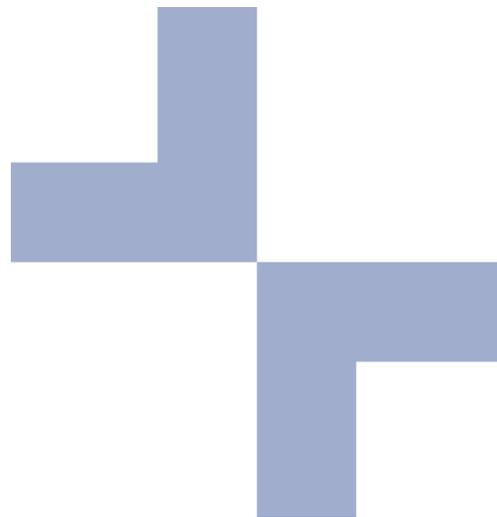




Assessing the Potential for Community Level HIV Self-Testing in Tanzania



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About SHOPS Plus: Sustaining Health Outcomes through the Private Sector (SHOPS) Plus is USAID's flagship initiative in private sector health. The project seeks to harness the full potential of the private sector and catalyze public-private engagement to improve health outcomes in family planning, HIV/AIDS, maternal and child health, and other health areas. SHOPS Plus supports the achievement of US government priorities, including preventing child and maternal deaths, an AIDS-free generation, and supporting the goals of FP2020. The project improves the equity and quality of the total health system, accelerating progress toward universal health coverage.



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Acronyms

ADDO	Accredited Drug Dispensing Outlet
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal care
ART	Antiretroviral therapy
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
FMCG	Fast-moving consumer goods
FP	Family planning
GoT	Government of Tanzania
HIV	Human Immunodeficiency Virus
HIVST	HIV self-testing
HIVSTK	HIVST kits
HTC	HIV testing and counseling
HTS	HIV testing services
KII	Key informant interviews
MOHCDGEC	Ministry of Health, Community Development, Gender, Elderly & Children
NACP	National AIDS Control Program
NHSF	Nyamagana Health Support Foundation
PLHIV	People living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission
PST	Pharmaceutical Society of Tanzania
RDT	Rapid diagnostic test
SHOPS Plus	Sustaining Health Outcomes through the Private Sector Plus
SRA	Stringent regulatory authority
TFDA	Tanzania Food & Drug Authority
THIS	Tanzania HIV Impact Survey
UNAIDS	The Joint United Nations Programme on HIV and AIDS
USAID	United States Agency for International Development
WHO	World Health Organization
WHO-PQ	WHO prequalification
WTP	Willingness to pay

Executive Summary

In Tanzania, nearly 50 percent of people living with HIV/AIDS (PLHIV) ages 15-64 are still undiagnosed and currently unaware of their status, 47 percent are on antiretroviral therapy (ART), and roughly 42 percent are virally suppressed.¹ There is also persisting incidence of new infections and significant gaps in testing and treatment coverage in particular communities, requiring urgent attention if the goal of epidemic control in Tanzania is to be achieved by 2030. Options for HIV self-testing (HIVST) are critical to helping the Government of Tanzania (GoT) and implementing partners achieve these goals.

Existing HIV rapid diagnostic products (intended for use by health professionals in a clinical setting) have been informally available and used by individuals for self-testing in Tanzania and other global settings.² HIVST, as defined in this paper, refers to testing products and technologies specifically designed and marketed for use by lay-consumers outside of a clinical setting. To date only OraQuick (saliva-based antibody sampling) and INSTI (blood-based antibody sampling) have received World Health Organization prequalification (WHO-PQ) status for global use. However, other blood-based products with stringent regulatory authority approvals are expected to receive WHO-PQ in the near future. Recent HIVST guidance from WHO³ highlights various considerations and approaches to HIVST mobilization, testing, and linkages to care, including considering when HIVST is delivered, where it is distributed, who distributes it, and what services and support tools are offered.

As HIVST is an emerging option in Tanzania, stakeholders across the health system are considering how and where to introduce HIVST. There is need for additional information to help guide the appropriate introduction of HIVST as part of a differentiated approach to HIV testing services (HTS). To address this need, SHOPS Plus carried out a technical assessment to explore the policy, commercial, and health system-related issues that support or detract from the feasibility of using Accredited Drug Dispensing Outlets (ADDOs) or other community-level private sector outlets as a potential venue for HIVST retail and distribution. This assessment was done in three phases:

- 1) Key informant interviews at national (Dar es Salaam), regional, and community levels (Mwanza and Mbeya) were carried out from January to June 2018.
- 2) A consumer preferences questionnaire was administered in Dar es Salaam and Mwanza in June and July 2018.
- 3) A multi-stakeholder validation roundtable in Dar es Salaam was hosted in July 2018.

Based on the assessment findings, ADDOs represent a feasible option for introduction of HIVST products, but doing so will require significant advocacy, changes in protocols from the Tanzania Food & Drug Authority (TFDA) and Pharmacy Council, capacity building, and extensive practical and logistical planning for rollout and ongoing regulation. Stakeholders endorsed the following priority actions if HIVST are to be introduced through ADDOs:

¹ https://phia.icap.columbia.edu/wp-content/uploads/2017/11/Tanzania_SummarySheet_A4.English.v19.pdf

² Availability of HIV Rapid Diagnostic Kits Over the Counter, January 2016, https://www.shopsplusproject.org/sites/default/files/resources/Availability%20of%20HIV%20Rapid%20Diagnostic%20Tests%20Over%20the%20Counter_0.pdf

³ <http://apps.who.int/iris/bitstream/handle/10665/275521/9789241514859-eng.pdf?ua=1>

- Ensure ADDO owners and dispensers are trained to appropriately dispense HIVST and inform clients
- Implement a surveillance system to capture service and retail data for HIV services
- Involve ADDO associations or other provider network platforms.

While stakeholders acknowledged that ADDOs could be used as platforms for HIVST retail, Pharmacy Council and other legislator informants mentioned that community pharmacies would initially be a more practical platform in the early stages of national introduction. Stakeholders believed that HIVST products have a long way to go in terms of legislation, product registration, and successful importing before fast-moving consumer goods channels became a possibility.

There are numerous clinical and logistical questions to be answered as mechanisms for HIVST rollout, retail, waste management, reporting, and monitoring are developed. Ongoing planning and dialogue will be critical to expanding opportunities for HIVST in ADDOs, community pharmacies, and other private sector outlets. To support these efforts, stakeholders should prioritize further research to identify and describe approaches for effective HIVST distribution and use.

Background

Effective HTS is an essential gateway to HIV treatment, care, and long-term support services that will advance the national HIV/AIDS response. The 90-90-90 targets outlined by the Joint United Nations Programme on HIV and AIDS (UNAIDS) seek to ensure that by the year 2020, 90 percent of all PLHIV will know their status, 90 percent of those diagnosed will have been initiated on life-saving ART, and 90 percent of people on sustained ART will achieve viral suppression.⁴ In Tanzania, only 52 percent of adults ages 15-64 are diagnosed and aware of their status.⁵ Among diagnosed PLHIV, the national response has been effective in the initiation of treatment, with approximately 91 percent on treatment and 87.7 percent of those on treatment achieving viral suppression.

However, when looking at the total epidemic (diagnosed and undiagnosed PLHIV), nearly 50 percent of PLHIV ages 15-64 remain undiagnosed and unaware of their status, only 47 percent are on ART, and less than 50 percent are virally suppressed. This is more pronounced for men, where only 45 percent of adult men are diagnosed, as compared to 56 percent of women.

Table 1. Tanzania's progress toward 90-90-90

	Age group	% achieved	Male	Female
Diagnosed	15–64 years	52.2	45.3	55.9
Diagnosed: on treatment	15–64 years	90.9	86.1	92.9
On treatment and virally suppressed	15–64 years	87.7	84.0	89.2

Source: Tanzania HIV Impact Survey (THIS) 2016-2017 (Summary Sheet, December 2017)

The 2016–2017 Tanzania HIV Impact Survey (THIS) indicates that the HIV epidemic in Tanzania is stabilizing. However, the incidence of new infections and significant gaps in testing and treatment coverage in target communities persists. The annual incidence of HIV among adults aged 15–64 years in Tanzania is 0.29 percent (0.40% among females and 0.17% among males), which corresponds to an estimated 81,000 new infections per year among this age group. Finding those undiagnosed and those at risk for new infection requires urgent attention if the goal of reaching the epidemic control in Tanzania by 2030 is to be achieved.

The Tanzanian Ministry of Health, Community Development, Gender, Elderly & Children (MOHCDGEC) and their implementing partners have prioritized the pursuit of more effective models of identifying PLHIV who are currently unaware of their status, providing them with diversified testing options and linking them to long-term ART care. Options for HIVST could be effective in helping the GoT achieve these goals.

⁴ <http://www.unaids.org/en/resources/909090>

⁵ https://phia.icap.columbia.edu/wp-content/uploads/2017/11/Tanzania_SummarySheet_A4.English.v19.pdf

HIV self-testing

HIVST, as defined by WHO and UNAIDS, broadly refers to “a process whereby a person who wants to know his or her HIV status collects a specimen, performs a test, and interprets the test result in private.”⁶ These are distinct from mail-in self-testing models of home specimen collection where an individual collects a specimen in private and sends it by post to a laboratory for external processing. According to guidance from WHO and UNAIDS, HIVST-focused testing products should be viewed as a screening tool only, as they do not provide a definitive diagnosis.

An individual who receives a positive HIVST result would be expected to present to a health facility or healthcare worker for further confirmatory testing. Use of the rapid diagnostic test (RDT) for HIV is restricted to healthcare professionals. HIV RDT is not meant to be used for HIV self-testing purposes. Although RDT products have been informally available and used by individuals for self-testing in Tanzania and in other global settings,⁷ HIVST refers to approaches for testing products and technologies specifically designed and marketed for use by lay-consumers.

HIVST products

To date only OraQuick (saliva-based antibody sampling) and INSTI (blood-based antibody sampling) have received WHO-PQ approval for global use. However, several other blood-based, consumer-focused HIVST products are expected to receive WHO-PQ and already have stringent regulatory authority (SRA) approvals including CE markings, a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area, and Global Fund Expert Review Panel approvals. Several of these products, including Biosure (Biosure, UK) and Autotest VIV (AAZ, France), are already sold over the counter in France, the United Kingdom, and South Africa. Other companies with products in development include Atomo Diagnostics and Chembio.

Global Efforts for HIVST

In response to HIVST recommendations from UNAIDS and WHO, several studies and pilot projects have been conducted in high and low-HIV prevalence settings to test acceptability, models of delivery, and preferences for HIVST among key populations. Early findings revealed the following:

- In Kenya, a study of truck drivers concluded that oral HIVST options were acceptable and can be administered independently and correctly, especially if the opportunity to ask questions was provided prior to self-testing (Herald and Brown 2016).
- A scoping study on acceptability of HIVST in Sub-Saharan Africa reported that the various benefits of HIVST include increased confidentiality and privacy, decreased burden on the healthcare system, decreased coercive testing by healthcare workers, and decreased stigma and discrimination associated with HTS (Harichund & Mosabela 2017).
- In Nigeria, a study using OraQuick showed that HIVST was deemed highly acceptable by users, and linkage to HIV treatment can be achieved with active follow-up and by promoting access to health facilities

⁶ http://www.who.int/hiv/pub/vct/self_test_tech_update/en/

⁷ Availability of HIV Rapid Diagnostic Kits Over the Counter, January 2016

SHOPS Plus Feasibility Assessment

Current literature provides some insight into the HIV context for Tanzania and the HIVST concept. Yet, it was essential to engage relevant stakeholders to assess their take on the feasibility of HIVST in retail outlets, such as ADDOs; some stakeholders have a role in policy development and influence policy implementation.

ADDOs, also known as duka la dawa baridi in Swahili, are small, retail pharmacy outlets located in peri-urban and rural areas of Tanzania that sell health commodities and essential medicines. These outlets are often located in remote areas where access to health facilities and community pharmacies is scarce. Ninety-five percent of Tanzania's population lives within five kilometers of an ADDO.⁸ Because of these factors, ADDOs are often seen as an ideal platform for scaling up public health campaigns and new innovations such as HIVST. Currently, the ADDO schedule of medicines does not include any HIV commodities. ADDO dispensers are typically required to have a basic medical or nursing background. In theory, a dispenser should be able to provide guidance and information to clients who are purchasing rapid tests for malaria, HIV, and other diseases. ADDOs can also be used as first points of diagnosis and immediate referral, strengthening linkage to health care facilities for any necessary treatment.

Methods and Key Informants

Key informant interviews (KIIs) at national, regional, and community levels. From January to June 2018, the project team carried out KIIs with the National AIDS Control Program (NACP), TFDA, Pharmacy Council, and the Private Health Laboratories Board. This was followed by ADDO-level interviews in Mwanza (20) and Mbeya (10). These regions were selected based on factors including HIV prevalence in the regions and presence of ADDOs and well established ADDO Associations. Respondents included both individual ADDOs and of the management teams of ADDO Associations. The focus of the interviews differed based on the interviewee, i.e., at the National Level, the focus was on policy making and high level opinions on implementation; at the ADDO Association managerial level, the focus was on regional representation of ADDOs; and at the individual ADDO level, the focus was on community-level implementation. The KIIs included questions regarding the feasibility, demand, and potential models of delivering any HIVST products via ADDOs or other community-based commercial outlets.

Consumer preferences questionnaire. In June and July 2018, 150 potential consumers of HIVST were interviewed by data collectors from the Pharmaceutical Society of Tanzania, supported by SHOPS Plus. Consumers responded to a rapid consumer preferences survey in Mwanza and Dar es Salaam to help gauge their general knowledge, interest, and ideas about HIVST products. Survey participants included university students, ADDO clients, private health laboratory clients, pharmacy clients, men employed as fisherfolk, and those working in the community transport industry, including bodaboda (motorcycle) and daladala (bus) drivers. These participants were selected based on the focus on retail outlets such as ADDOs, community pharmacies, and private health laboratories along with a focus on men and students that are identified as high-risk populations for HIV.

Multi-stakeholder validation roundtable. In July 2018, SHOPS Plus hosted a multi-stakeholder validation meeting to present results of the KIIs and consumer questionnaire and

⁸ <http://www.drugsellerinitiatives.org/publication/altview/tanzaniapresentations/ADDO%20Model%20in%20Tanzania/>

gain insight on next steps and priority issues around HIVST in ADDOs and other community-level outlets, using information gained from key informant interviews and initial findings from the consumer preferences survey.

Assessment Findings

Status of HIVST in Tanzania (2018)

The GoT has prioritized combination testing strategies that reach priority and key populations currently being missed by conventional testing strategies. Hence, HIVST remains an emerging option in Tanzania. Given that national HTS efforts are hampered by a lack of qualified personnel in health facilities,⁹ fear of stigma associated with testing in health facilities,¹⁰ and lack of facilities in the healthcare system with adequate privacy for patient-health worker interactions,¹¹ HIVST could prove a powerful addition to the national HIV/AIDS response. However, stakeholders in Tanzania need additional information to help guide the appropriate introduction of HIVST as part of a differentiated approach to HTS.¹²

Policy Environment

HTS in Tanzania are guided by the *National Comprehensive Guidelines for HIV Testing & Counseling (2017)*¹³, which are based on relevant national and international WHO recommendations for best-practice HTS. These national guidelines mention the potential benefits of self-testing and acknowledge current global advances in HIVST technologies. However, Tanzania's current guidelines state that "Tanzania does not permit HIV self-testing" and emphasizes that the use of existing HIV RDT test kits in both public and private settings "shall not be used for this (self-testing) purpose." As highlighted in the text box, specific sections of Tanzania's existing HIV testing and counseling (HTC) guidelines restrict the use of HIV RDTs to healthcare workers or those holding a certificate of competence.

In late 2017 and early 2018, discussions related to the registration, import, and distribution of HIVST commodities began to receive increased attention from Tanzania's Parliament, the MOHCDGEC and the National AIDS Control Program (NACP). This positive momentum for HIVST resulted in two key developments in 2018: 1) the advancement of NACP/donor implemented HIVST pilot projects and 2) the GoT's creation of an updated HIV Act that includes reference to HIV self-testing permissions. The Act was expected to be tabled in Parliament in November 2018, but recent

Relevant Sections of Tanzania's National Comprehensive Guidelines for HIV Testing & Counseling (February 2013)

Section 7.3 Ethical Standards: "When a decision to introduce non health professionals in the delivery of HTC services is made, the MOHSW shall formulate a code of conduct to regulate the conduct and performance of these non-health cadres"

Section 8.1 Quality Assurance for HIV Testing: "Persons performing HIV tests must complete rapid test training, including a practical component and must be awarded a certificate of competence"

⁹https://www.researchgate.net/publication/301315243_Barriers_to_accessibility_and_utilization_of_HIV_testing_and_counseling_services_in_Tanzania_Experience_from_Angaza_Zaidi_programme

¹⁰ <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0201644>

¹¹ <https://www.pepfar.gov/documents/organization/285852.pdf>

¹² <http://apps.who.int/iris/bitstream/handle/10665/275521/9789241514859-eng.pdf?ua=1>

¹³ www.nacp.go.tz/site/download/NATIONAL_DECEMBER_2017.pdf

reports indicate that this has been pushed to parliamentary sessions scheduled June 2019.

Status of HIVST pilot testing, 2018

As of December 2018, there were two United States Agency for International Development (USAID)-funded HIVST pilot projects approved by NACP underway in Tanzania. NACP is leading an eighteen-month pilot, with ICAP, the HIV implementing partner at the Columbia University Mailman School of Public Health) and Jhpeigo that is focused on the distribution of 56,000 OraQuick self-tests to key populations in 14 regions across the country. This study

focuses on free distribution of the test via an index client approach. Individual patients presenting for an HIV test at a facility are instead provided with three OraQuick tests (one for themselves, one for their immediate sexual partner, and one for a peer) for independent testing in private. The clients are encouraged to self-report by voluntarily returning to the site where they obtained the test, reporting through an SMS system or a phone call, or going to an HTS or care and treatment clinic, if they need a confirmatory test. The tests are tracked through unique identifying numbers so that test result reporting, confirmation, and linkage to treatment can be monitored.

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) conducted an HIVST feasibility assessment for antenatal care (ANC) and prevention of mother to child transmission (PMTCT) clients as part of the John Snow International-led global AIDSFree project. The overall aim of this study was to generate evidence on demand and willingness to pay (WTP) for HIVST among pregnant women presenting for facility-based ANC care in the private health sector.

In October, 2018 EGPAF reported out on the main conclusions of the study:

- The study reported generally favorable views toward HIVST among all (ANC/PMTCT) respondents.
- GoT is very committed to establishing access to HIVST kits in the country and working at high policy levels on this initiative.
- There is broad agreement that before HIVST can be scaled, consensus must be reached on design and the systems to support rollout and ensure customers receive access to counseling support, confirmation of result, linkage to care if positive, and documentation of self-test kit use.
- Pharmacies will play a key role in HIV self-test kit access. There is need to engage pharmacists to follow systems/guidance.

HIVST products available in Tanzania

Given that existing national policy has restricted the rollout of HIVST, mainly to reduce the illicit use of current HIV-RDT technologies for self-testing purposes, there are currently no consumer-focused HIVST products registered for national import and distribution by the TFDA. However, as of May 2018, a local importer and distributor, SCIEX Tanzania, had received a limited-scope

HIV Act

Discussions regarding the change in laws that will allow HIV self-testing in Tanzania are currently ongoing. It is anticipated that this law will be voted on during the June 2019 parliamentary session.

Following the passing of this law, various agencies such as TFDA, PC, and the NACP would be able to develop policies for HIV self-testing, including guidance on the registration and distribution of HIV self-testing commodities.

importation permit from the TFDA to import OraQuick HIVST kits (HIVSTK) specifically for the NACP, ICAP and Jhpiego-led pilots. The permit was based on the protocol developed among the partners and the NACP. SCIEX Tanzania is currently the sole distributor of OraQuick in Tanzania; however, they are not currently registering OraQuick due to the country's current laws that prohibit HIV self-testing. Once the HIV Act and other key laws are ratified in 2019, importers and wholesalers like SCIEX have indicated interest in the commercial distribution of OraQuick and mentioned a potential retail price of USD \$7. At the time of this report, there were no TFDA registration processes underway for blood-based HIVST products.

Free versus commercial distribution approaches

Historically, HIV commodities, tests, and services have been provided free of charge in Tanzania through the financial support provided by various international donors and the GoT. Findings from TFDA, MOHCDGEC and key informant interviews (KIIs) suggest that HIVSTK (at least OraQuick) will also be provided free of charge through pilots and early service delivery efforts carried out by NACP and their IPs in the future. In addition to any free distribution that occurs through programmatic channels, informants interviewed during this assessment also highlighted the need to promote cost-sharing and cost-recovery models of HIVST distribution that include open access and non-restricted options for distribution in commercial retail settings, such as pharmacies and potentially ADDOs. These commercial retail options are being promoted in order to encourage a sustainable total market approach for HIVSTK, where products are available from the outset that are not reliant on long-term donor support or subsidy.

ADDOs as a potential venue for HIVST distribution

The TFDA regulates the schedule of health commodities and pharmaceuticals that ADDOs are allowed to procure, stock, and dispense. This schedule does not currently include any HIV-related commodities, and interviews with ADDOs in Mwanza, Mbeya and Dar es Salaam districts confirmed that there are no ADDOs stocking HIV RDTs, HIVST products, or any other HIV related commodities. However, ADDO personnel are interested in providing HIV services, as this would add a revenue stream for them and allow them to provide a wider range of services to the communities they work in.

Perspectives from National and District Stakeholders

Public Authorities

The Pharmacy Council is responsible for overseeing ADDOs and other community level retail pharmacy outlets. This oversight function includes ensuring that ADDO facilities are well maintained, and they conduct regular inspections of the premises, practice, and professionals operating at the outlet. Pharmacy Council representatives, including the ADDO Program Coordinator and the Head of the Pharmacy Practice and Inspection Department, stated that, assuming all requisite registration and importation requirements have been secured, ADDOs would be a valuable platform for ensuring HIVST availability at the community level.

However, citing limited regulatory capacity and varying degrees of ADDO dispenser qualifications, Pharmacy Council leadership believed that the personnel in ADDOs may not be appropriately-positioned to introduce HIV testing or other HIV services. The current ADDO dispensers training, while touching on various pharmaceutical aspects, does not provide adequate education on HIV-related counseling or referrals, both essential for the dispensing of any HIV-related commodities. The Pharmacy Council believes that further training would be

needed to prepare ADDO dispensers for pre-test counselling and other HIVST-related tasks, including dispensing, monitoring, and reporting.

The TFDA is responsible for managing the schedule of medications that ADDOs and other community pharmacy outlets are allowed to store and dispense. At TFDA we spoke with Drug Registration Officers who were interested in the idea of HIV self-testing. There are currently no HIV provisions on the present schedule of medications for ADDOs, including any HIV RDT or HIVST product allowances. TFDA leadership stated that although ADDO involvement in HIV commodity distribution was conceivable, the TFDA has concerns about effective pharmacovigilance of HIV commodities in ADDOs and in particular the appropriate reporting and monitoring of HIV commodity distribution since no such system is currently in place in ADDOs.

As an agency of the MOHCDGEC, the NACP is mandated to coordinate all activities related to the HIV/AIDS response in Tanzania. During an interview with the project, the NACP Supply Chain Officer for HIV commodities and the HIV Testing Services Coordinator stated they were supportive of the idea of HIVST in Tanzania. They offered that the introduction of HIVST is essential to improving the country's HIV testing performance and that current pilot studies are meant to inform stakeholders about implementation of HIV Self-Testing in country before decisions on approach and scale are made. However, they shared concerns raised by other national stakeholders related to ADDO dispenser preparedness to engage in HIV related commodity distribution or services. Specifically, there is concern that ADDO personnel lack the requisite knowledge to provide HIVST consumers with correct HIV information, deliver appropriate pre-test instruction or counselling, or give post-test referral options. They granted that this knowledge gap could be filled through targeted training. This approach would require a significant investment to arm ADDO dispensers with appropriate HIVST knowledge. NACP representatives interviewed as part of this assessment clarified that their preference is the introduction of oral-based HIVST technologies, given concerns voiced within the MOHCDGEC regarding the safe disposal of blood-based tests and infection control risks. They emphasized that any HIVST distribution, commercial or otherwise, would follow parliamentary guidance on HIVST and application of home-based screening products in the country.

Key takeaways from public authorities

ADDOs currently do not have the training or appropriate systems in place to effectively administer counseling, which is a critical requirement

Of critical importance is determining the qualification process for ADDOs or other community outlets to dispense HIVST (and other HIV related) commodities.

Pharmacovigilance of HIVST products and supervision of ADDOs selling them will be a key challenge at community level

The MOH and NACP want more information on consumer demand and willingness to pay

ADDO managers and dispensing personnel

SHOPS Plus interviewed both ADDO owners, those who legally own and manage the financial aspects of the day-to-day working operations of ADDOs, and ADDO dispensers, who are trained and certified by Pharmacy Council to dispense products in ADDOs. Currently the ADDO

dispenser training treats HIV from an educational point of view and has no details about aspects such as dispensing, reporting, monitoring, or referrals. Both groups felt that ADDOs could and should take a stronger role in HIV service delivery because they are embedded in their communities, deemed trustworthy, and considered where people first seek care. ADDO dispensers expressed willingness to learn about HIV care and motivation to

provide these services to their existing clientele. However, several ADDO owners and dispensers expressed that without the requisite training and improved regulatory support, they would lack confidence to dispense HIV commodities.

Potential Consumers Interviewed by SHOPS Plus

- 30 employed men: fisherfolk (10), bodaboda (10) and daladala drivers (10)
- 20 clients exiting private laboratories
- 20 clients exiting private pharmacies
- 28 clients exiting ADDOs
- 52 university students

Key takeaways from ADDO managers and personnel

ADDO dispensers expressed a willingness to engage in HIV care (including HIVST)

Lack of HIV knowledge and confidence among many ADDO dispensers would require additional training and regulation

ADDOs may be able to extend retail HIVST to lower-income communities if the price point is affordable

Nyamagana Health Support Foundation ADDO Association

SHOPS Plus interviewed representatives from the Nyamagana district ADDO association, the Nyamagana Health Support Foundation (NHSF), in order to ascertain the association's opinion on the feasibility of HIV-related services and commodities in ADDOs. Formed in 2017, the association brings together all registered ADDOs in Nyamagana district under one banner, which then represents Nyamagana ADDOs during discussions with regulatory bodies such as the Pharmacy Council and TFDA. The association also established mechanisms for peer regulation, member access to finance, and discounted pooled procurement of commodities through wholesalers.

Representatives of the association felt that ADDO involvement in HIVST would depend on the commodities being classified for commercial distribution, which would allow ADDOs to procure and sell them at retail prices. They were not interested in involving ADDOs in free distribution. The NHSF representatives felt that including HIVST commodities on the schedule of approved medications for ADDOs and establishing a price-point for HIVST in ADDOs, would likely prove significantly challenging given that there is no existing process for ADDOs to access or deliver any HIV commodities. In terms of price-point, NHSF representatives highlighted that ADDOs typically cater to a low-income market where product affordability may be a challenge.

ADDOs procure all of their pharmaceutical, medical, and over-the-counter commodities from commercial pharmaceutical wholesalers, such as Jeet Pharmacy and SAG Pharmacy. Currently, ADDOs do not have any access to the national Medical Stores Department supply chain. Given the current legislative and supply chain challenges, if ADDOs were to sell HIVST products, the commodities would need to be available for wholesale purchase at commercial

pharmaceutical wholesalers. According to the schedule of medicines and its governance, ADDOs are not allowed to dispense any HIV related commodities. In addition, they are unable to access any HIV-related commodities from the national supply chain or commercially. The ADDO association relayed that if HIVST commodities were made available via commercial wholesale channels, ADDOs would be well placed to access HIVST commercially and ideally at reduced cost via high volume pooled procurement options.

The “Word on the Street”: Assessing Potential HIVST Consumers Preferences

SHOPS Plus, in collaboration with the Pharmaceutical Society of Tanzania (PST), conducted a consumer perceptions assessment using a semi-structured questionnaire in order to gain insights on community knowledge of and potential preferences for HIVST products. The project conducted face-to-face interviews with 150 people identified by convenience sampling at various private sector or community-based outlets in Dar es Salaam and Mwanza.

The SHOPS Plus consumer survey provided a snapshot of potential consumer perspectives to inform programmatic activities. It should not be interpreted as representative of the opinions of the general population. To ensure complete confidentiality of the survey, no identifying information was collected, e.g., gender, age, and socioeconomic status. It was therefore not possible to analyze consumer demographic information.

The survey questionnaire explored several topics related to HIVST products and services, including where consumers might buy an HIVST, if they prefer a blood-based or oral product, what type of pre-test and post-test instruction they would require or prefer, the price point they might find reasonable for an HIVST product, and what they would do post-test with either a negative or positive result. Although questions about price points were included to get a sense of what consumers might expect to pay, the methodology and design do not satisfy the requirements of a willingness to pay study and should not be interpreted as such.

The SHOPS Plus rapid survey targeted consumers at community outlets, therefore the data do not likely represent higher wealth quantile populations. SHOPS Plus considered each of the groups above to be informed proxies but not wholly representative of potential consumers of HIVST products. Emerging themes and potential preferences are outlined below:

Current HIV testing behavior

Of the 150 potential HIVST consumers interviewed by SHOPS Plus, the majority stated that if they were to seek out an HIV test, they would go to a health facility or hospital (69%). Among those who responded, 47 percent (n=65) stated that they knew where they could currently buy an HIV test, which could include laboratory-based serology, or an HIV-RDT in a health facility or commercial setting. Of note, 46 percent (n=69) respondents stated that they currently know of a place to test themselves in private. This was most pronounced among private laboratory and pharmacy clients.

Desire to test in private

Given that many consumers in Tanzania are unaware that HIVST products exist, potential consumers were asked about their desire to test for HIV in private, where they would prefer to purchase such a product, general ideas around oral- or blood-based products, potential cost

and format of purchase. Most respondents (77%, n=115) stated they would test themselves for HIV, if possible to do so in private (any private setting). Given reasons included that they would be the first to know their HIV status, to ensure confidentiality of testing and the result, and the ability to be alone while conducting the test. Those who did not want to test themselves in private were primarily concerned about their ability to administer and/or interpret the test accurately while alone.

Preferences for blood-based or oral-based HIVST products

Potential HIVST consumers, in line with HIVST users in other countries, demonstrated a preference for a blood-based HIVST testing method. Seventy percent (70.7%, n=106) said they would prefer a blood-based finger-prick test as opposed to an oral test involving a cheek swab. When asked why they might prefer one method over the other, potential consumers stated that a blood-based method aligned with their understanding that HIV is found in the blood, that it would be easy to interpret, and they felt it would be accurate.

Several respondents stated that they were confused about how a cheek swab would be administered or interpreted, and several stated that they were surprised oral methods could test for HIV since health messaging has been that HIV is not found in saliva. Among respondents who would prefer an oral self-testing method, 29.3 percent stated that they perceived it would be less painful than a test involving a finger prick.

Preferences for purchasing HIVST products

When asked where they might prefer to purchase a self-testing product for HIV testing, the most preferred location across all groups was a community pharmacy (63%). Bodaboda drivers and private laboratory clients also mentioned health centers as a potential preferred source. Respondents offered ease of access and perceived lower cost of product as primary reasons for these stated preferences. Interestingly, only 21 percent of respondents across all groups specifically mentioned an ADDO.

Reasonable price points for HIVST products

Respondents were asked what they thought would be an appropriate price point for an HIVST product in order to roughly gauge acceptable retail price points. Note that this did not involve a rigorous measurement of willingness to pay. Of the 150 potential consumers surveyed, 91 percent (n=137) said they would be willing to pay for an HIVST. The suggested cost ranged widely from 100 Tanzanian shillings (TSh) (USD \$0.43) to 50,000 TSh (+/-USD\$21.88). The average accepted price in all groups was TSh 2,852 (+/- USD \$1.25), the highest average amount being TSh 4,700 (+/-USD \$2.06) among bodaboda drivers, and lowest average amount TSh 1,470 (+/-USD \$0.46) among fisherfolk.

It must be noted that SHOPS Plus did not explore or analyze further willingness to pay. Therefore, the comments above should be interpreted as demonstrating a general desired retail price point among respondents and not a reliable or valid indication of WTP at various price-points. Further research more rigorously measuring consumers WTP for various HIVST products is critical for formulating competitive product pricing strategies necessary for commercial distribution.

Support during the testing process

SHOPS Plus asked respondents questions about their potential behaviors, concerns, and actions during a hypothetical self-testing process. All respondents mentioned that they would want some form of pre-test counselling.

Respondents were asked if they would prefer to receive pre-test instructions from a person, or in written and/or pictorial form, and 50 percent said they would prefer written instructions with pictures, 38 percent personal instruction, six percent written instruction only, and 2.7 percent pictures only. When asked about what other pre-test support would be desirable, 63 percent stated they would like access to a phone hotline or SMS system for pre-test instruction, and 25 percent said they would like online or web-based options for pre-test instruction.

Appeal of HIVST

When asked what the best part of HIVST would be, roughly one-third of respondents were attracted to the assurance that their confidentiality would be maintained. However, when asked what would be most difficult about testing in private, 94 percent stated that they had concerns over correctly administering the test or successfully interpreting the result. Twenty-two percent of respondents stated that they were concerned over the possible psychological impact of learning their result while alone. Many respondents said they would visit a health facility or hospital if they had difficulty administering the test or interpreting the result. Other locations where they might seek assistance included community pharmacies (7%) and laboratories (5%) or ADDOs (5%). In addition, five percent said they would go online for help administering or interpreting the test.

Testing behaviors and linking to care

When asked what they would do if they tested negative, 70 percent said their first step would be to dispose of the HIVST product, and five percent said they would show it to a friend, relative, or other person as proof of status. Additionally, respondents said that if they tested negative, 56 percent would test again after three months, 11 percent said they would test regularly or after engaging in unsafe behavior, and 2.7 percent said they would never test again.

When asked what they would do with the HIVST product if they tested positive, 40.7 percent said they would throw the HIVST product away (anywhere), and 14 percent said they would keep the test and results private and not disclose their status. Respondents were further asked if, after hypothetically self-testing positive, they would present to a health facility for confirmation or treatment. Sixty percent (n=88) said they would seek care or confirmation from a health facility or laboratory after a positive result. Among respondents who would seek care, 57 percent of those respondents said they would prefer a public source of care, 29 percent preferred a private source, and 11 percent a non-governmental organization source.

Consumer perception on HIVST in ADDOs

SHOPS Plus asked respondents questions about their knowledge of ADDOs and preferences for product purchase at these locations. Ninety-two percent (n=133) said they were aware of an ADDO in their area, but only 85 out of 133 respondents said they felt ADDOs would be a good source to purchase an HIVST product. Among those who said an ADDO would be a good source, ease of access and expected lower cost were the predominant reasons. Of note, eight percent (n=12) felt that ADDOs would not be a good source to purchase an HIVST product, citing concerns over less capable ADDO staff.

Key takeaways from potential consumers

- Majority of consumers surveyed stated they would like to test themselves in private for HIV
- HIVST is perceived to offer confidentiality and control over learning one's status
- Potential consumers appear to prefer blood-based products over oral products
- Almost all potential consumers stated they would want some form of pre-test instruction (either in person, written/pictorial, or virtual)

Findings from the SHOPS Plus multi-stakeholder validation meeting

In August 2018, SHOPS Plus conducted a multi-stakeholder¹⁴ validation roundtable in Dar es Salaam to validate findings from the stakeholder interviews and potential consumer survey. This discussion was attended by a wide array of public and private stakeholders involved in some aspect of HIVST advancement in Tanzania. SHOPS Plus held a brief presentation highlighting key findings as outlined above and then opened the floor for stakeholder dialogue. Issues discussed included HIVST introduction in Tanzania, specific issues related to oral- or blood-based products, considerations for retail or commercial approaches, and programming considerations for last-mile introduction via ADDOs. Highlights included:

There is considerable political will within Parliament and the MOHCDGEC to advance HIVST options throughout Tanzania. It is expected that the new HIV Act (likely June 2019) will reverse the broad prohibition on HIVST, although it is unclear how long it will take for ratification and enactment and what the specific language will reference. It is anticipated that when the policy change takes effect, the MOHCDGEC, TFDA, Pharmacy Council and other regulators will advance additional standard operating procedures (SOPs), guidelines, or protocols related to specific HIVST products, methods, and associated subsidized or retail introduction.

¹⁴ Attendees included the Ministry of Health, Community Development, Gender, Elderly & Children (MOHCDGC), USAID/Tanzania Health Promotion Unit, PEPFAR, Tanzania Commission for AIDS (TACAIDS), Pharmaceutical Society of Tanzania (PST), Population Services International (PSI), ICAP, EGPAF, Results for Development, Lancet Laboratories, Medical Laboratory Scientists Association of Tanzania (MeLSAT), the Christian Social Services Commission (CSSC), Henry Jackson Foundation, Medical Research International, T-Marc, Global Health Supply Chain-TA Tanzania, Samiro Pharmacy Bahari Pharmacy, Tanzania Association of Pharmaceutical Industry.

There is support for both oral and blood-based HIVST products, but all new products will need to address several legislative and MOHCDGEC protocol considerations. In the recent past, there has been a preference among the MOHCDGEC and GoT for oral HIVST products, probably due to the fact that OraQuick was the only product with WHO-PQ status. Government respondents stated that this preference is also due to the perceived ease of waste management of oral tests in comparison to blood-based tests. It was further clarified that, in principle, government officials have no specific resistance to registering and introducing a blood-based HIVST product, however, any blood-based product seeking registration would need to take the following into consideration:

- Any new HIVST product would need to be registered by the TFDA and adhere to any additional MOHCDGEC protocols regulating medical consumables and equipment.
- Any new oral or blood-based HIVST product designed for broad distribution for private, at-home use would need to be registered by the TFDA as a screening product.
- Any diagnostic self-test (oral or blood-based) would need to adhere to all relevant infection control, waste management, or other existing protocols as deemed relevant by TFDA, MOHCDGEC, and other authorities. This requires attention when considering possible donor or commercial rollout efforts.

Stakeholders agreed that there is a perceived demand for HIVST in Tanzania. However, they cited challenges access and uptake, including affordability and persisting HIV stigma.

Marketing of HIVST as screening products is a critical issue. The stakeholders emphasized that as HIVST products are introduced, they must be marketed properly as a screening tool rather than a definitive test. Whether promoted through donor-funded projects or commercial channels, marketing should promote reporting results and effective linkage to care from the outset.

Stakeholders agreed that effective systems must be in place for counselling and instruction through the pre-test, test application, interpretation, and post-test processes. Several stakeholders felt that pre-test counselling was a prerequisite to the introduction of HIVST. The consumer survey demonstrated that among the 150 potential consumers interviewed, there were many questions related to how the test product functions, how to administer and interpret the test, how to safely dispose of it, and how to handle the result, positive or negative. Stakeholders agreed that numerous resources, including written and pictorial instructions, websites, hotlines, or other support, would need to be established or strengthened to support users during the testing process.

Safe disposal and waste management was also mentioned as a critical issue, especially when considering blood-based products. MOHCDGEC representatives stated that until a blood-based HIVST product is introduced and registered by TFDA, it will be hard to determine specific rollout barriers. At a minimum, a blood-based product may likely have to adhere to additional MOHCDGEC infection control and waste management protocols that OraQuick and other oral products would not. Stakeholders suggested that bins could be installed in health facilities or other approved settings where users could safely dispose of HIVST products. As products are introduced by manufacturers and the TFDA, MOHCDGEC legislators and stakeholders would determine relevant protocol adherence.

Encouraging users to report their results (positive or negative) was cited as a potential challenge. Representatives from organizations participating in the ongoing HIVST pilot highlighted the initial observations that HIVST users are rarely reporting either negative or

positive results, and that although positive testers are being successfully connected to care, tracking HIVST users has required significant program investment. Government agencies present were also concerned that if HIVST was made broadly available, there would be significant challenges tracking results as part of the national response and programmatic decision-making. Stakeholders highlighted that there have been discussions regarding financially incentivizing HIVST users to report their results.

Effective post-test linkage is of critical importance to the NACP. All stakeholders agreed that if HIVST approaches are to be effective, there must be a clear and strong pathway to care for those who test positive. The role of technology was highlighted in facilitating HIVST users to self-report their results and/or present to a health center if testing positive. Mobile applications, online submission of anonymous results, and other platforms were mentioned. However, it was also acknowledged that those using HIVST products and already avoiding health centers may not choose to self-report (requiring some form of incentive), and caution should be used when discussing issues of reporting and identification in the case of key or vulnerable populations.

ADDOs are a feasible location for introduction of HIVST products, but significant changes to protocols and medicine schedules will be required to use this platform. ADDOs could serve as a powerful community-based outlet for HIVST products. However, stakeholders agreed that (as with malaria rapid tests and family planning (FP) commodities) there are concerns about increased responsibilities for ADDOs and their capacity to take on additional roles in health service provision or retail. Several private sector stakeholders felt that ADDOs and ADDO dispensers could handle additional HIV and HIVST responsibilities, but supplementary training and capacity development would be necessary.

Affordability and price-point of HIVST products will be central to determining success and uptake. Stakeholders agreed that a mixed-market is envisioned for OraQuick in Tanzania given the commitments already made to donor subsidies and the government's intentions to pursue free-to-client OraQuick distribution models through the public sector and via IPs. Although there is no envisioned prohibition on retailing OraQuick, the presence of the same commodity for free will make the proposed retail price of OraQuick a central issue. As blood-based products are introduced that are not being subsidized or heavily used by the government in free-to-client models, there will be options for broader retail in ADDOs, pharmacy outlets, and through Fast-Moving Consumer Goods (FMCG) outlets.

Private sector pharmaceutical importers envisioned quantification challenges with OraQuick. Given the expected mixed-market for OraQuick, pharmaceutical importers stated that quantification challenges may dissuade some importers from pursuing OraQuick and that establishing effective price-points may prove a challenge for private sector retailers.

Discussion

This assessment compiled a broad range of perspectives, preferences, and considerations from a wide array of legislators, regulators, program implementers, private sector importers, and potential consumers to assess the feasibility of introducing HIVST products in Tanzania.

Overall, our findings demonstrate that:

- There appears to be significant interest in direct-to-consumer retail of HIVST products in

Tanzania among potential consumers, government stakeholders, and program IPs interviewed by SHOPS Plus.

- Potential consumers indicated there may already be some self-testing behavior occurring with HIV-RDTs, though this has not been quantified or confirmed as part of this assessment.
- There is strong preference for a blood-based HIVST sampling product. However, for regulatory and technical reasons (i.e. waste management and product disposal, invasive procedure legislation, and adherence to relevant clinical protocols) there is a current preference among MOHCDGEC and IPs for an oral sampling product. There is a significant need for patient education related to confusion over the transmission of HIV via saliva, as OraQuick or other oral-based testing methods.
- There appears to be willingness to pay for an HIVST products among those surveyed as part of this assessment. However, more discussion is needed to match price-point, affordability, and WTP among various groups.
- Potential consumers' responses indicate that a wide-array of instructional and counselling resources will be required to support HIVST users for pre-test preparation, administration and interpretation, and appropriate post-test actions. Product inserts, online, and telephone-based resources will be influential in this regard.
- Users will need to be encouraged and incentivized to report their negative and positive results. Significant discussion is required regarding methods to promote and monitor post-test linkage to care. Although more than 50 percent of potential consumers interviewed said they would present to a health-facility with a positive result, practical experience from existing pilot projects suggests otherwise.
- Regardless of the mode of distribution, an effective monitoring and evaluation system will need to be established to monitor the supply, usage, and effectiveness of HIVST products.
- Several potential consumers said they would test regularly at three months or with unsafe behavior, suggesting that three-month retesting protocols are being effectively communicated to potential HIV testers and that many HIVST users may become regular/repeat users if testing negative.
- Significant public education is needed during marketing and introduction of HIVST products so that users know it is only a screening tool, and that they should present to a health facility for confirmatory testing if the self-test result is positive. By making this clear in promotions and rollout clients may be more inclined to report their results.
- A significant portion of potential consumers reported that they would be likely to throw the test away after using it. While this may be of less concern with oral-based products, this may pose additional concerns when considering blood-based products. SHOPS Plus received responses that HIVST products might be thrown in the toilet, burned, or thrown in the woods suggesting that patient education regarding safe disposal is required.

Assessing the feasibility of introducing HIVST in various community private sector outlets

What is the feasibility of introducing HIVST products in ADDOs?

Based on our combined assessment findings, ADDOs are a feasible option for introduction of HIVST products but doing so will require significant advocacy, protocol changes at TFDA and Pharmacy Council, ADDO education and capacity development, and extensive practical and logistic planning for rollout and ongoing regulation.

Overall national stakeholders, TFDA, ADDO management, and consumers felt that HIVST products would be a positive move forward and would support the increase of testing in Tanzania. They felt that HIVST could help address stigma-related causes of HIV testing avoidance by allowing individuals to test in private. Additionally HIVST would result in cost savings by reducing reliance on facility-based services and would promote routine and regular testing among those interested in the product.

However, ensuring ADDOs were trained to appropriately dispense HIVST and inform clients, implementing a surveillance system to capture service and retail data for HIV services, and appropriately involving ADDO associations or other community provider networks will all be critical priorities.

Are community pharmacy settings preferable?

The Pharmacy Council and other legislator informants believe that HIVST retail through community pharmacies would be more practical and comfortable for stakeholders in the early stages of national introduction. Reasons for this included:

- Pharmacy Council informants felt that community pharmacies had better capacity to offer HIVST and other more complex services than the average ADDO outlet.
- Community pharmacies require the presence of a registered pharmacist operating as superintendent of the pharmacy. Registered pharmacists in Tanzania are required to spend time at a community-based therapeutic care facility during their training, and as a result they are usually well versed with basic HIV information and case management. ADDO owners or dispensers are simply required to undergo a focused training overseen by the Pharmacy Council which currently does not include HIV or extended health care training.
- Community pharmacies are generally located in urban areas where clients are more likely to have the ability to pay for HIVST products and are expected to be better informed and able to understand instructions to administer HIVST products.
- Although both community pharmacies and ADDOs are regulated, TFDA has afforded community pharmacies a much broader schedule of medicines and products than ADDOs. Community pharmacies are already involved in HIV-related dispensing (of rapid test kits and ARVs) as well, which would make HIVST introduction much more expedient.
- Stakeholders felt that the kind of support required for clients during the pre-test or post-test period would be easier if delivered via community pharmacies.

Alternative channels

During the SHOPS Plus validation meeting several stakeholders with experience marketing condoms in Tanzania highlighted that in the case of basic and premium condom distribution only about 30 percent was through pharmaceutical channels, with well up to 70 percent of retail sales accounted for in FMCG channels. Stakeholders felt that HIVST products had a long way to go in terms of legislation, product registration, and successful import before FMCG channels became a possibility. However, HIVST products could be retailed in FMCG outlets such as supermarkets or bars/nightclubs in the future if (a) legislation allowed it, (b) HIVSTK came with clear packaging and instruction, (c) hotline or online instruction resources were included, and (d) the appropriate post-test reporting and linkage to care considerations were in place.

Conclusion

As the legislative and clinical protocols for HIVST continue to develop in Tanzania, it is important that public-private dialogue continues between the NACP, Pharmacy Council, TFDA, USAID and other donors, implementing partners, and private sector wholesalers and product distribution agents. There are numerous clinical and logistic questions to be answered as mechanisms for HIVST rollout, retail, waste management, reporting and monitoring are developed. Previous experiences in offering malaria rapid tests at ADDOs demonstrates policy and regulatory challenges even in the presence of successful pilot projects. Ongoing planning and dialogue will be critical to expanding opportunities for HIVST in ADDOs, community pharmacies, and other private sector outlets. However, the need for further research and evidence regarding the effective distribution and use of HIVST is a priority for Tanzania in its path to reach HIV epidemic control.



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