) Community channels will involve the provision of self-testing to community members who find it difficult going to pick from health facilities...”

“(II) Workplaces will also be used to distribute self-testing kits for employees through the HIV workplace programs...”

3.2.2 Private sector settings

“Distribution of HIVST in private settings will be done through private pharmacies....”

[A figure in this section shows that HIVSTKs could also be available through vending machines.]

6.1.5 Quantification, Procurement and Distribution

“MSD is responsible for importing and distributing HIVSTKs to the public sector and designated faith-based facilities. Private importing agencies will do the procurement of the commercial HIVSTKs, i.e., private pharmacies, commercial kits, and private health facilities.”

[A figure in this section shows that HIVSTK distribution can also be through ADDOS.]

¹⁰ Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2016

Discussion

While the HIVST Implementation Framework points to several different delivery channels through which HIVST kits can be accessed, **current practice does not allow (yet) for the widespread availability of HIVSTKs in the workplace, pharmacies, ADDOs, or vending machines** (which are mentioned in national policies) and are still mostly limited to a subset of public health facilities. Further national level discussions are necessary to determine how to best expand access through these various delivery modalities.

E. Who is Allowed to Distribute HIV Self-Testing Kits (to clients)?

The table below summarizes characteristics and requirements for providers/distributors of HIVSTKs.

World Health Organization

WHO encourages country programs to define a minimum support package to accompany HIVST implementation which can include basic support (e.g., use of standard, manufacturer provided instructions and manufacturer provided telephone hotline) to more intensive support (e.g., one-on-one in-person HIVST demonstration and/or observation of supervision of self-testers). WHO does specify that “when considering resource-intensive support options, such as training, in-person demonstration and supervision, the added benefit needs to be weighed against use of resources. Such resource-intensive support mechanisms can limit scalability and should be considered for a limited time...”¹¹

HIV AIDS Act, 2019**Section 16B**

“I) A person shall not provide or supply self-testing kits unless he has undergone training in HIVST recognized by the Ministry”

II) A person who provides or supplies self-testing kits, shall, before providing or supplying such kits:

- Provide pre-testing counseling to the user in accordance with provisions of this Act
- Instruct the user on the proper procedures of HIVST and disposal of used HIVSTKs
- Inform the user that HIV self-testing does not provide definitive and conclusive diagnosis
- Advise the user to visit a health facility or authorized HIV testing service for confirmation of results”

Tanzania HIV Self-Testing Implementation Framework, 2020

4.2 “All persons involved in the implementation of HIVST at program and service delivery levels must have a similar understanding of the rationale and procedures of issuing the test kits...”

Service providers in the public, including health care workers, community health workers, peers, and pharmaceutical technicians/technologists should be oriented on providing information about HIVST and interpreting the results, disposal and collection of adverse events and social harm related to HIVST. They

¹¹ WHO recommends HIV self-testing – evidence update and considerations for success. Geneva: World Health Organization; 2019

should be trained in the use of data collection tools and reporting. This should be aimed to equip them with knowledge and skills to support users.

Service providers in the private sector, including private hospitals, pharmacies and ADDOs should also undergo training similar to service providers in the public sector. The training, should, however, be contextualized to the needs and dynamics of the private sector.”

Discussion

Global guidance from WHO does not specify specific training requirements for lay providers/distributors of HIVSTs and highlights that the benefits of intensive-support options need to be weighed against available resources (as they can limit scalability); however, Tanzania’s national policies stipulate that providers must undergo a training on HIVST recognized by the Ministry.

The approved HIVST training package is currently five days long and may limit scalability in the private sector. The Implementation Framework does however, leave room to contextualize these trainings to “the needs and dynamics of the private sector” potentially allowing for a reduction in the number of training days or offer possibilities for blended virtual/in-person training modalities.

F. How to Interpret HIV Self-Test Results?

HIVST is a test for triage and does not provide a definitive HIV-positive diagnosis. Policies identify the populations that should be re-tested based on HIVST results. Interpretation of a non-reactive self-test result will depend on the ongoing risk of HIV exposure.

World Health Organization¹²

*“A reactive positive HIVST result is not equivalent to an HIV-positive diagnosis. **All reactive HIVST results need to be followed by further testing by a trained provider to confirm HIV status, starting with the first test in the national testing algorithm.***

***Nonreactive HIVST results should be considered HIV-negative, with no need for immediate further testing except for those starting pre-exposure prophylaxis (PrEP).** For people starting or already taking PrEP, HIVST cannot replace initial or subsequent quarterly facility visits and testing.*

*Those with **invalid results need to repeat the test** using another HIVSTK or to seek testing from a trained provider. Any person uncertain about their HIVST result should be encouraged to seek testing from a trained provider.*

HIVST is not recommended for people with HIV who are on ART, as false-negative HIVST results can occur. Those who are HIV-positive but not on ART should be encouraged supported to initiate ART. Re-testing following a negative self-test is necessary only for those at ongoing risk, such as people from key populations and those reporting potential HIV exposure in the preceding 12 weeks.”

National Comprehensive Guidelines on HIV Testing Services, 2019

¹² WHO recommends HIV self-testing—evidence update and considerations for success. Geneva: World Health Organization; 2019.

Definition of Terms: “HIV Self-Testing (HIVST) is a process in which an individual collects his or her specimen (Oral fluid or blood) and then performs a test and interprets the test result often in private. Both reactive and non-reactive test results must be followed by additional HIV testing services”

Section 4.5 HIV Self-Testing “The HIVST does not provide a definitive diagnosis. A reactive (positive) result always requires further confirmatory testing from a trained HTS provider using the relevant validated national HIV testing algorithm.”

Tanzania HIV Self-Testing Implementation Framework, 2020

Section 2.1 “HIV self-test is a screening test; hence a reactive result is not a final HIV-positive diagnosis. All HIVST results should be followed with further testing by a trained health services provider”

Discussion

- There is agreement across global and national policies that HIVST does not provide a definitive HIV-positive diagnosis and all persons with reactive tests need further testing from a trained provider to confirm HIV status.
- WHO policy is more nuanced in describing the re-testing measures for non-reactive tests, stating that no further immediate follow-up is necessary if a test result is negative with the exception of: those starting PrEP; those at ongoing risk; or those who had potential HIV exposure in the preceding 12 weeks. Tanzania’s policies suggest that all reactive and non-reactive tests require further testing which could lead to wastage of resources if not necessitated.

G. Pricing for HIV Self-Test Kits

Affordable pricing is an important consideration to ensure access to HIVSTK. Currently Global Fund (and PEPFAR in emergencies) supports the procurement of HIVSTK for the public sector in Tanzania where they are provided for free to clients through facility-based and community-based distribution. As access through private delivery channels expands, there must be consideration around fair pricing strategies to ensure that targeted users are able to access HIVSTK. The below table summarizes WHO and national level guidance around pricing, and additionally provides publicly available pricing information on HIVSTK.

World Health Organization

“WHO supports free distribution of HIV self-test kits and other approaches that allow self-test kits to be bought at affordable prices. WHO is also working to reduce costs further to increase access.”

Tanzania National Health Policy 2007

The Tanzania National Health Policy 2007 defines vulnerable groups that should be exempt from cost sharing for accessing quality health services. People living with HIV/AIDS are included among the defined vulnerable populations.

7.4 Exemption of Cost Sharing to Vulnerable Group

“The government recognizes the existence of vulnerable groups including elderly, under-fives, pregnant women, people with disabilities, and people with chronic disease like HIV/AIDS, Diabetes, Heart Diseases, TB and Leprosy and Mental diseases.”

Globally Reported Prices for HIVSTK

- Donors like Global Fund are working with manufacturers to lower prices and speculate that in the future a \$1/HIVSTK may be achievable. The Global Fund's reference price list from June 2022 provides an ex-works reference price for HIVSTK between USD\$1.50-\$3.59.
- In 2018, Global Fund reported that Orasure offered its oral-based HIVSTK for \$2 ex-works in 50 LMICS.¹³ In 2021, Viartis announced that the blood-based HIV self-test they distribute will be available for under \$2 across 135 low and middle-income countries¹⁴ and in 2022 Abbott declared pricing of \$1.40 for their blood-based HIV self-test kit.¹⁵

Discussion

Tanzania National Health Policy stipulates that there should be cost-sharing exemptions for some vulnerable groups including persons living with HIV/AIDS. As such, antiretroviral medicines (ARVs) are provided for free in the public sector. However, HIV testing in the general population does not clearly fall into this exemption category. In fact, at the outset of HIVSTK introduction in Tanzania, policymakers considered distribution through private channels where they would be sold. Under SHOP+, a rapid consumer assessment was administered and found that some consumers were willing to pay on average TZS 5,000 (~USD\$2.17) for a HIVSTK, and the PSI pharmacy pilot in Tanzania suggested a recommended retail price of TZS 3,000 (~USD\$1.3). A deeper **understanding of willingness to pay among various target consumers (e.g., men, AGYW, and other key and vulnerable populations) is required to develop pricing strategies that consider various market segments.**

H. Monitoring and Evaluation for HIVST

Monitoring and evaluation is a critical component of HIVST to ensure implementation is as effective as possible and to be able to report on its impact towards the 95 goals. The below summarizes guidance from WHO as well as what Tanzania National policy stipulates.

World Health Organization^{16,17}

WHO General Principles on HIVST M&E:

- **Integrate HIVST monitoring into existing tools and approaches used to monitor HIV testing services, such as HIV testing and ART registers. Additional HIVST-specific monitoring and reporting tools will sometimes be needed**
 - **Use multiple data sources**
- Data collection should not be intrusive or burdensome (there is a need to protect confidentiality and privacy of individuals) and not make monitoring a deterrent from use of HIVST
- Need to consider the Human and Financial cost of active monitoring

¹³ https://www.theglobalfund.org/media/8128/psm_2018-12-rapiddiagnostictestsuppliermeeting_presentation_en.pdf

¹⁴ <https://unitaid.org/news-blog/access-to-hiv-self-tests-significantly-expanded-and-costs-halved-thanks-to-unitaid-agreement/#en>

¹⁵ 2022. Global Fund HIVST M&E approaches [webinar: HIV self-testing monitoring & evaluation: lessons learnt from West and Central Africa] [online]. WHO. 28 April 2022.

¹⁶ [WHO HIV Self-Testing Strategic Framework: Guide for Planning, Introducing and Scaling-Up, 2018](#)

¹⁷ 2022. Global Fund HIVST M&E approaches [webinar: HIV self-testing monitoring & evaluation: lessons learnt from West and Central Africa] [online]. WHO. 28 April 2022.

- **Prioritization should be on the use of routine data + data triangulation** (look at ATLAS project on the work they have done to measure impact of HIVST)

Tanzania HIV Self-Testing Implementation Framework, 2020

8.1 “It is critical to monitor the implementation of HIVST as it is for all HTS approaches. Unlike other HTS modalities and approaches, **monitoring and reporting of HIVST are somewhat challenging due to its discreet and private nature**. Such information includes the effectiveness of the HIVST implementation, tracking of users' experiences, and tracking of possible social harms.”

Monitoring methods may include:

- Community-based surveillance and surveys HIVST
- Service delivery outlet/facility monitoring tools

8.1.7 Key HIVST Indicators

- Age
- Sex
- Test result
- Geographic area
- Service delivery point
- Facility-based
- Clinics
- Community-based

Discussion

- WHO’s guidance based on learnings from the ATLAS and STAR Initiatives (implemented across 16 countries in Africa and Asia) is that **it is important not to make M&E too onerous and complex** – more pragmatic approaches are necessitated (using routine data sources + data triangulation). WHO asserted that developing and implementing M&E systems that monitor from the point in time when a HIVSTK is distributed to a user to the time they are linked with treatment is **highly costly, difficult, and not feasible in a national scale-up**.
- M&E for the private sector is not clearly defined in National policy. As Tanzania defines its M&E approach, particularly for the private sector, it’s important that best practices and lessons learned from other countries are taken into consideration - and that M&E doesn’t become a deterrent for access.

Conclusion

Tanzania has made some important initial steps to ensure access to HIVST by enacting policies, such as the Amendment of the HIV and AIDS (Prevention and Control) Act, (Cap. 431). Comprehensive HIV Testing Services Guidelines, and the HIVST Implementation Framework, which support the inclusion and introduction of HIVST as a complementary HIV testing services approach. However, HIVST has not yet achieved its full potential in Tanzania, as service delivery modalities remain limited (largely through a limited number of public health facilities) and key target populations that could benefit from HIVST are

prohibited from accessing HIVST (e.g., youth ages 15-18 years). Additionally, confusion remains among stakeholders about the type of HIVSTKs (blood-based vs. oral) that are allowed for distribution and use in the country. Currently, there is only one oral-based product produced by one manufacturer that is available for use in Tanzania. This poses a real risk to the uninterrupted supply of HIVST kits in the country. Monitoring and Evaluation of HIVST if too onerous and complex for both private sector and clients may pose as a deterrent for access. Best practices from other countries should be built on (where applicable) to inform national policy and strategy. Finally, the definition of HIVST may also need to be expanded in the future to allow for the market entry of innovative HIVST products (e.g., urine-based HIVSTK).

Further discussions led by the Government are required to determine how to best align existing policies with practice so that stakeholders' efforts best support expanded access to the individuals in need of these testing services. Through these efforts, at-risk individuals who have been missed through other testing approaches can be identified, learn their status, and ultimately be linked to the necessary support, care, and treatment services. This will help the country move closer toward the 95-95-95 goals.

Summary Table of HIVST-related Global and National Policies (WHO)

HIVST POLICY	WHO	TZ	Comment
A. What is HIVST?	<i>“HIV self-testing is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts.”</i>	<i>“HIV self-testing means the process of a person collecting his own specimen, oral fluid or blood, performing a test and interpreting the results in a private setting, either alone or with someone he trusts.”</i>	<ul style="list-style-type: none"> • WHO & TZ definitions are mostly aligned • May need to expand definition of bodily fluids to allow for new technology (e.g., urine-based HIVSTK)
B. Target Population	<p>Low prevalence setting: 1) partners of people with HIV; 2) key populations</p> <p>High prevalence setting: 1) men; 2) serodiscordant couples and partners; 3) adolescents and young people; 4) key and vulnerable populations</p>	<ul style="list-style-type: none"> • Men • Youth +18 years • Key and vulnerable populations • Partners of PLHIV • Mobile populations • Certain occupations (e.g., truckers, fisherfolk) 	<ul style="list-style-type: none"> • Tanzania policy does not allow key target population group (youth age 15 to 18 years) to access HIVSTK
C. Recommended HIVSTK	WHO-PQ blood-based or oral-based	WHO-PQ and TMDA registered oral-based	<ul style="list-style-type: none"> • Tanzania’s key National HIV/AIDS policies are not aligned on the use of oral vs. blood-based self-test kit • Need to update the HIVST Implementation framework to allow for blood-based HIVST
D. Service Delivery Locations for HIVSTK	1) Facility-based; 2) community-based; 3) Provided through pharmacies, vending machines,	1) Public health facilities; 2) Community channels; 3) workplaces; 4) private pharmacies and other	<ul style="list-style-type: none"> • Current practice in Tanzania does not allow (yet) for the widespread availability of HIVST kits

	internet or other public and private sector channels	private channels (e.g., ADDOs and vending machines)	in the workplace, pharmacies, ADDOs or vending machines (which are mentioned in national policies) and are still mostly limited to a subset of public health facilities
E. Who can distribute HIVSTK?	No specific training requirement recommended	Person who has undergone HIVST training	<ul style="list-style-type: none"> • The approved HIVST training package is currently 5 days long and may limit scalability in the private sector • The HIVST Implementation Framework does, however, leave room to contextualize these trainings to the “needs and dynamics of the private sector”
F. How to interpret HIVST results?	<ol style="list-style-type: none"> 1) All reactive HIVST results need to be followed by further testing by a trained provider to confirm HIV status 2) Nonreactive HIVST results should be considered negative except for those starting pre-exposure prophylaxis 3) Resting following a negative self-test is necessary only for those at ongoing risk (e.g., key and vulnerable populations, those with possible HIV exposure in the previous 12 weeks) 	All HIVST results (reactive and non-reactive) should be followed with further testing by trained health services provider	<ul style="list-style-type: none"> • WHO policy is more nuanced in describing the re-testing measures for non-reactive tests • Tanzania’s policies suggest that all reactive and non-reactive tests require further testing which could lead to wastage of resources if not necessitated

	4) Invalid results need to repeat the test		
G. Recommended Pricing for HIVSTK	Free or affordable prices	Cost-sharing exemptions for vulnerable populations; Policies do not explicitly recommend pricing for HIVSTK	<ul style="list-style-type: none"> Understanding willingness to pay among various target consumers (e.g., men, AGYW, and other key and vulnerable populations) is required to develop pricing strategies that consider various market segments.
H. M&E for HIVSTK	<ol style="list-style-type: none"> M&E should not be too onerous and complex Human and financial costs need to be taken into account Use routine data + data triangulation to measure impact (refer to ATLAS program best practices) Tracking distribution of HIVSTK to clients to the time when they are linked with treatment is costly and not feasible in a national scale-up 	Monitoring and reporting of HIVST are somewhat challenging due to its discreet and private nature M&E for private sector is not clearly defined	<ul style="list-style-type: none"> It is important that best practices and lessons learned from other countries are taken in to consideration and that M&E doesn't become a deterrent for access

Annex 9. HIVSTK Market Development Workshop #2

HIVSTK Market Workshop #2

The Slipway Yacht Club Road

Wednesday, July 6, 2022

10:30am-12:30pm

Meeting Objectives:

- Recap the objectives of the HIVST working group and the outcome of Workshop #1
- Focus on learnings from different HIVST service delivery modalities to address some of the information gaps identified in Workshop #1
- Provide an opportunity for blood-based HIVSTK manufacturers/representatives to present their products to the group
- Summarize and create a plan to address [additional] information gaps that were identified during the session that need to be addressed in order to better understand current market performance

Time	Session	Facilitator
10:30-10:45	Welcome <ul style="list-style-type: none"> • Opening remarks • Recap HIVST Workshop #1 and overview of objectives of Workshop #2 • Participant Introduction 	• Farhan Yusuf, FHM Engage
10:45-10:55	WHO/ATLAS/STAR HIVST M&E lessons from West and Central Africa [Webinar Summary] <ul style="list-style-type: none"> • Summary Presentation 	• Sarah Alphas, FHM Engage
10:55-11:25	Overview of the PSI Pharmacy Model Presentation on the Pharmacy model/pilot for HIVST Key takeaways/highlights from ongoing HIVST evaluation <ul style="list-style-type: none"> • Facilitated Q&A 	• Dr. Raymond Bandio, PSI
11:25-11:55	Overview of AMREF supported HIVST models Presentation on Facility & Community models for HIVST <ul style="list-style-type: none"> • Facilitated Q&A 	• Emma John, AMREF
11:55-12:15	Abbott & Mylan Presentation on blood-based self-test kits	• Abbott and Mylan representatives
12:15-12:30	Next steps & Closure	• Farhan Yusuf, FHM Engage

HIVSTK Workshop #2 – Participant List

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HIVSTK Market Development Workshop #2

Date: July 6, 2022

Time: 10:30am-13:00pm

Venue: Slipway Hotel

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 HIVSTKs 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.

Workshop Proceedings

Workshop objectives: The meeting objectives included:

- Recap of the objectives of the HIVST working group and the outcome of Workshop #1
- Focus on learnings from different HIVST service delivery modalities to address some of the information gaps identified in Workshop #1
- Provide an opportunity for blood-based HIVSTK manufacturers/representatives to present their products to the group
- Summarize and create a plan to address (additional information gaps that were identified during the session that need to be addressed 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: TACAIDS, USAID, T-Marc, Sciex (representing Orasure), Synermed (representing Mylan HIV self-test kit), Nebula Health Care (representing Bionnex), MyService, TAYOA, PSI, FHI360, Amref, Pathfinder, and the FHM Engage team.

Presentation 1: Workshop #1 Recap

Prior to discussing the Workshop #2 agenda, the FHM Engage team 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 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 - TMDA, Pharmacy Council, TACAIDS, civil society organizations
- Advocacy with groups in collaboration with 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 HIVSTs imported, distribution, and data capture.

Presentation II. WHO/ATLAS STAR HIVST M&E Lessons from West and Central Africa

The purpose of the HIVST Market Development Group is to co-create and collectively implement interventions that will introduce and encourage uptake of HIVSTs through public and private channels. Developing effective interventions requires understanding key challenges and their root causes and learning from the experience of others. M&E was cited in Workshop #1 as a challenge in various delivery modalities in Tanzania potentially posing as a barrier to scaling-up the Pharmacy Distribution Delivery model. Because of this, the FHM Engage Team decided to summarize an important webinar hosted on June 21, 2022 by WHO/ATLAS/STAR Initiative on HIVST M&E lessons learned from West and Central Africa. The webinar presentations summarize WHO guidance on 1) HIVST M&E; 2) best practices for data triangulation from the ATLAS program and 3) emerging opportunities to implement technology (e.g., WhatsApp Chatbot) to collect information on the HIVST process.

Webinar Link: [WHO/STAR/ATLAS Webinar on HIVST M&E lessons](#)

WHO Presentation Key Takeaways:

- We need to be able to measure the impact of HIVST access on the 95s 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 HIVST is distributed to a user to the time they are linked with treatment **is highly costly, difficult, and not feasible in a national scale-up.**
- **WHO General Principles on HIVST M&E:**
 - Use multiple data sources
 - Data collection should not be intrusive or burdensome (we need to protect confidentiality and privacy of individuals) and not make monitoring a deterrent from use of HIVST
 - Need to consider the Human and Financial cost of active monitoring
 - **Prioritization should be on the use of routine data + data triangulation** (look to ATLAS project on the work they have done to measure impact of HIVST)
 - (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 HIVST in 3 countries: Senegal, Mali, and Ivory Coast
- **Lessons on M&E from the ATLAS Program**
 - Systematic data collection/report for HIVST distribution is mandatory to monitor program implementation
 - **Systematic data collection on HIVST 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 HIVST outcomes and indirect impact**
- Key variables required to replicate the ATLAS data triangulation methodology
 - Number of HIVSTs distributed
 - Number of conventional HIV tests performed
 - Number of new diagnoses/positive tests
 - Number of new 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 HIVST Chatbot App or “virtual counselor” which can be used to:
 - Direct client where to access HIVST
 - Generate e-vouchers for HIVST access and post-test services
 - Privately access curated info about health issues/products/services
 - Screening tools integrated to assess risk profile and whether to test for HIV and whether eligible for PrEP
 - Automated follow-ups and reminders
 - Receive feedback from a human
 - **Share and collect data from HIVST process**
- Takeaways
 - Chatbot provides a good opportunity to educate about HIV prevention, care and testing and promote self-testing, learn how to use self-test kits
 - Efficient way to engage with large audience and access info on health issues and services and access points, especially for young people
 - Uses multiple languages and can accommodate various nationalities and ethnicities
 - It can accommodate multiple self-test kits and link to other self-care products, FP, PrEP
 - Opportunity with human interface and helpline
 - **Chatbot is being expanded in Tanzania**

Global Fund HIVST M&E Approaches

Global Fund uses a mix of programmatic, budgetary, and procurement data for HIVST 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**
 - PPM 2018-2021
- Currently one supplier represents 84% of total HIVST market orders placed through PPM.
- The presenter posed a question about potential price reductions on HIVST in the future and getting closer to US\$1/test, as Abbott’s self-test kit is a new entrant to the market w/ an announced price of US\$1.40.

Questions & Discussion:

- USAID representative asked if there is a tool for regression analysis to be adapted. The FHM Engage team 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, AGYW, KPs

- Price: It was noted that pharmacies were issued kits freely from PSI and [the pharmacies] were instructed to sell at a price of a maximum Tsh 3,000 (subsidized price)
- Partners: STAR project partnered with Pharmacy Council Tanzania, Pharmaceutical Society of Tanzania, and NACP
- Demand Creation: PSI shared Pharmacy distribution model entailed demand creation for STKs through: IEC materials; training pharmaceutical personnel to identify potential clients; and use of CHW from nearby health facilities to generate demand
- Training: Trained pharmacists were trained on screening clients eligible for HIVST, counseling clients, registration and records keeping, and issuing the kits over the course of 3 days
- Unassisted modality: It was noted that HIVST 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 HIVST services
- **Major achievements**
 - 13 National trainer of trainers oriented and are available to facilitate scale-up
 - 60 private pharmacies engaged to implement HIVST distribution
 - 60 pharmaceutical personnel successfully trained
 - 18,550 HIVST kits distributed through private pharmacies
 - HIVST pharmacy reporting tool developed and in use
 - HIVST integrated in the Pharmacy Council's USSD reporting platform
 - IEC materials produced, distributed and IPC demand creation conducted
- **Implementation Challenges**
 - Low return rate noted [Out of 18,550 tests distributed only 684 clients voluntarily self-reported using the kit]
 - Limited visibility of distribution data, developed DHIS2 dashboards were not published
 - Trained Pharmaceutical personnel's turn over. Some of trained personnel moved from to other pharmacies not supported by STAR project
- **Lessons learned and Recommendations:**
 - Private pharmacy is a promising channel for HIVST distribution, scale-up should be considered
 - Population-level HIVST 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 HIVST should be encouraged to stimulate private sector led HIVST distribution and promotion
 - Considering going to the lower ADDOs will increase access to the HIVST
 - Considering deploying different product/packaging from the public used HIVST 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 to 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: 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 HIVST 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 HIVST 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 HIVST kit 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 HIVST kits in the pharmacies?

A. About 3,000 HIVST kits remain at private pharmacies.

Q. What were the STAR targets for the Pharmacy Distribution Model?

A. STAR anticipated that 40% of 120,000 HIVST kits 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 HIVSTK high or low?

A: Demand is there, hard to say if it's low or high but 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 5,000TZS from SHOP+ assessment.

Q. What are the next steps on the Pharmacy Model Evaluation?

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 HIVST model and is expected start in August 2022 and to 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 government in development of the platform that will offer virtual counselling & linkage to care and treatment services, etc.
- Ministry is interested to see if the system can do the delivery itself, i.e., ICT model.

Presentation IV. Afya Kamilifu (Amref) HIVSTK Implementation Experience

- Afya Kamilifu was implemented in Tanga, Simiyu, and Mara Regions
- **Training:**
 - Health Facilities in the targeted areas received National HIVST training package (5 day training)
 - Peers (community outreach volunteers) received a 4 day training
 - R/CHMTs sensitization meeting (1 day)

AK project distributes HIVSTK 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 OPD, secondary distribution for antenatal, family planning clients, and direct distribution during HTS optimization. Clients test on site, at the private area within the facility.
- **Secondary distribution:** Enhance index testing through referral option, social network

- testing peer to peer (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 SBCC for KPs and AGYWM.
 - Targeted population for HIVSTK service are all persons aged 18 and above, who provided verbal informed consent as per the national HTS guidelines, clients 15-17 who are sexually active, pregnant or otherwise, and hard to reach populations at risk of HIV such as:
 - Female sex workers and their partners
 - Male having sex with Male 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 HIVSTK supply?

A: Amref receives free HIVSTKs through the public sector (MSD) only.

Q. As all of the HIVSTK 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 HIVST (for 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 HF in the assisted vs. unassisted testing modalities?

A: There was a higher return rate of clients who were assisted with HIVST than those not assisted. Amref shared that high rate of return clients (over 98%) was due to investments made to engage community outreach volunteers, CHW, and peer educators who create demand and conduct post follow ups and link clients to HFs and outreaches for confirmatory tests

Presentation IV. Viatrix/Mylan HIV Self-Test Demonstration

The Mylan representative presented on their WHO-PQ & TMDA registered blood-based HIVSTK which is accurate, safe to use, and convenient, with easy to interpret results.

Link: [Mylan HIV self-test demonstration](#)

I. Next Steps (some continuing from Workshop #1)

1. FHM Engage will work with stakeholders to finalize the dates for Workshop #3
2. FHM Engage to follow-up with the ATLAS program on their regression model and share with the HIVST working group
3. Continue to address data challenges (identified in Workshop #1)
 - i. FHM Engage to share the draft HIVST policy brief for review prior to Workshop #3 to be validated by NACP/TMDA
 - ii. Document and share learning from other countries
 - iii. Conduct rapid research on consumer preferences and willingness and ability to pay
 - iv. Understand issues around HIVSTK import, distribution, and data capture
4. Engage NACP on how to best support the development of distribution guidelines

5. Work with UNAIDS to commence HIVST advocacy with i. Prime Minister, ii. NACP, iii. Religious leaders iv. Sports figures
6. Work with CSSC and APFHTA to expand supply in private facilities
7. Assist CSSC (and other FBOs) and APFHTA to document i) current supply, ii) experience to date, and iii) barriers to expansion
8. Develop a quick action plan to expand HIVSTKs in private facilities

Annex 10. HIVSTK Market Development Workshop #3

HIVSTK Workshop #3

Slipway Hotel

Thursday, August 25, 2022

Meeting Objectives:

- Agree & develop framework for HIVSTK market strategy
- Define next steps to further develop and finalize the HIVSTK market strategy

Time	Session	Facilitator
08:30-08:45	Welcome <ul style="list-style-type: none"> • Opening remarks • Meeting objectives/agenda • Participant Introduction 	Farhan Yusuf, FHM Engage
08:45-09:00	Recap <ul style="list-style-type: none"> • Purpose of HIVSTK Development Group • Summary of Workshop 1 & Workshop 2 	Farhan Yusuf, FHM Engage
09:00-10:00	Update on Draft HIVSTK TOC <ul style="list-style-type: none"> • Summary of HIVST policy brief/benchmarking/Learnings from different service delivery modalities • Discussion on how to modify HIVSTK Theory of Change based on new information 	Sarah Alphas, FHM Engage Barbara O'Hanlon, FHM Engage
10:00-10:15	Tea break	All
10:15-11:30	Vision and Scenario Planning <ul style="list-style-type: none"> • Group discussion 	Haika Mandari, FHM Engage Barbara O'Hanlon, FHM Engage
11:30-13:00	Break out groups to discuss scenarios	All
13:00-14:00	Lunch	All
14:00-15:00	<ul style="list-style-type: none"> • Group presentations on scenario discussions • Define scenario to work towards 	All
15:00-16:00	Market barriers discussion <ul style="list-style-type: none"> • Define critical actions; lead/partners & roles and responsibilities 	Sarah Alphas, FHM Engage Barbara O'Hanlon, FHM Engage
16:00-16:15	Tea break	All
16:15-17:00	Next steps (next phase of market strategy—actual articulation of who does/who pays)	Farhan Yusuf, FHM Engage

HIVSTK Workshop #3 Participant List

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HIVSTK Market Development Workshop #3 Meeting Report

Slipway Hotel

Thursday, 25th August 2022

Summary

The FHM Engage team organized the third workshop, but due to extenuating circumstances – traffic created by torrential rains and census requirements to stay at home – less than half of the confirmed participants showed. As a result, the team decided to reorient the workshop to a ½ day meeting that focused on discussing the key findings from the various analyses, sharing new information and developments on HIVSTKs, and soliciting participant feedback on the MDA process. Below are participant comments and staff observations:

- The meeting participants regard the preliminary meetings to validate the diagnosis as critical because they: (i) brought both public and private actors together, (ii) focused the markets actors on a common task that created a “safe” space for discussions from different perspective, and information share from different sources, (iii) connected private market actors who normally don’t have access to government officials related to their market areas, and (iv) similarly, introduced government officials to their private counterparts.
- Familiarity with the Total Market Approach (TMA) has laid the foundation for the HIVSTK market actors to quickly grasp many of the core concepts of MDA. Indeed, because TMA is based on market principles, like supply and demand and segmenting the market, they were able to easily able to understand and transition to many of the core concepts of MDA – supply and demand, market operations, and market underperformance – because of the familiarity of TMA.
- The market actors value the data generated by and synthesis of the market scoping, legal/regulatory review, and regional benchmarking. They particularly appreciated the fact that the meetings have broken down the silos to information and so now all have the same information when discussing the HIVSTK market.
- Although it was a challenge to get a significant number to participate in the 3rd workshop, many consider the preliminary workshops a necessary condition to form a cohesive group, develop a common understanding of the current picture, and to collect additional data / information to further deepen market scoping analysis.
- Moving forward, the market actors agreed that the work – finalizing the market strategy and designing the implementation plan – can be divided into small groups, conducted in multiple meetings and also using virtual technology. For example, to increase and ensure consistent public sector participation, participants suggested the next big workshop can be held in two locations – one in Dodoma and another in Dar – using technology to integrate the groups. Another suggestion is to hold a workshop in Morogoro – a half-way point between Dodoma and Dar.
- The team (i) developed and tested the facilitation methods and exercises to design the strategic framework for the HIVSTK market for the workshop and (ii) a draft TOC for the HIVSTK market.

About FHM Engage

Frontier Health Markets (FHM) Engage is a five-year cooperative agreement (7200AA21CA00027) funded by the United States Agency for International Development. We work to improve the market environment for greater private sector participation in the delivery of health products and services and to improve equal access to and uptake of high-quality consumer driven health products, services, and information. Chemonics International implements FHM Engage in collaboration with Core Partners: Results for Development (co-technical lead), Pathfinder, and Zenysis. FHM Engage Network Implementation Partners include ACCESS Health India, Africa Christian Health Association Platform, Africa Healthcare Federation, Amref Health Africa, Ariadne Labs, CERRHUD, Insight Health Advisors, Makerere University School of Public Health, Metrics for Management, Solina Group, Strategic Purchasing Africa Resource Center, Scope Impact, Stage Six, Strathmore University, Total Family Health Organization, and Ubora Institute.

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