Expanding Access to HIV Self-Testing

A MARKET DEVELOPMENT APPROACH

Population Services International with support from Accenture Development Partnerships

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ABBREVIATIONS

5As	Availability, Assured quality, Appropriate design, Awareness, and Affordability
3IE	International Initiative for Impact Evaluation
ADP	Accenture Development Partnerships
AHWP	Asian Harmonization Working Party
AIDS	Acquired Immunodeficiency Syndrome
AIDSTAR	AIDS Support and Technical Assistance Resources (USAID)
ANC	Antenatal Care
ART	Antiretroviral treatment
CDC	Centers for Disease Control
CE	Conformité Européene (European Conformity)
CeSHHAR	Centre for Sexual Health HIV and AIDS Research (Zimbabwe)
CHAI	Clinton Health Access Initiative
CITC	Client-Initiated Testing and Counseling
CIFF	Children's Investment Fund Foundation
COGS	cost of goods sold
COP	Country Operational Plan
DALY	Disability-Adjusted Life Years
DOH	Department of Health
DREAMS	Determined, Resilient, Empowered, AIDS-Free, Mentored, and Safe women
FDA	Food and Drug Administration (United States)
GHTF	Global Harmonization Task Force
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HTS	HIV Testing Services
IFU	Instructions For Use
IVD	In Vitro Diagnosis
LSHTM	London School of Hygiene and Tropical Medicine
MDA	Market Development Approach
MOH	Ministry of Health
MSF	Médecins Sans Frontières (Doctors without Borders)
NASCOP	National AIDS & STI Control Programme
OGAC	Office of the U.S. Global AIDS Coordinator
PAHWP	Pan African Harmonization Working Party on Medical Devices
PEPFAR	President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated Testing and Counseling
PLHIV	People Living with HIV
PQ	Prequalification (WHO)
PrEP	Pre-Exposure Prophylaxis
PSI	Population Service International
RDT	Rapid Diagnostic Test
SRA	Stringent Regulatory Authority
STAR	Self-Testing Africa Project
TPP	Target Product Profile
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Emergency Fund
USAID	United States Agency for International Development
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

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About PSI
PSI is a global health network of more than 60 local organizations dedicated to making it easier for people in the developing world to lead healthier lives and plan families they desire by marketing affordable products and services. PSI works to develop health markets to ensure that all people have the products and services they need without suffering financial hardship. Learn more at www.psi.org

EXECUTIVE SUMMARY

In 2014, an estimated 36.7 million people were living with HIV globally. The Joint United Nations Program on HIV/AIDS estimates that globally 60% of people living with (PLHIV) know their status[1]. In 2014, the United Nations launched the ambitious "90-90-90" targets to accelerate progress to end the HIV/AIDS epidemic. These goals call on the global community to ensure that by 2020, 90% of PLHIV are diagnosed, 90% of those diagnosed are linked to antiretroviral treatment (ART), and 90% of people on ART to achieve viral suppression[2]. While the scale-up of testing and treatment has been significant, a substantial testing gap remains with 40% of all people living with HIV remaining undiagnosed globally. Closing this testing gap through increased coverage and the scaling-up of approaches that can reach individuals with undiagnosed HIV and at high ongoing HIV risk will be critical to achieve the first 90.

HIV self-testing (HIVST) is a new approach that has significant potential to extend access to HIV testing beyond the limitations of the current infrastructure and address barriers to testing[i]. HIVST may be offered through a diversity of existing and new channels, including health facilities, community-based programs and pharmacies. HIVST delivered in these channels may provide directly assisted or unassisted HIV self-testing.

HIVST has the potential to support efforts to achieve global HIV testing goals in three key ways:

1. HIVST may increase the uptake of HIV testing among populations not currently reached by existing channels, including men, young people, and key populations (sex workers, men who have sex with men, and people who inject drugs),

2. HIVST may increase testing frequency among certain population groups with high ongoing risk of HIV infection,

3. HIVST may increase the efficiency of existing HIV testing services (HTS) by improving the coverage of provider-initiated testing and counseling (PITC), and/or by reducing the number of individuals testing negative for HIV in these facilities.

Recognizing the potential for HIVST, UNITAID financed the HIV Self-Testing Africa (STAR) Project as a four-year initiative in Malawi, Zambia and Zimbabwe to catalyze the market. To complement STAR, the Bill & Melinda Gates Foundation funded Population Services International (PSI) to analyze the global HIVST market. The project was guided by PSI's Market Development Approach (MDA). For PSI, taking a market development approach involves identifying market constraints and determining the most appropriate interventions needed to improve demand and supply as well as the enabling environment to result in an equitable and sustainable healthy market.

PSI envisions a healthy market for HIVST to be one that is supported by multiple buyers and suppliers and that delivers on Availability, Assured Quality, Appropriate Design, Awareness, and Affordability (5As) to achieve public health goals. Realizing this vision for the HIVST market will require consideration of two key markets—public and private sectors. While HIV testing has traditionally been driven by the public sector, HIVST opens up the possibility of utilizing private sector pharmacies to expand and extend the reach of testing.

The UNITAID/WHO HIV Rapid Diagnostic Tests for Self-Testing Technology Landscape summarizes the latest technologies for HIVST[4]. To date, four HIV RDTs for self-testing have been approved by a founding member of the Global Harmonization Task Force (see Appendix 4) and at least nine other products are in the development pipeline. Most HIVST products are HIV RDTs for professional-use that are being repurposed for self-testing. Although this repurposing speeds products' path to market, it does mean that only a few manufacturers are engaging in any type of innovative product development to achieve the recommendations laid out in the UNITAID/WHO Technology Landscape and PATH's target product profile (TPP) for an HIV RDT for self-testing[5].

Market Size

PSI, in partnership with Accenture Development Partners (ADP), developed a model to estimate the size of the HIVST market and highlight how the HIVST market is likely to evolve, where investments are needed in market development and the impact of different distribution strategies at the country level. The model scope included nine countries: Kenya, Malawi, Mozambique, Nigeria, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe. The model focused on the case-finding required to meet the 90-90-90 targets and did not consider markets resulting from other prevention activities such as PrEP and VMMC. To inform model scenarios and triangulate outputs, PSI conducted a Delphi survey of 17 HIV testing experts[ii].

Recognizing the uncertainty in the HIVST market, PSI developed three scenarios that represented conservative, moderate, and

i HIVST is a process by which an individual wanting to know his or her HIV status collects a blood or oral fluid specimen, performs an HIV test, and interprets the results by him or herself. HIVST does not provide a definitive HIV-positive diagnosis, and all reactive self-test results need to be confirmed by a trained provider using a national validated testing strategy and algorithm[3]. Studies show that HIVST can achieve high sensitivity and specificity in the hands of a layer user.

ii The Delphi survey is a group facilitation technique, which is an iterative multistage process, designed to transform opinion into group consensus[6]. It is frequently used when the market for a new product is weakly defined or few data are available, the product is still fluid, and relevant historical information is limited[7].

TABLE 1: REFINED MARKET SIZE ESTIMATION BY SCENARIO AND DISTRIBUTION CHANNEL

CHANNEL	CONSERVATIVE	MODERATE	AGGRESSIVE
Community-based channels	2.4 – 3.5M	4.6 – 7.0M	5.5 – 10.5M
Private-sector pharmacy	-	3.3 – 4.3M	6.6 – 8.5M
Facility-based testing (excluding ANC)	-	1.2 – 1.7M	1.6 – 2.1M
Secondary distribution at ANC	-	0.7 – 0.8M	2.7 – 3.0M
Secondary distribution in facility-based	-	0.07 – 0.10M	0.22 – 0.28M
Key Populations	0.8 – 2.1M	0.8 – 2.1M	0.8 – 2.1M
TOTAL	**3.3 – 5.7M**	**11.3 – 15.34M**	**18.1 – 25.5M**

aggressive levels of investment in adoption and demand creation. The scenarios were developed with inputs from the Delphi survey and broadly include the following assumptions:

- Conservative: HIVST is offered in 30% of community-based testing channels and quality assured HIVST are not offered in the pharmacy channel;
- Moderate: The pharmacy channel accounts for 10% of all HIV testing, HIVST is offered in 50% of community-based testing channels and is also offered to a limited degree in facility-based and secondary distribution channels;
- Aggressive: The pharmacy channel accounts for 20% of all HIV testing, HIVST is offered in 70% of community-based testing channels and is also offered to a limited degree in facility-based and secondary distribution channels.

The range of estimates generated by the scenarios was refined based upon the frequency of testing in key populations, likely presence of a supportive enabling environment, and the time required to reach scale. The refined estimates for the three scenarios are included in Table 1. Key assumptions are included in Appendix 11.

For countries to meet their 90-90-90 targets, the total number of people needing to test for HIV each year will need to increase from 48.6M adults tested in 2016, to approximately 71-92M adults tested in 2020. This would require a compound annual growth rate of 14% (+/- 3%). Under a moderate set of assumptions, the market for HIVST could be at least 11-15 million tests per year. However, achieving this estimate will require that donors invest in the development of both public and private sector markets and that a number of market constraints be overcome.

Market Constraints

To better understand the factors constraining the development of a healthy market, PSI and ADP conducted multiple rounds of structured interviews with representatives from 11 manufactures. In addition, more than 30 stakeholders were interviewed. Thematic analysis of the interviews identified the following prioritized constraints currently faced by manufacturers.

Constraint 1: Lack of demand for quality-assured HIVST translating into concrete purchase orders
Manufactures universally cited the lack of concrete demand as a major factor constraining their investment in product and market development. It was unclear to them who will pay for self-tests and if, or when, potential demand will materialize into actual orders. Within the public sector, the major issues constraining the actualization of orders centered around policy, donor guidance and implementation planning. Within the private sector, constraints were rooted in a lack of understanding of the potential of the market and a fear that non-quality assured products could undermine any possible market opportunity.

Constraint 2: Price pressure from donors and governments
Manufacturers perceive strong signals from governments and donor agencies that the price of HIV self-tests will need to be very low. Several cited pressure to keep the ex works price comparable and competitive with the product pricing of existing HIV RDTs for professional-use, which are currently available to

donors and government buyers at prices of US$0.80 - US$1.20[8]. No manufacturer reported this to be a viable price point for an HIV RDT for self-testing given the nascent state of the market and the need for further product innovation to make self-tests easy to use.

Constraint 3: Lack of incentives to innovate for further product development
Manufacturers generally recognize that their products require innovation in order to improve ease of use and align with the target product profile. However, most manufacturers are not investing in product development beyond single unit packaging, pictorial instructions for use (IFU), and individual-use component designs (e.g. single-use buffer). One manufacturer who noted that "there is a need to optimize the (repurposed) test to reduce the number of steps and opportunities for user error", however, he also noted that the company had "no additional product development planned". Despite recognizing room for improvement, manufacturers do not perceive that innovation will be rewarded.

Constraint 4: Fragmented and uncertain regulatory environment
Many manufacturers entering the HIVST market have limited experience in Sub-Saharan African markets and, therefore, did not know how to navigate these political and regulatory environments. Manufacturers consistently flagged the time, cost, and uncertainty associated with in-country regulation as a major constraint to market entry. They cited concerns about the potential need to conduct validation studies in "all 54 African countries" in order to register their products. One manufacturer noted that these validation studies could take multiple years while another estimated that each study could cost US$50,000 or more. In addition, the literature review and stakeholder interviews revealed that, at minimum, Burundi, Kenya, Rwanda, Uganda, Ethiopia, Nigeria, and South Africa may have policies that restrict the marketing and advertising of in-vitro diagnostics[9].

Constraint 5: Lack of ownership of and investment in key market functions
Manufacturers and global experts universally agree that effective systems to link people to care, promote products, and educate end users are necessary if the HIVST market is to develop. However, these activities require significant investment and manufacturers stated that their margins would not allow them to invest in wide-scale promotion to drive demand or be responsible for linkages to care. In particular, manufactures noted that facilitating linkage to care was a role for other market players, such as NGOs and ministries of health.

Recommendations

In order to overcome the constraints identified in the previous section, a number of actions will need to be taken by various players in the market. These recommendations are designed to ensure that future donor investment is efficiently targeted in key areas to rapidly achieve a healthy market with maximum public health benefit.

Recommendation #1: Engage a market manager
A market manager should play a project management role to help the market actively evolve from operational research studies to concrete demand and market development at scale. As outlined in Table 3, key activities should include coordination and advocacy; go-to-market strategic planning; regulatory support and guidance; and the collection of market intelligence. All of these activities should take place at both global and country levels in partnership with governments, the WHO, manufacturers, NGOs and other direct and indirect market players. The primary goals of the market manager would include building demand and facilitating market entry.

Recommendation #2: Conduct demonstration projects to understand the potential of specific distribution channels, especially through the private sector
Additional information is needed to better understand how HIVST can expand and extend the existing HIV testing infrastructure. Given their potential impact on market size, investigation of private sector and facility-based channels is critical.

A large-scale, multi-country demonstration project should be conducted to evaluate the feasibility, acceptability and impact of HIVST programs that directly target consumers through pharmacies. Manufacturers and stakeholders noted that a private sector market for HIVST is likely to develop and the Delphi panel of experts estimated that this could account for 10-30% of the entire HIV testing market. However, if the private sector is left to develop on its own, it is likely that non-quality assured tests will dominate the channel.

Conduct studies to understand the role of HIVST within PITC. There remains a gap in understanding of how HIVST should interact with existing PITC. Such integration within PITC could substantially expand the HIVST market size. This includes how HIVST may be used within public health facilities to increase provider-initiated testing by offering HIVST in overburdened public facilities, followed by a confirmatory test if the result is positive. Secondary distribution of HIVST by individuals recently diagnosed with HIV may also be considered.

Recommendation #3: Fund research on HIVST service delivery costs and cost-effectiveness across various contexts
Limited data on the public health impact and cost-effectiveness of HIVST across various geographic, epidemic, and delivery contexts continues to limit donor and government investment. Generating data to facilitate investment and calibrate appropriate levels of price pressure from donors on manufacturers is of the utmost importance for HIVST market development.

Support cost-effectiveness studies in alternate geographic and epidemic contexts: Cost-effectiveness is likely to be the most critical information for donors and country government decision-making. Costing for other service delivery models (private sector and provider-initiated use of HIVST) should be prioritized, as should collection of costing data from more diverse geographic settings. There is urgent need for cost-effectiveness modeling in

TABLE 2: KEY FUNCTIONS AND ACTIVITIES TO BE CONDUCTED OR COORDINATED BY THE MARKET MANAGER.

FUNCTION	GLOBAL ACTIVITIES	TARGET MARKET ACTIVITIES
COORDINATION AND ADVOCACY	• Engage key decision makers within large funding agencies to advance the procurement of quality assured HIVST kits. • Facilitate the sharing of information, especially market research, with manufacturers and other direct market players.	• Landscape private- and public-sector markets in key target countries • Develop advocacy strategies and coordinate market players and stakeholders to adopt WHO Guidelines, develop supportive national policies, national HIV testing strategies, and testing algorithms. • Identify key remaining "country specific evidence gaps
GO-TO-MARKET STRATEGIC PLANNING	• Prioritize key target countries for support, based on discussions with governments, funding agencies and manufacturers • Support manufacturers with limited experience in low and middle income country markets with market-entry strategies, including partnerships at country level	• In partnership with manufacturers, country stakeholders, and other players; develop launch plans including distribution and financing strategies. • Coordinate market research to inform development of marketing strategies, including launch and scale-up. • Support the adoption of WHO operational guidance on linkages to care, monitoring and evaluation, quality assurance, and waste disposal.
REGULATORY SUPPORT	• Promote draft regulatory framework for HIVST • Engage with key stakeholders to ensure HIVST remains a key consideration of medical device regional harmonization efforts	• Update manufacturers about evolving regulatory frameworks at country-level • Provide or engage support for manufacturer registration, where needed
MARKET INTELLIGENCE AND MARKET DYNAMICS	• Monitor impact of demand actualization on donor price and supplier capacity • Forecast and aggregate demand. • In partnership with WHO, ensure that HIVST forecasting is linked into existing models and workstreams of the Diagnostics Forecasting Working Group.	• Monitor national policies to ensure they encourage market entry of multiple suppliers • Collect data and monitor trends in the marketplace (e.g. price, volume, market share and availability) for both quality-assured and non-quality assured HIVST in the public and private sectors.

additional resource-limited settings with varied epidemiological trends (e.g. concentrated epidemics), low baseline HIV testing coverage and a large private sector.

Evaluate the impact of product innovations: Cost-effectiveness modeling will be based on data from HIVST programs employing repurposed HIV RDTs for professional-use that do not meet many of the requirements contained in the TPP. Improvements in product design, resulting in better alignment with the TPP, may impact the cost-effectiveness of self-testing. Modeling should be undertaken to identify, at a high level, the impact of product changes that may improve sensitivity and specificity, reduce supervision requirements, or better facilitate linkages to care.

Recommendation #4: Facilitate market entry for blood-based HIVST

The majority of products in the pipeline are blood-based RDTs and their entry into the market could lower prices and increase competition, innovation, and supply security. To accelerate the introduction of blood-based products, the following interventions are needed:

Conduct research on blood-based products: A large research study should be conducted to evaluate the usability, feasibility, and acceptability of blood-based HIV self-tests in low and middle-income countries. This work should include a comparison to oral fluid tests in order to identify the relative benefits of each specimen type and consumer preference. The research should develop solutions to specific stakeholder concerns related to blood-based HIVST, such as waste management. By addressing the specific concerns of country stakeholder, the research will reduce barriers to formal adoption of blood-based products and signal to companies and funders that a market for such products does exist in low and middle-income countries.

In addition to these usability studies, investments should also be made in the development of an HIVST that can detect acute HIV infection. Currently, the majority of HIVST products on the market, as well as the majority in the pipeline, are second generation tests that can detect HIV beginning 28 days after an exposure. A test to detect infection earlier will increase the impact of HIVST programs and will be a critical innovation if HIVST is to support the delivery of PrEP. A reliable 4th generation HIVST may be one option for achieving earlier detection, although the risk of increased false reactive results will need to be considered.

BACKGROUND

In 2014, an estimated 36.7 million people were living with HIV globally. The Joint United Nations Programme on HIV/AIDS estimates that globally 60% of people living with (PLHIV) know their status[1]. In 2014, the United Nations launched the ambitious "90-90-90" targets to accelerate progress to end the HIV/AIDS epidemic. These goals call on the global community to ensure that by 2020, 90% of PLHIV are diagnosed, 90% of those diagnosed are linked to antiretroviral treatment (ART), and 90% of people on ART to achieve viral suppression. While the scale-up of testing and treatment has been significant, a substantial testing gap remains with 40% of all people living with HIV remaining undiagnosed globally. Closing this testing gap through increased coverage and scaling-up approaches that can reach those with undiagnosed HIV and at high ongoing HIV risk will be critical to achieve the first 90.

As a new innovation that has significant potential to extend beyond the limitations of the HIV testing infrastructure and address existing barriers to testing, HIVST could play a substantial role in accelerating progress towards this goal. HIVST is a process by which an individual wanting to know his or her HIV status collects a blood or oral fluid specimen, performs a HIV test, and interprets the results by him or herself. HIVST may be offered in a diversity of channels, including health facilities, community-based structures, and pharmacies. HIVST delivered in these channels may be provided using either a directly assisted or unassisted model.[10]

HIVST has the potential to support efforts to achieve global HIV testing goals in three key ways:

1. HIVST may increase the uptake of HIV testing among populations not currently reached by existing channels, including men, young people, and key populations (sex workers, men who have sex with men and people who inject drugs),

2. HIVST may increase testing frequency among certain population groups with high ongoing risk of HIV infection,

3. HIVST may increase the efficiency of existing HTS by improving the efficiency of provider-initiated testing and counseling, and/or by reducing the number of individuals testing negative for HIV in facilities.

Studies across multiple settings have demonstrated high acceptability and feasibility of HIVST among target populations.[11] A systematic review of available multi-country evidence also shows that HIVST can achieve good levels of sensitivity and specificity when delivered through a variety of models.[12] In Sub-Saharan Africa, research trials conducted in Malawi and Kenya demonstrated that HIVST can achieve high uptake through community-based distribution, as well as secondary distribution of tests by female sex workers and women accessing ante- and post-natal care.[13,14] Further, modeling in Zimbabwe demonstrates that HIVST has the potential to be cost-effective, averting disability-adjusted life years (DALYs) and achieving savings on healthcare.[15] Additional information about HIVST can be found at hivst.org.

Project scope

In 2015, the Bill & Melinda Gates Foundation requested PSI to conduct a landscape analysis of the global HIVST market, focusing on the market for quality-assured HIV RDTs for self-testing. The project was designed to identify key barriers to the successful scale-up of this promising new technology and to develop potential interventions to speed market development.

The project included three key components:

- An analysis of the potential size of the market in nine priority African countries (selected based upon total population, the number of PLHIV, and the number of HIV-positive individuals unaware of their status)

- Identification of constraints to market development in low and middle income countries from the perspective of manufacturers

- Recommendation of interventions to promote the development of the HIVST market at global and country level.

This analysis is complementary to recent investments made by UNITAID to better understand the HIVST market, including UNITAID and WHO's recently released HIV RDTs for Self-Testing Technology Landscape (2nd Edition).[16]

HIV Self-Testing Africa (STAR) Project Complementarity

The UNITAID/PSI HIV Self-Testing Africa (STAR) Project is a four-year initiative to catalyze the market for HIV self-testing (HIVST). The project will be implemented in two phases. Phase One (2015-2017) will generate crucial information about how to distribute HIVST products effectively, ethically and efficiently. The project will generate multi-country public health evidence to inform WHO normative guidance and support development of national-level policy on HIVST. With funding support from UNITAID, nearly 750,000 HIV self-tests will be distributed across Malawi, Zambia and Zimbabwe in Phase One of the project. Phase Two of the project (2017-2019) will scale up successful distribution models and demonstrate the population-level health impact of HIVST.

The HIVST Market Dynamics project serves as a complement to the STAR Project, which focuses its efforts on the downstream components of the value chain (HTS providers, ART/VMMC providers, and consumers). The HIVST Market Dynamics project focuses on filling those gaps of the value chain analysis that are not addressed by the STAR project, by developing an understanding of global market players on the upstream end of the value chain, particularly manufacturers.

PSI's market development approach

This project was guided by PSI's Market Development Approach (MDA). The MDA process examines health markets across the entire value chain from production (manufacturers) to use (consumers). It assesses the ability of direct market players in the value chain (manufacturers, distributors, wholesalers, retailers or providers, consumers) to perform core functions of demand and supply in the market, as well as the impact of enabling environment factors. More specifically, the MDA considers:

- Core functions of demand and supply through the lens of the 4Ps of marketing: Product, Price, Place, and Promotion;
- Supporting functions which include information, coordination, guidance, quality assurance, and labor capacity;
- Rules compromised of policy, regulations, and other issues such as taxes and tariffs.

For PSI, taking a MDA involves identifying market constraints and determining the most appropriate interventions needed to improve market performance and achieve health impact. Interventions are targeted to strengthen core functions of demand and supply and ensure an enabling environment that results in an equitable and sustainable health market. This analytical approach utilizes an analysis of market failures and appropriate intervention along a production to use matrix that is included in Appendix 6.

Methodology

This analysis employed literature reviews, secondary data analysis, and primary research, including interviews with HIV RDT manufacturers and stakeholders at the global and country level. Semi-structured in-depth interviews were conducted by PSI and ADP with 31 global experts– including international donors, leading researchers, UN agencies, Ministries of Health, and in-country implementers.[iii] In-depth interviews were conducted with 11 manufacturers including the majority of manufacturers who are developing an HIV RDT for self-testing and those with significant market share in the professional-use HIV RDT market.[iv] Second round interviews were conducted with seven manufacturers who stated intended plans to enter the HIVST market.

Two methods were used to build a better understanding the potential size of the market and its key drivers. First, PSI partnered with ADP to develop an analytical model to estimate the market size based on potential marketfor HIV testing, actual market for HIV testing, and the likelihood of adoption of HIVST in key distribution channels. The model scope included nine countries: Kenya, Malawi, Mozambique, Nigeria, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe. Model outputs were intended to show the relative impact of potential distribution channels and likely roll-out strategies. As new evidence becomes available, the model can be updated to reflect new information and assumptions.

To inform model assumptions, PSI and ADP did an exhaustive review of evidence, examined potential channels, developed an understanding of the dynamics and trends in the existing HIV testing market, and surveyed experts. The model leverages this information and uses the best evidence available to lay out a number of potential scenarios in which HIVST could play a role in meeting 90-90-90 targets in each country. Key assumptions are included in Appendix 11. The model focused on the case-finding required to meet the 90-90-90 targets and did not consider markets resulting from other prevention activities such as PrEP and VMMC.

Second, PSI also conducted a Delphi survey on HIV testing with a panel of 17 experts at global and country level in order to triangulate model outputs with expert opinion, inform the development of adoption scenarios, and validate assumptions around channel estimates. PSI conducted two rounds of questionnaires that asked a panel of experts to make estimates of the future of the market for HIVST in Kenya and South Africa. The surveys explored the future size of the market, the likely adoption of HIVST in certain channels, perceived constraints in the market, and key factors that would enable the development of the market.

PSI sent the surveys to 42 experts and received 17 responses (41% response rate) to the first round of surveys and nine responses (53% of first round respondents) to the second round of surveys. Respondents were diverse and represented implementers (6), government ministries (3), the WHO (3), manufacturers (2), researchers (1), civil society groups (1), and donors (1).

iii Annex 1 contains a list of the stakeholders interviewed
iv Annex 2 contains a list of the manufacturers interviewed

THE HIV RDT SELF-TEST MARKET

The market for HIV RDTs for self-testing has been described previously by WHO and UNITAID, most recently in the aforementioned 2016 technology landscape.[17] This document builds on that landscape and provides a detailed examination of the market from the perspective of manufacturers.

Vision of a healthy market

Understanding how well a market functions, first requires a clear vision of how that market should function if it is healthy. A healthy market should be characterized by the following:

- Growing demand to ensure high-quality products and services are used by all target groups;
- Robust supply that can reliably meet demand through sufficient delivery points, with a diverse range of high quality, appropriately designed and affordable products;
- An enabling environment composed of supporting functions, such as coordination and quality assurance systems, and rules, such as policies and regulations, that maximize the incentives and capacities of the market players to allow the market to function efficiently and grow sustainably.

Based on the analysis of stakeholder interviews and input from PSI's technical advisory group, PSI articulated a vision for a healthy HIVST market in line with these characteristics. A healthy HIVST market is one that is supported by multiple buyers and sellers and that delivers on Availability, Assured Quality, Appropriate Design, Awareness, and Affordability to achieve public health goals..

5AS OF A HEALTHY MARKET FOR HIVST

- **Available**: HIVST are available in all countries through a variety of channels and accessible to all target populations.
- **Assured Quality**: HIVST meet minimum performance (i.e. accuracy) standards. HIV RDTs for self-testing that do not meet these standards are not available in any channel.
- **Appropriate Design**: HIVST are designed to be easy to use and accurate.
- **Awareness**: Target consumers demand HIVST and know how to correctly use the product.
- **Affordability**: HIVST are affordable for end users.

Realizing this vision for the HIVST market will require consideration of two key markets: public and private sectors. The majority of the current professional-use HIV RDTs in low and middle income countries are financed and procured by donor and/or government funding and distributed through public-sector channels. The **public-sector market** for HIVST is likely to be similar, with donors and governments funding purchases of large volumes that are then distributed through public-sector channels, either free of charge or at highly-subsidized prices for the end user.

However, HIVST has the potential to extend existing testing infrastructure through the private sector, reaching additional users otherwise unable or unwilling to interface with the public health infrastructure due to reasons of privacy, confidentiality, and opportunity cost. In the **private-sector market,** a portion of HIVST procurement may be financed directly by consumers who are willing to pay for all or part of the costs required to promote and distribute HIV RDTs for self testing. The private sector market for HIV RDTs for professional-use is small in Sub-Saharan Africa. Development of this market for HIVST is likely to require an initial period of significant investment in go-to-market strategies and activities, including promotion and distribution.

The market for professional-use HIV RDTs

To understand the market for HIV RDTs for self-testing, it is important to understand the current HIV testing market which consists of professional-use RDTs. In 2014, the three largest buyers – the Global Fund, President's Emergency Plan for AIDS Relief (PEPFAR) and South African Department of Health – purchased nearly 100 million professional-use HIV RDTs valued at over US$85 million.[18] The total market is likely to be larger as these estimates do not include HIV RDTs procured through other funding channels. At least 52 HIV RDTs for professional-use testing are on the market,[19] and 24 have been prequalified by the WHO or approved for procurement by the Global Fund based on their registration and approval for use by a founding member of the Global Harmonization Task Force (GHTF). Fifteen companies and their subsidiaries manufacture these 24 WHO-prequalified or GHTF-approved products (see Appendix 4 for list of approved tests by manufacturer).

Alere currently dominates the HIV testing market in low and middle income countries. In 2014, within the donor-funded segment of the market, Alere captured 83% of the value market share and 86% of the volume market share[20]. The second manufacturer, Trinity Biotech, captured 3.4% of the volume market share, but this reflected Trinity's dominant position in the confirmatory testing space.[21] The high concentration of sales is likely due to Alere and Trinity's presence in the national testing algorithms of many low and middle income countries. Despite WHO recommendations that national algorithms be updated every 3-5 years, they are infrequently changed and can present a barrier to entry for those companies not included. Beyond donor-funded sales, the government of South Africa procured large quantities of tests.

JAL Innovations, a Singapore-based company, won South Africa's 2014-2017 tender and has supplied over 21 million professional-use HIV RDTs to South Africa[22].

The HIVST product

Unlike HIV RDTs for professional-use, HIV RDTs for self-testing are often employed by lay users who must collect a whole-blood or oral fluid specimen, perform the test, and interpret the results, potentially with little to no assistance. This requires that products be designed for ease of use to achieve accuracy, to facilitate interpretation of results, and to support linkage to care.

In 2014, PATH released a TPP to guide research and development of an HIV RDT for self-testing.[23] Some of the key recommendations include:

- High clinical and analytical sensitivity and specificity
- Low invalid and test failure rates
- Pictorial instructions for use with any text-based instruction translated into local languages
- Low number of test steps which could be achieved through integrated systems to deliver buffer or other such innovations
- Simple to interpret test results which require little instruction
- Reduction in time to result to 5 minutes or less (time from test performance to interpretation)
- Increased stability of test results

Interviews with stakeholders echoed the need for these requirements, and highlighted that significant modifications to existing HIV RDTs for professional-use would be required to achieve the TPP. Manufacturers unanimously cited that designing products to ensure ease of use and accuracy, as well as linkages to care, were likely to be key factors in the success of the HIVST market in the short and long run.

Currently no HIV RDT for self-testing fulfills the TPP's minimum requirements. The vast majority of products on the market or in the pipeline are repurposed HIV RDTs for professional-use. Product landscaping done by UNITAID, WHO, and PSI indicates that most HIV RDTs for self-testing in development or already in the market are second generation tests (can detect HIV beginning 28 days after exposure) that have five to six steps for use and interpretation of results, a read window of 15-20 minutes, and test results that are stable from 5-60 minutes after running the test.

Current product development and supply pipeline

To date, only four HIV RDTs for self-testing have been approved by founding member of the Global Harmonization Task Force, and three are currently available in developed countries (see Appendix 4). Orasure's OraQuick In-Home HIV Test was approved by the US Food and Drug Administration and launched in the US in 2012. In 2015, BioSure UK and AAZ-LMB received CE markings and launched private-label versions of Chembio's Sure Check HIV1/2 Assay in the UK and French markets, respectively. The INSTI HIV Self-Test, manufactured by bioLytical, received CE marking in July of 2016 and will be launched in the UK, France, and other key European countries by the end of 2016. The majority of current HIV RDTs for self-testing are sold online or through pharmacies to consumers at prices ranging from US$25-48 (Oraquick In-Home HIV Test: US$40/test in the United States; Biosure HIV Self-Test: US$42-48/test in the UK; Autotest: US$25-28/test in Europe; INSTI HIV Self-test: US$36/test in Europe). All of these products are based on existing HIV RDTs for professional-use.[24]

There is also a significant and growing pipeline of products for the HIV self-test market. In addition to the four tests available today, there are at least nine HIV RDTs for self-testing in the development pipeline, most of which are targeted for low and middle income countries.[25] Similar to the current HIVST products on the market, most products under development are HIV RDTs for professional-use that are being repurposed for self-testing. Detailed technical specifications for many of the products under development can be found in the 2016 WHO/UNITAID HIV RDTs for Self-Testing Technology Landscape.

Manufacturers entering the HIVST market vary widely (a summary of manufacturers is available in Appendix 5). Some manufacturers, including Alere, Trinity, and JAL Innovations, have deep experience in the African markets based upon their donor-funded HIV RDT professional use market. However, these companies have not yet developed an HIV RDT for self-testing. Other manufacturers, including Orasure, AAZ, and BioSure, have each commercialized a self-test product that has been approved by stringent regulatory authorities (SRAs) in the US, UK, and France. Chembio, by licensing its product to AAZ and BioSure, has also gained experience in the self-test product development process. However, none of these companies has deep experience in the African markets. Critically, no manufacturer has both experience in the self-test market and in low and middle income countries with a high HIV burden.

Capacity to scale

In the short to medium term, manufacturing capacity is unlikely to be a constraint in the HIVST market. This is based on the market size estimates developed within the scope of this project as well as discussions with manufacturers in terms of their ability to scale. All manufacturers have capacity to produce at least several hundred thousand tests per year and this capacity can generally be expanded within 6-12 months as demand materializes. If large manufacturers such as Alere or Trinity enter the HIVST market, production capacity can increase significantly.

FIGURE 1: MATRIX OF HIV RDT MANUFACTURERS BY EXPERIENCE IN LOW AND MIDDLE INCOME COUNTRIES AND IN DEVELOPING HIV RDTS FOR SELF-TEST USE

EXPERIENCE IN LOW AND MIDDLE INCOME MARKETS	NO	YES
DEEP	Alere Trinity JAL Innovations	
LIMITED	Atomo Beijing Wantai Biological Pharmacy bioMerieux BioSure	Orasure(1) Chembio AAZ(2) bioLytical Calypte

EXPERIENCE IN DEVELOPING HIV RDTS FOR SELF-TEST USE

(1) Orasure is the only company to take a product from R&D to commercialization for the HIV self-testing market.

(2) AAZ and Biosure entered the self-test market using private label self-test versions of Chembio's professional-use Sure Check HIV1/2 Assay.

Path to market

HIV RDTs for self-testing need to go through the following steps to get to market: product development, trials, regulatory approval, in-country registration, and purchasing. In order to expedite their path to market, manufacturers are currently entering the self-test market by repurposing existing professional-use products. This means they can skip several steps in product development, including discovery and proof of platform. By limiting significant changes to their professional-use RDT, manufacturers are also attempting to avoid additional lengthy approval, regulatory, and registration processes from the WHO PQ Program and national regulatory authorities. Figure 2 depicts how manufacturers taking a repurposing strategy significantly abbreviate their path to market. Although this repurposing speeds products to market, it does mean that fewer than three manufacturers are engaging in any type of innovative product development to to align their products with the TPP.

Manufacturer outlook on the HIVST market

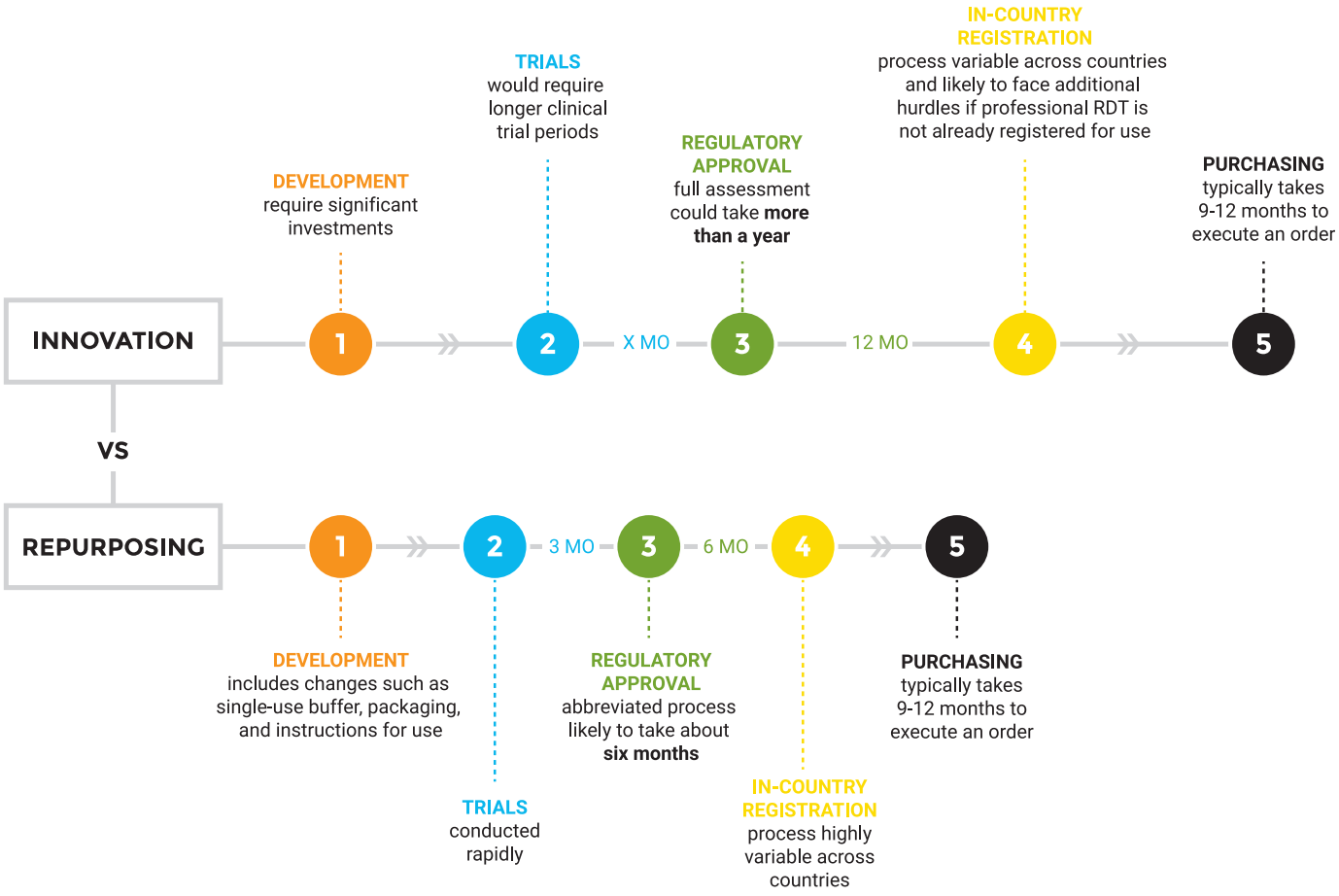
The majority of manufacturers entering the self-test market expect the market to be driven by large-scale purchases funded by global donors and/or governments in low and middle income countries. They also expect that low and middle income countries with high HIV burdens are the most likely countries to adopt HIVST and drive early volumes. Specific markets of interest include South Africa and Kenya.

However, there is considerable range in manufacturer outlook on the HIVST market. Generally, manufacturers with a strong presence in low and middle income country markets view the market with some skepticism. It is not clear to them that high volumes will necessarily materialize from existing or new channels or that Ministries of Health will support the transition from professional testing to the more user-empowered and less supervised self-test settings. As a result, these manufacturers are largely adopting a "wait-and-see approach." As a pre-requisite to invest resources into the market, these manufacturers expect critical elements to be in place such as WHO normative guidance, country-level policy adoption, and unambiguous demand signals from the WHO, donor agencies, or government bodies.

> *We see a projection of three to five years – at least – from where we are today to having five or six countries fully implemented with HIVST and everyone aligned. Until that point, we'll react to market forces, we will engage in clinical studies, but we would not be relying on revenue from HIVST.*
>
> *–HIV RDT Manufacturer*

Other manufacturers are much more optimistic about the HIVST market. These manufacturers tend to be small and mid-sized players with far less experience in low and middle income country markets. They see HIVST as inevitable given the need to increase testing in order to reach the first 90. One manufacturer

FIGURE 2: PRODUCT PATH TO MARKET



commented that HIVST is "a natural progression to normalize the disease" and another noted that it is "the major way to reach the first 90 percent." Manufacturers in this segment expect relatively quick and widespread adoption of self-test products in African markets. These players recognize that WHO guidance and PQ is needed, but they expect this to happen much more quickly than established players. They also show more willingness to invest in product development.

Despite their differences on the outlook of the HIVST market, manufacturers universally agreed that there were major barriers and constraints in the market that would need to be overcome.

It's clearly possible that 90 percent of our revenue stream could come from Sub-Saharan Africa in two to three years. But that will only happen if everything goes right in removing barriers to self-testing. Unfortunately, we are not in control at all.

-RDT Manufacturer

MARKET SIZE

The size of the market for quality-assured HIVST is uncertain for a number of reasons. First, the market is nascent. Product development, including packaging and positioning, is ongoing and is likely to be influenced by channel adoption. Additionally, consumer pricing has yet to be tested across channels. Second, the role of HIVST has not yet been established in most settings, and its potential impact through different distribution channels still needs to be determined. Overcoming these challenges will require investment, effective marketing campaigns, and the presence of a supportive enabling environment in each country. With limited public health evidence available to date, the degree to which governments, donors, and commercial actors will commit funds towards such activities is unclear.

In light of the need to understand how the HIVST market is likely to evolve, where investments are needed in market development, and the impact of different distribution strategies at the country level, PSI, in partnership with ADP, developed a model for the HIVST market. The model calculates HIV testing need and current HIV testing use and estimates the size of the HIVST market overall and across different distribution channels.

In 2015, the nine countries modeled had had a total population of 259 million adults,[26] 18.7 million of whom are living with HIV, of which 9.3 million are on ART.[27] In 2015-2016,[v] they also tested approximately 48.6 million adults; diagnosed 2.5 million HIV-positive cases; and initiated 1.6 million people on ART.[28] A detailed table of population and HIV testing data is included in Appendix 10.

Approach

With support from ADP, PSI developed an Excel-based Monte Carlo simulation model[vi]. As shown in Figure 3, the model consists of the following steps:

1. Potential HIV Testing Market: An estimate of the number of people who would need to be tested each year in order for countries to meet their 90-90-90 objectives. The potential market was calculated by estimating the number of people who would need to be tested in order to meet ART initiation targets. It should be noted that the potential market was capped by the 90-90-90 policy objectives and does not reflect testing that may occur outside of meeting these objective, including additional testing for PrEP and VMMC.

2. Actual HIV Testing Market: The number of adults who were tested for HIV in the most recent 12 months for which there is national data available. The testing gap was calculated as the difference between the potential and actual markets and represents the number of new people who will need to test beyond existing efforts to meet the 90-90-90 targets.

3. Adoption of HIVST: The estimated degree to which HIVST is offered to, and adopted by, those testing in new and existing channels. Adoption rates were broken down by population segment (age and gender), testing history (new and existing users), and distribution channel. Existing channels included community and facility-based testing while new channels included pharmacy and secondary distribution. Recognizing the uncertainty in the role of HIVST in the HIV response, the model allows for three scenarios that represented conservative, moderate, and aggressive levels of investment in coverage and demand generation across a number of channels.

4. Refined Market Size Estimation: Estimates generated through the previous steps were further refined based upon the frequency of testing in key populations, likely presence of a supportive enabling environment, and the time required to reach scale.

A list of key assumptions is included in Appendix 12.

Findings

All figures and estimates noted in this section are exclusively for the nine countries included in scope.

1. Potential HIV Testing Market:

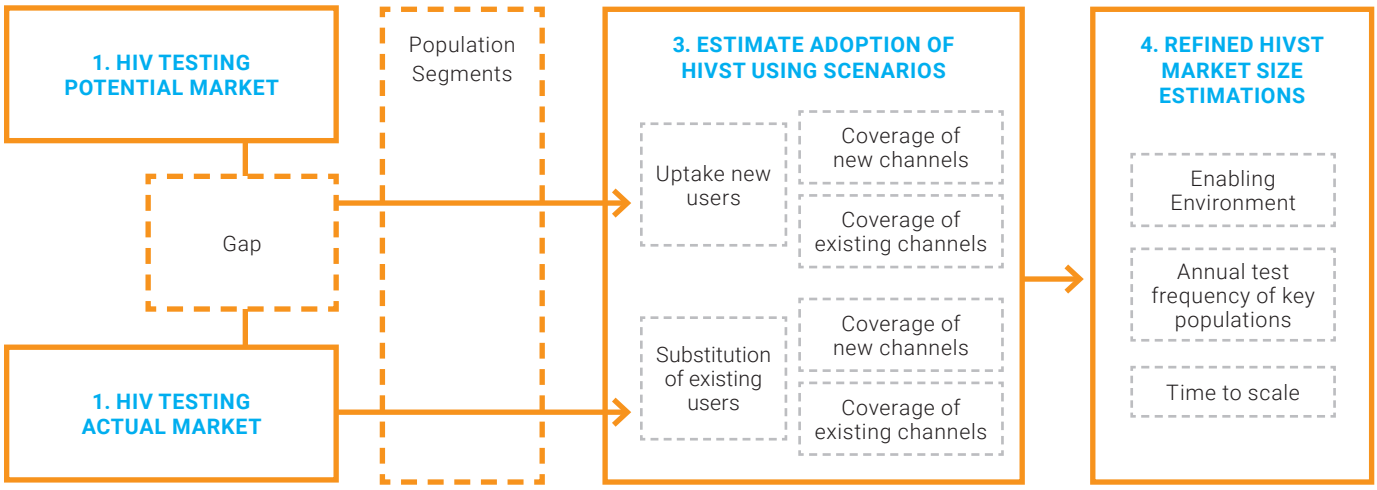
The number of people needing to test for HIV each year among the target countries will need to increase from 48.6 million adults in 2016, to approximately 71-92 million adults in 2020. This would require a compound annual growth rate of 14% (+/- 3%), which, while high, is in line with historical trends. From 2010-2015, the market grew at a compound annual growth rate of 19%. Figure 9 shows the number of adults and children tested for HIV from 2004-2015, a linear projection of historical trends, and the model estimates of the size of the potential market in 2020.

PSI's potential market estimations were consistent with expert opinion. For example, PSI estimated that 10.8 -13.8 million adults would need to be tested in South Africa in 2020, while the median of estimations made by the Delphi panel was 13 million adults tested (N=11, IQR: 9 – 16M). Similarly, for Kenya, PSI modeled that 7.3 – 10 million adults would need to be tested in 2020, while the median of panel estimates was 9.6 million ((N=6, IQR: 9.2 – 14.5M).

v National testing data were reported in the FY2015 and FY2016 PEPFAR COPs for the 12 months preceding publication of the COP. Data for six countries was extracted from FY2016 COPs published in July, 2016. At the time of writing, three other countries: Tanzania, Mozambique, and Zimbabwe had not yet published FY2016 COPs and, therefore, data was extracted from the FY2015 publications.

vi A Monte Carlo simulation performs risk analysis by substituting probability distribution for input variables that have inherent uncertainty. PSI modeled yield and retention rates as distributions.

FIGURE 3: OVERVIEW OF THE MARKET SIZE ESTIMATION METHODOLOGY



The findings also appear to be broadly consistent with the global figures presented by Avenir Health on behalf of the Diagnostics Forecasting Technical Working Group in 2015.

Factors that most impact the size of the potential HIV testing market include the degree to which case finding can be improved within existing testing models, the ability of programs to link and retain PLHIV in care and treatment services, and the degree to which a large market like Nigeria scales up its efforts to meet the 90-90-90 targets. Nigeria's impact on the potential market of the nine priority countries is significant because it has the second largest HIV burden in the world spread across a large undiagnosed population. In 2015, it had an ART coverage rate of just 25%, and to meet its 90-90-90 objectives Nigeria will need to increase testing from 8 million adults per year in 2016, to at least 18-24 million adults per year in 2020.

> *"In order to place close to everyone on ART, more identifications will be needed and targeting of high-yield populations will be challenging given that the epidemic will remain generalized. Therefore, yields will continue to decline as more people are placed on ART, requiring more tests to be conducted."*
>
> *-Delphi panel expert*

As case finding improves in line with efforts to increase testing efficiency, more people will need to be tested in order to find the remaining individuals living with HIV. The model currently estimates declining positive yield rates over the next five years, in line with expectations of improved case finding. This trend is consistent with findings from the Delphi survey, actual data reported by countries in 2015 and 2016 and PEPFAR targets in FY2016 and FY2017. Between 2015 and 2016, national yield rates fell by an average of 22% in Kenya, Nigeria, South Africa, Malawi, Zambia, and Zimbabwe.[29] Even in PEPFAR priority districts, PEPFAR target yield rates as reported in the COPS generally fell between FY2016 and FY2017 projections.

The size of the potential market is also driven by the degree to which programs can effectively link individuals to care and retain them in treatment programs. Similar to PSI's modeling, most programs estimate the number of people needing to test based upon estimates of the number of people needing to initiate ART treatment to meet the objective of the second 90, having 90% of PLHIV who know their status on ART. If linkages and retention rates are high, then fewer people need to be tested to meet the 90-90-90 target. Achieving these high linkage rates will likely require countries to implement test and treat, while achieving high retention rates will likely require differentiated care models.

2. Actual HIV Testing Market:

In 2015-2016, approximately 48.6 million adults were tested for HIV through a variety of channels including facility-based (PITC and client-initiated testing and counseling [CITC], and antenatal clinics) and community-based channels. PITC and CITC facility-based testing accounted for approximately 27.8 million (57%) adults tested, while antenatal care (ANC) and community-based channels accounted for 9.1 million (19%) and 12 million adults tested (25%) respectively. As the number of adults who need to test grows, the gap between the actual market and potential market will be approximately 25-43 million adults. A table of estimates of HIV testing data by channel and country is included in Appendix 8.

3. Adoption of HIVST:

> *"I am sure people will take HIVST up if offered, but am unsure that investment will be made in these approaches to achieve scale."*
>
> *-Delphi panel expert*

HIVST will need a clearly defined implementation strategy, including the development of refined distribution channels which will reach the country-specific target populations. Because HIVST is still a nascent product and operational research projects are ongoing, there is considerable uncertainty over what this strategy will consist of and to what degree it will be funded. To date, in all nine priority countries, operational research has been limited to semi-restricted and clinically restricted models. Unrestricted settings, such as the pharmacy channel, have yet to be rigorously investigated.

To accommodate for the unknowns in the role and financing of HIVST, PSI developed three scenarios to outline the potential adoption and uptake of HIVST across a range of distribution channels and levels of investment. The scenarios were heavily informed by the Delphi survey of experts and represent the best information available at the current time. Subsequent to estimates of coverage, acceptability rates were applied across all channels based on findings from operational research studies. Detailed descriptions of the assumptions for each scenario are included in Appendix 10.

4. Refined Market Size Estimations:

After accounting for increased frequency of testing amongst key populations, each country's enabling environment and the time required to scale, the model estimated the likely size of the HIVST market in 2020. It was assumed that key populations would test 2-4 times per year. The refined estimates are detailed in Table 3.

Discussion

Private sector pharmacies

> *"There is strong political will to adopt HIVST in the private sector in Kenya in order to reach [undiagnosed] PLHIV who don't typically attend health facilities."*
>
> *-Delphi panel expert*

Private sector pharmacies have the potential to play a key role in the market for HIVST. HIV testing experts in the Delphi panel estimated that private-sector pharmacy sales would account for approximately 20% (N=17, IQR: 10 – 30%) of the entire HIV testing market in South Africa and Kenya. While there was significant variability in estimates; 14 out of 17 experts (82%) estimated that it would account for at least 10% of all HIV tests conducted. Based upon these assumptions, the moderate and aggressive scenarios show that HIVST in private-sector pharmacies could result in distribution of 3.3-8.5 million HIVST RDTs per year by 2020. However, without marketing and distribution investment in the channel it is likely to be dominated by low-cost, non-quality-assured products. If that happens, the market for quality-assured products may be very limited and this case is reflected in the conservative scenario.

Community-based distribution

> *"In community, outreach, and home-based testing channels a greater percentage of tests will be self-tests; however, there will always be individuals who will require some form of supervision."*
>
> *-Delphi panel expert*

While extremely promising, the adoption of HIVST in community-based channels may be limited by acceptability which has been shown to range from 100% in young adult populations to less than 50% in older adult male cohorts[vii]. In addition, HIVST may not prove to be cost-effective in all community-based testing modalities. Realizing high-impact, cost-effective distribution of HIVST at community level will require investments in targeted promotion and distribution to ensure uptake in populations in greatest need of HIV testing. Delphi panel experts estimated that HIVST would account for 50% [20-60%] of all HIV tests provided in Kenya and South Africa via community-based channels. Across the nine countries, this could account for 4.6-10.5 million HIVST RDTs per year by 2020.

Facility-based channels: HIVST RDTs distributed through facility-based channels may be used to increase coverage of PITC where coverage is low. Alternatively, it may also be used to provide clients with an alternate testing choice where they may be hesitant to accept professional services. Evidence to support these hypotheses remains sparse and there is significant debate regarding the utility of HIVST in facility-based channels. The vast majority of experts in the Delphi survey believed that HIVST in facility-based testing channels would be limited, accounting for approximately 10% of all tests (N=17 IQ: 5-20%). In line with expert opinion, PSI modeled three cases where HIVST could account for 0, 10%, and 20% of facility-based tests. Even in the aggressive scenario, HIVST in facilities accounted for, at most, approximately 2.1 million tests per year in 2020.

Secondary distribution: PSI examined two modalities for secondary distribution: secondary distribution at ANC clinics and secondary distribution in other facility-based settings. Secondary distribution at ANC clinics has been studied in Kenya (Thirmuthy et al 2016) and has been shown to result in high uptake among the partners of women

vii Choko, A., MacPherson, P., Webb, E.L., Wiley, B.A., Feasy, H., Sambakunsi, A.M., Makonbe, S.D., Desmond, N., Hayes, R., Maheswaran, H., & Crobett, E.L. (2015). Uptake, Accuracy, Safety, and Linkage into Care over Two Years of Promoting Annual Self-Testing for HIV in Blantyre, Malawi: A Community-Based Prospective Study. PLOS Medicine. 12(9): e1001873. doi:10.1371/journal.pmed.1001873

TABLE 3: REFINED MARKET SIZE ESTIMATION FOR 2020 BY SCENARIO AND DISTRIBUTION CHANNEL

	CONSERVATIVE	MODERATE	AGGRESSIVE
Refined market size estimation for 2020	**3.3 – 5.7M**	**11.3 – 15.34M**	**18.1 – 25.5M**
Channels:			
Community-based channels	2.4 – 3.5M	4.6 – 7.0M	5.5 – 10.5M
Facility-based channels including PITC and CITC	-	1.2 – 1.7M	1.6 – 2.1M
Pharmacies	-	3.3 – 4.3M	6.6 – 8.5M
Secondary Distribution at ANC	-	0.7 – 0.8M	2.7 – 3.0M
Secondary Distribution at PITC	-	0.07 – 0.10M	0.22 – 0.28M
Increased Frequency			
Key Populations	0.8 – 2.1M	0.8 – 2.1M	0.8 – 2.1M

attending antenatal and post-partum care. Given the large size of the ANC channel, secondary testing could result in volumes of at least 3 million HIVST tests per year by 2020 with the proper investment.

Secondary distribution in other facility-based settings may be used to facilitate disclosure and increase couples testing. This channel has yet to be investigated and is likely to be much smaller. In the model, it was assumed that only individuals testing positive in a facility-based PITC or CITC setting would be offered an HIVST test to take home and offer to their sex partner. In this case, the size of the market is likely less than 0.5 million.

Availability of financing and investment:

> *"There is a major risk that HIVST interventions will not be rolled out and that scale-up in overall testing will not happen due to unstable government finances and declining donor funds"*
>
> *-Delphi panel expert*

The availability, or lack thereof, of financing to support a scale-up in HIV testing and the investments required to build the HIVST market will have a major impact on the market's size.

In 2015, total expenditure on HTS was more than $300 million in the nine target countries, $66 million of which was spent on the direct procurement of rapid diagnostic kits.[30] The majority of HTS expenditure was financed by PEPFAR (52%), national governments (32%), the Global Fund (11%), and a number of other donors (4%).[31]

Though PEPFAR continues to be the largest financier of HTS, its funding for HTS peaked in 2008 and steadily declined until 2015.[32] Furthermore, analysis of PEPFAR COPs indicates that PEPFAR funding is likely to significantly decrease in South Africa and Nigeria in FY2017. The reduction in funding will need to be offset by additional expenditure by the Global Fund, domestic governments, and private-sector spending. Beyond simply offsetting PEPFAR reductions, additional expenditure will be needed to generate demand, develop a private sector, and expand the market.

Beyond the 90s: The demand size estimates referenced in the preceding section constrained demand based upon the 90-90-90 policy objectives. The model may not address all testing within a prevention context nor does it model alternative approaches that could be facilitated by HIVST, such as mass testing campaigns. If policy objectives change, then the assumptions within the model will need to be adjusted accordingly. Finally, while the 90-90-90 objectives are currently driving the HIV testing market and will be expected to do so for at least the next several years, the testing environment could significantly change once the 90-90-90 objectives have been met and sustained.


lenovo

MARKET CONSTRAINTS

PSI's primary research with manufacturers and inputs from stakeholders and technical experts identified significant constraints in the development of a healthy HIVST market. The analysis resulted in the prioritization of the following market constraints.

1. Lack of demand for quality assured HIVST translating into concrete purchase orders,
2. Pressure from donors and governments for manufacturers to lower the price of HIV RDTs for self-testing,
3. Lack of incentives to innovate for further product development of HIV RDTs for self-testing,
4. Fragmented and unclear regulatory environments, and
5. Lack of ownership of and investment in key market functions.

Addressing these constraints is critical to achieving the vision of a healthy HIVST market laid out earlier in this report.

Constraint 1: Lack of demand for quality assured HIVST translating Into concrete purchase orders

Manufactures universally cited the lack of concrete demand as a major factor constraining their investment in product and market development. It was unclear to them who would pay for self-tests and if or when potential demand will materialize into actual orders. Manufacturers also expressed a need for better forecasts, and they wanted forecasts to be clearly linked to a funding commitment to ensure large purchases. Several cited that currently available estimates, of 4-80 million,[33] were of limited use due to the large range of uncertainty and lack of commitment in terms of orders.

> *"If someone like the Global Fund or PEPFAR can say, 'All right we believe that this is going to happen and that demand will ramp up and in 2017 we will do a US$5 million order.' It doesn't have to be huge. It has to be a real number that they can say we have a tender for US$5 million. So a specific number – that flowed to procurement would really help."*
>
> *-HIV RDT manufacturer*
>
> *"Volume estimates are still highly speculative. The market is attractive from a 'do-good' perspective, but as a small company, we need to evaluate the opportunity vs. other investment opportunities."*
>
> *-HIV RDT Manufacturer*

Manufacturers spoke to several factors constraining the actualization of orders including a lack of investment to build public-sector demand and a lack of financial opportunity in the private-sector market. Within the public sector, the major issues constraining the market were around policy, donor guidance, and implementation planning. Within the private sector, constraints were rooted in a lack of understanding of the potential of the market and a fear that non-quality-assured products could undermine any possible market opportunity.

Policy: Although more and more countries are adopting policies supportive of HIVST, national policies remain fragmented and varied (Figure 4[viii] and Appendix 7). Some countries, like Kenya, have legalized HIVST with some restrictions. Other countries do not have HIVST policies, and some even explicitly discourage its use. Limited movement in HIVST policy is driven, in part, by the lack of a WHO recommendations for HIVST, concerns about linkage to care, and questions regarding whether the potential benefits of HIVST outweigh the risks. In many countries, there remains a lack of coordination and advocacy to ensure findings from other contexts are evaluated and country-specific information gaps are identified and addressed in order to advance policy adoption.

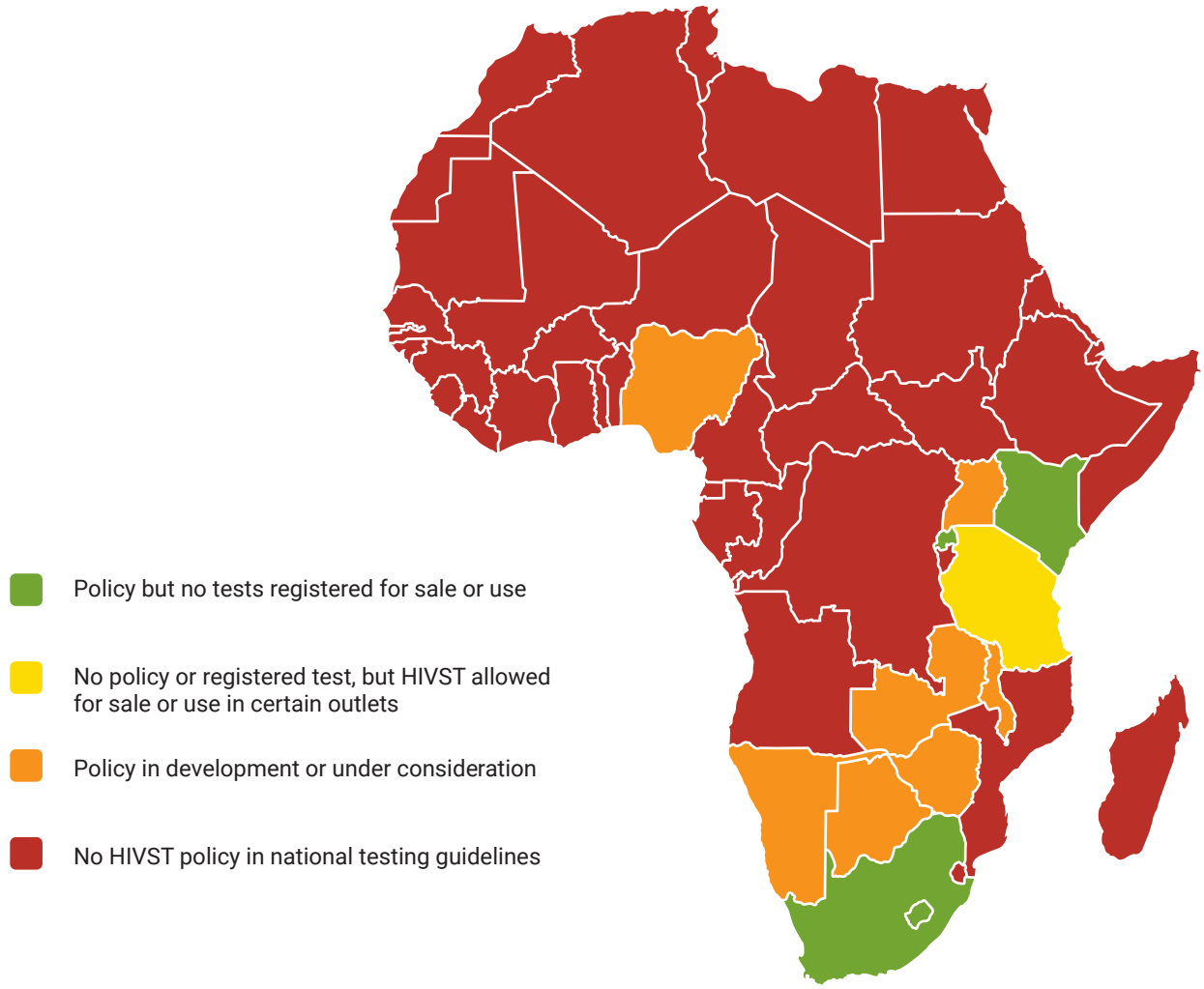
Donor Guidance: Manufacturers reported that they saw no clear signals from large buyers that high-volume procurement was likely or imminent. Indeed, currently no major donor supports HIVST at scale and investments are limited to funding for trials and research studies. PEPFAR's Technical Considerations for 2016 Country Operational Planning (COP) mentions HIVST as an emerging approach to be considered in high-burden areas and PEPFAR-implementing agencies have supported some HIVST research. However, the guidance does not endorse widespread use. Global Fund's information notes on HIVST recommends only the inclusion of the approach for operational research. As a result, HIVST is, by and large, not reflected in current grant planning and funding requests to major donors such as PEPFAR and the Global Fund. This may begin to shift with the upcoming release of WHO HIVST guidance in late 2016

Strategy and Implementation Planning: Manufacturers also recognize that supportive HIVST policies are a necessary, but insufficient for converting demand into commitments for purchases. Policies need to be translated into national strategies and implementation plans, including inclusion of HIVST in national testing strategies and algorithms. As several experienced RDT manufacturers noted, this process can take years. Manufacturers expressed a need for coordination of activities to drive policy changes, address regulatory barriers, make demand more predictable, and share market intelligence.

Uncertainty in the potential of a private market that directly targets consumers: There has been limited investment or research from donors and governments signaling that private sector channels will be prioritized for HIVST promotion and

viii Policy map represents the best information available at the time of publication. Information was primarily sourced from hivst.org.

FIGURE 4: AFRICA HIVST POLICY LANDSCAPE[viii]



distribution. The vast majority of operational research studies currently funded by a range of donors focus on semi-restricted and restricted models in existing distribution channels. Public health bodies appear unsure of the potential role that the private sector may play as their experience is limited to existing HTS that are currently concentrated in the public sector.

Manufacturer uncertainty in the private sector also appears to be rooted in a lack of data about the size and structure of this market, and on their negative perceptions of the HIVST product introduction in the US. Many question the ability and willingness of consumers in low and middle income countries to pay for HIVST. Others noted that they did not have the sales and distribution partnerships with country-level partners that could enable them to adequately assess the market.

"We know that [Orasure in the US HIVST launch]… they've spent excessive amounts of money to reach a percentage of (the projected US market) themselves… they are now spending lots and lots of money on advertisement to support pull in the market…that (market entry) is associated with a big spend."

-HIV RDT Manufacturer

Lack of perceived risk of non-quality-assured products: As in other contexts where geographic reach and significant subsidy of public-sector health services is present, large portions of the population still prefer to seek health care, including diagnostics, in the private sector.[34] Data drawn from population-weighted Sub-Saharan Africa Demographic Health Surveys conducted in early 2000s show that 48.7-52.4% of people access healthcare in the

private sector, across all population quintiles.[35] In private sectors that are largely unregulated and driven by cost competition, this can result in public access to low-cost but low-quality test products, to the detriment of public health objectives. Evidence from Namibia, Kenya, South Africa, and other countries indicates that low -quality tests are already appearing on the market.[36,37] Manufacturers noted this and often commented on the risk that substandard products could undermine opportunities in the private sector and underscored the importance of regulation and enforcement to protect public health.

> *"The idea of these devices going into pharmacies like what you see in Spain or in the United States – it's going to happen. Unfortunately, it's going to happen mostly through black market products."*
>
> *-HIV RDT Manufacturer*

> *"Unregulated products should not be in the market, and that – and that's really the job of the in-country regulators, the in-country department of health, the in-country national AIDS control program. And some countries are good at that, and some countries are not very good at that. And I think that self-test or no self-test, the vigilance of the regulators in a country is absolutely important to maintain the supply of quality products. In countries where anything – it's completely unregulated, and the government will accept any old rubbish as long as it's cheap, I think that is not a very attractive market to be in."*
>
> *-HIV RDT Manufacturer*

Constraint 2: Price pressure from donors and governments

Representatives from most large donors and country governments agreed that the target price for an HIV RDT for self-testing should be dependent on the "return on investment" as measured by public health impact and cost-effectiveness. Nevertheless, manufacturers perceive strong signals from governments and donor agencies to keep the HIV self-test product price low in order to be comparable and competitive with the product pricing of existing HIV RDTs for professional-use. These are currently available to donors and government buyers at US$0.80 - US$1.20.[38] No manufacturer reported this to be a viable price point for an HIV RDT for self-testing.

> *"Price plays a major role in market attractiveness and it ultimately impacts the margins the company can achieve. If the global health community requires a $1 test, the market opportunity is no longer attractive and manufacturers will likely look toward other investment opportunities offering better returns."*
>
> *-HIV RDT manufacturer*

There are a number of reasons why there is a wide difference between the price expectations among donors/governments and the price that manufacturers may require in order to enter the market at scale with appropriately designed products. These reasons include donor assumptions that product price will be a primary driver of cost savings in testing programs, a lack of recognition that the HIVST market is nascent and that short-term prices may not be indicative of future price until product development is completed and volumes established, and a lack of recognition that innovation around self-test products is needed and will likely require a price premium as improved HIVST products are developed.

Assumption that product price will drive cost savings: Data on the cost and impact of HIVST across multiple channels is limited. With currently available data, the cost that can be easily compared across existing HTS and HIVST is that of the HIV RDT product used. Given the significant volumes, HIV RDTs for professional use are significantly cheaper than HIV RDTs for self-test use, which have lower sales volumes and must be individually packaged with tailored instructions to improve ease of use by lay users.

However, the introduction of HIVST may produce significant cost-savings by reducing costs associated with HIV testing in both the health system (e.g. reduction in infrastructure and health worker time required) and opportunity costs among users (e.g. eliminate transport costs and time away from work). It may also reach hard-to-reach groups who do not currently access HTS, and therefore, ultimately reduce the amount of testing required to meet policy objectives. Indeed, HIVST may be both cost saving and cost-effective, even at a higher product price point. Preliminary cost-effectiveness modeling from Zimbabwe suggests this to be true for some models of distribution.[39]

Manufacturers underscored this issue, calling attention to the fact that the current focus on the product price fails to account for the potential impact of HIVST.

> *"We are more expensive than the…standard kind of testing kit. We cannot compete on price. But there is no talk of quality, of usability, of errors, of accuracy. So it seems like there's just so much attention paid to pricing rather than the whole package. What we say is you don't pay for the test; you pay for results."*
>
> *-HIV RDT manufacturer*

Limited recognition that HIVST is a nascent market with products still in development: The nascent stage of the HIVST market makes it extremely difficult for manufacturers to price their product. There is limited understanding on the part of buyers that pricing is difficult when product development is not complete. HIV self-tests may require changes depending on the findings of the trials and research studies. There is also likely to be different pricing for the different distribution channels, as packaging and linkage information may be likely to change. While innovation for product improvement is limited, that which does occur is likely

to have a similar impact. All of this could alter the current cost of goods sold (COGS).

Even once products are developed, the nascence of the market impacts pricing because manufacturers of HIV RDTs for self-testing have not yet faced the head-to-head competition in the market which would normally bring about price competition. Furthermore, HIV RDTs for self-testing, unlike professional-use HIV RDTs, have not yet been exposed to economies of scale that would drive price reductions. These fundamental differences between markets is often unappreciated by stakeholders when pricing for self-tests is anchored to HIV RDTs for professional-use. This anchoring may be driven by the fact that limited product innovation in self-testing has been undertaken, so the two types of products appear to be undifferentiated.

Constraint 3: Lack of incentives to innovate for further product development

Investments in innovation to make HIV RDTs for self-testing a consumer product are limited. Most manufacturers are not investing in product development beyond including single unit packaging, simplified IFU, and individual-use component designs (e.g. single-use buffer). In the short term, stakeholders and manufacturers recognized that the repurposing of tests was likely having a positive effect on the market because it allows manufacturers to reduce the time that it takes to obtain regulatory approvals and enter the market.

However, as the market develops, additional investment in product innovation will be needed. Innovation has the potential to improve the ease of use and accuracy of HIVST, reduce the window period, and improve linkage to care. Manufacturers widely recognized that current tests could be improved, however, few manufacturers had firm plans to invest in the product development and innovation that would be needed to drive those improvements.

One manufacturer who noted that his company had "no additional product development planned" also added, "there is a need to optimize the (repurposed) test to reduce the number of steps and opportunities for user error." Similarly, another manufacturer who planned to take their existing professional-use test to market conceded, "perhaps, it's (the repurposed test) not the easiest thing to handle as a non-trained-user." Despite this recognition, manufacturers are not receiving signals from the market that innovation is needed and will be rewarded.

Four major issues drive this dynamic in the market: manufacturers' expectation of price-driven procurement policies, reluctance to trigger a lengthy WHO Prequalification (PQ) assessment, limited market experience, and a lack of traction for the HIVST TPP.

Expectation of price-driven procurement policies: The procurement systems of major buyers including PEPFAR, the Global Fund, and South African government currently do not reward product improvements that extend beyond the minimum standards of regulatory approvers. As a result, manufacturers are not convinced that product improvements will enable them to win market share or charge a price premium. In fact, several referenced that improvements would increase COGS and thus make them less competitive.

Several manufacturers cited lessons from the malaria RDT market as reason not to invest heavily in HIVST product development. In their view, that market turned into a "race to the bottom" that made it very difficult to achieve any return on investment. One manufacturer noted that you might have "*180 million malaria tests being sold – a huge operational burden – but if they're only making $0.01 profit, then from a business and shareholder perspective further investment isn't compelling.*" Manufacturers feared that the same dynamic could play out in the HIVST market and, therefore, they were hesitant to commit major investment.

Reluctance to trigger a lengthy WHO PQ assessment: Manufacturers estimated that the PQ process for a new product typically takes 12-18 months. However, WHO will offer an abbreviated review process for products that have previously been pre-qualified for professional-use. Manufacturers often cited their interest in accessing this abbreviated process as a major reason for repurposing and minimizing the difference between the professional-use and self-test versions of an HIV RDT. They feared that slight product modifications could trigger a full assessment by the PQ program, costing both money and time given the need for new trials and a full assessment. It is possible that some innovations may not trigger the process, but there was a reported lack of clarity regarding what changes would do so.

> *"So, Prequalification may say, 'Well, we've now got a different buffer or dispenser – we need to revalidate that. We need a minimum number of samples tested, et cetera.' If you have a case where the nozzle is exactly the same as the coupling on the current bottle but you have less in it, is that then a change request that requires a validation or not? Those are the sort of things that get a little bit more complicated when you're looking at changing the product to make it more user friendly."*
>
> *-RDT Manufacturer*

Lack of traction for the HIVST TPP: PATH's 2014 TPP for HIVST, described above, has not been widely adopted as a standard by regulatory agencies and normative bodies. As a result, manufacturers do not have clear guidance on standards and product specifications beyond the basic performance and quality standards required for PQ, which should be released in mid- to late-2016.

One reason for the lack of traction for the target profile is that public health evidence suggests that current sensitivity, specificity, and overall product performance may be adequate to drive public health impact. Trials and studies conducted with current repurposed tests have shown high uptake and good accuracy. However, few studies reflect unsupervised self-testing in low-literacy settings where innovation in-line with the TPP may be

critical to ensuring accurate use and, thereby, public health impact. Additionally, if HIVST is expanded for use alongside other public health interventions, such as delivery of pre-exposure prophylaxis (PrEP), innovation in test technology will be critical. Additionally, no studies have assessed how limited alignment to the TPP may impact the cost-effectiveness of HIVST.

Limited market experience: Lack of innovation may also be driven by the nascence of the market. As the intervention is rolled out at scale in low and middle income countries, it is possible that additional usability issues will emerge which may affect uptake. For example, large scale demonstration projects in southern Africa have already identified that innovations to make the test more stable or improve accuracy of interpretation may be particularly critical as the product enters markets at scale.[40] Consumers may also provide pressure for innovation, particularly in the private sector.

The HIVST market has also been slow to grow in parallel high income country markets, depriving low and middle income country markets of a driver of consumer-focused product innovation. There is not a single developed market in which multiple HIVST products have competed for market share, so manufacturers have not yet needed to differentiate their products to gain a competitive edge. The 2016 introduction of INSTI in European markets may provide some indication of how competition may affect dynamics of innovation.

Constraint 4: Fragmented and uncertain regulatory environment

Manufacturers consistently flagged the time, cost, and uncertainty associated with in-country regulation as a major constraint. They cited concerns about the potential need to conduct validation studies in "all 54 African countries" in order to register their products. One manufacturer noted that these validation studies could take multiple years while another estimated that each study could cost US$50,000 or more. Additionally, many manufacturers had limited experience in Sub-Saharan African markets and, therefore, did not know how to navigate these political and regulatory environments.

> *"The impression to-date has been that each country will have different requirements and different implementation processes, making it challenging for manufacturers to navigate the various political environments and product registration processes."*
>
> *-HIV RDT Manufacturer*

Beyond registration and validation studies, national controls on the marketing of in-vitro diagnostics could constrain the development of a private sector market that directly targets consumers. Literature reviews and interviews with stakeholders revealed that, at minimum, Burundi, Kenya, Rwanda, Uganda, Ethiopia, Nigeria, and South Africa have policies that restrict the marketing and advertising of in-vitro diagnostics.[41]

The fragmented and unclear regulatory framework results from the novelty of the product and its perceived risks, weak regulatory systems, and a lack of market experience amongst some early entrants.

Novelty of the product and its perceived risks: HIV RDTS for self-testing are subject to more scrutiny because of the novelty of the product and its perceived risk. The Global Harmonization Task Force on Medical Devices[ix] classifies HIV diagnostics, including HIV RDTs, as Class D devices that carry high personal and public health risk. The same system is used by the WHO PQ Program, as well as many in-country regulators. As a result, HIV diagnostics generally receive more scrutiny than other products such as pregnancy tests and blood glucose tests, which are considered moderate to low risk.

Weak regulatory systems: In addition to issues that are specific to HIVST, the literature review and stakeholder interviews revealed that the fragmented and unclear regulatory environment is the result of wider systemic weaknesses in the regulation of medical devices in low and middle income countries. In many countries, the regulation of diagnostic products is poorly defined and, as a result, there are often tensions between organizations that oversee clinical laboratories and those that primarily regulate medicines.[42] Early evidence from the landscaping of regulatory systems in STAR project countries indicate this is already emerging as a challenge in the HIVST space.[43] A number of regional harmonization efforts including the Latin America IVD Alliance, the Pan African Harmonization Working Party on Medical Devices and Diagnostics (PAHWP) and the Asian Harmonization Working Party (AHWP) have been launched in recent years to address .regulatory, weaknesses, but stakeholders reported that the speed of these efforts was unlikely to yield clear processes that would encompass HIVST in the short-term.

Lack of information and manufacturer experience: The regulatory issue is further complicated by the fact that many of the new entrants to the HIVST market have limited experience in African markets. Several manufacturers, especially those without a strong presence in low and middle income countries, noted that they simply did not know the steps to getting their product into these markets. That limited familiarity often correlated with limited staff available to manage registration. This may make this constraint particularly important for manufacturers new to African markets.

ix Founding members included the European Union, the United States, Canada, Japan, and Australia.

Constraint 5: Lack of ownership of and investment in key market functions

Manufacturers and global experts universally agree that effective systems to link people to care, promote products, and educate end users are necessary if the HIVST market is to develop. However, these activities require significant investment and manufacturers stated that their margins would not allow them to invest in wide-scale promotion to drive demand or be responsible for linkages to care. In particular, manufactures said that facilitating linkage to care was a role for other market players, such as NGOs and ministries of health.

> *I'm categorically saying to you now that manufacturers will not be in a position to do – to have anything to do with follow-up to care.*
>
> *-HIV RDT Manufacturer*

Complexity of linkage to care: Manufacturers were adamant that, beyond package inserts, the role of supporting linkage to care belongs to governments or other implementing agencies working to provide HTS. Manufacturers believed that undertaking such a responsibility, as was required in the US market, would undermine any return on investment they may have in the market. They noted that the markets are highly fragmented and complex with different languages, healthcare systems, and cultural nuances.

In addition to cost and complexity, one manufacturer noted that if the goal is to create a market with multiple manufacturers to promote a strong, reliable, and diverse market, it would not make sense for each manufacturer to independently set up systems to link patients to care. This would be duplicative, likely to significantly increase cost and lead to fragmentation and confusion at the country level.

History of prior HIV testing promotion and education: HIV services, including HIV testing, is a space that has traditionally been driven by the public sector and financed by donors. The vast majority of HIV RDTs for professional-use are purchased by donors and governments and then distributed through facility and community-based channels that are managed by governments or non-governmental organizations. HIV RDT manufacturers have benefited from this situation and, for the most part, have not needed to directly engage in stimulating demand for their products at the country level.

Manufacturers noted the importance of promotional activities in driving uptake in both the private sector and public sector markets. However, they also stated that they do not intend to take on a promotional role they have little experience in or margin for. They expressed concern that they do not see other market players, particularly governments and donors, clearly stepping in to finance and perform this role.

> *"We're being hammered down to a price of $1.00 or $2.00 a test and that doesn't leave a lot of money for advertising. I think that's something that people like the World Health Organization, people like the big NGOs, like PSI, need to think about because they'll have a role to play."*
>
> *-HIV RDT Manufacturer*

Implications for Market Development and Consumer Access to HIVST

The constraints outlined above directly influence the actions of current and potential HIVST manufacturers and hinder market development. They present a direct threat to achieving the vision of a healthy HIVST market which delivers against the 5As. As a result, consumer access to HIVST is limited. Table 4 details what aspects of the healthy HIVST market vision are threatened by the identified constraints.

TABLE 4: HOW MARKET CONSTRAINTS WILL AFFECT CONSUMER ACCESS TO HIVST

MARKET CONSTRAINTS	AVAILABLITY	AFFORDABILITY	APPROPRIATE DESIGN	ASSURED QUALITY	AWARENESS
Lack of demand for quality assured self-test translating into concrete purchase orders	X	X	X	X	
Price pressure from donors and governments	X		X		
Lack of incentives for innovation			X	X	
Fragmented and uncertain regulatory environment	X	X	X		
Lack of ownership and investment in key market functions	X				X

RECOMMENDATIONS

Systematic intervention will be required to overcome the constraints limiting development of the HIVST market and achieve the vision of a healthy HIVST market that delivers public health benefits. Four interventions, each designed to address specific market constraints analyzed earlier in this report, have been prioritized for future donor investment.

1. Engage a market manager for HIVST;
2. Conduct demonstration projects to understand the potential of specific HIVST distribution channels which have not yet been evaluated;
3. Fund research on HIVST service delivery costs and cost-effectiveness across various contexts;
4. Facilitate market entry for blood-based HIVST

The interventions, and their relationship to market constraints, are outlined in Table 5.

Recommendation #1: Engage a market manager

Manufacturers cited a lack of concrete demand as the largest issue constraining their entry and investment in the HIVST market. Building and sustaining this concrete demand can be a high-touch, high-resource, and long-term activity for new markets.[44] It will involve the coordination and facilitation of activities for a large number of players and will require advocacy, go-to-market strategic planning, regulatory support, and additional market dynamics work. Without active management, the realization of concrete demand at scale may not happen or may be severely delayed. One manufacturer spoke to the need for such coordination, stating:

> *"The introduction of HIVST will require significant coordination of efforts. Who is going to coordinate it? Governments and Ministries of Health Donors Global stakeholders?"*
>
> *-HIV RDT Manufacturer*

A market manager should play a project management role to help the market actively evolve from operational research studies to concrete demand and market development at scale. As outlined in

TABLE 5: HOW RECOMMENDATIONS MAP TO MARKET CONSTRAINTS

	CONSTRAINTS				
RECOMMENDATIONS	**UNCERTAIN DEMAND ACROSS PUBLIC & PRIVATE-SECTOR MARKETS**	**PRICE PRESSURE FROM DONORS AND GOVERNMENTS**	**LACK OF INCENTIVES TO INNOVATE**	**FRAGMENTED AND UNCERTAIN REGULATORY ENVIRONMENT**	**LACK OF OWNERSHIP OF KEY MARKET FUNCTIONS**
1. Engage a market manager for HIVST	X	X	X	X	X
2. Conduct demonstration projects to understand the potential of specific HIVST distribution channels, especially through the private sector	X	X	X		X
3. Fund research on HIVST service delivery costs and cost-effectiveness across various contexts		X	X		
4. Facilitate market entry for blood-based HIVST	X		X		

Table 6, key activities should include coordination and advocacy; go-to-market strategic planning; regulatory support and guidance; and the collection of market intelligence. All of these activities should take place at both global and country levels in partnership with governments, the WHO, manufacturers, NGOs and other direct and indirect market players. The primary goals of the market manager would include building demand and facilitating market entry.

Coordination and Advocacy: Market development will require the successful identification and coordination of a diverse set of direct and indirect market players in both the public and private sectors. To achieve this, the market manager should landscape key markets, develop and execute an advocacy strategy, and coordinate information sharing across the value chain.

The market manager will need a detailed understanding of all players along the value chain for product and service delivery at country level, and their barriers to engaging in or supporting the HIVST market. This report, as well as efforts by the WHO and UNITAID, have built an understanding of market players and constraints at a global level and should be complemented by efforts to better understand market players, constraints and opportunities within key countries. The market manager should conduct in-depth landscaping in these countries, addressing both public and private sector markets.

The knowledge gap around the private-sector market is most significant and should be prioritized for landscaping. As noted in the market size model above, global experts generally agreed that the private sector could account for a significant portion of

TABLE 6: KEY FUNCTIONS AND ACTIVITIES TO BE CONDUCTED OR COORDINATED BY THE MARKET MANAGER

FUNCTION	GLOBAL ACTIVITIES	TARGET MARKET ACTIVITIES
Coordination and advocacy	• Engage key decision makers within large funding agencies to advance support for HIVST, based on evidence to date • Facilitate information sharing with manufacturers, particularly market research	• Landscape private and public sector markets in key target countries • Develop advocacy strategies and coordinate market players and stakeholders to develop supportive national policies, national HIV testing strategies, and testing algorithms • Identify key remaining country-level evidence gaps
Go-to-market strategic planning	• Prioritize target markets • Develop operational guidance on linkages to care, monitoring and evaluation, quality assurance, and waste disposal • Support manufacturers with limited experience in low and middle income markets with market entry strategies, including partnerships at country level	• Develop launch plans including distribution and financing strategies • Coordinate market research to inform development of marketing strategies, including launch and scale-up
Regulatory support and guidance	• Draft regulatory framework for HIVST	• Support development of HIVST regulatory processes and train key stakeholders • Ensure continued consideration of HIVST in medical device regional harmonization efforts • Support registration if necessary
Collection of market intelligence	• Monitor impact of demand actualization on donor price and supplier capacity • Forecast and aggregate demand	• Monitor national policies to ensure they encourage market entry of multiple suppliers • Collect data and monitor trends in the marketplace

all HIV testing in several key countries. Landscaping the private sector will enable manufacturers and donors to better understand its potential, identify key players and potential partners, and characterize the current informal market for HIV RDTs sold for self-testing. The landscape can also inform investments that might be needed to catalyze the development of a consumer market for quality-assured products.

The market manager should also create and execute strategic engagement plans that articulate the evidence, messaging, and approach required to gain support for HIVST from key donors and country-level policy makers. The outcome of this engagement should be a clear HIVST policy, in line with WHO Guidance, which articulates how HIVST will contribute to the national HIV response in key target market and advances orders and procurement of quality-assured HIVST kits. Development of this advocacy strategy should identify gaps in the evidence base that need to be filled at country level, informing future program priorities. However, the market manager should ensure that the existing evidence base for HIVST is used to inform policy makers and duplicative research is avoided. The World Health Organization is already leading many efforts to advance policy and evidence generation at global and country levels. The market manager should not replace this function but should instead work closely with WHO to support ongoing efforts and ensure that policy generation is coupled with strategic planning for rapid market introduction and high procurement volumes, as the policy environment evolves.

At a global level, the market manager should use strategic engagement to shape the donor and stakeholder narrative towards understanding the potential of HIVST and the need for upfront investment in market development, shifting pressure away from product pricing at this early stage of market development.

The market manager must also facilitate and coordinate information sharing across market players. At country level, the market manager should ensure that technical working groups (or sub-groups) are established within existing structures in Ministries of Health. These working groups will facilitate information sharing between market players and stakeholders and can coordinate execution of advocacy and go-to-market activities. Technical working groups established in STAR project countries may provide a model for other markets.

The market manager should also act as a key conduit with manufacturers. Based on this report's findings, critical information to share includes: recommended product refinements based on market entry experiences, information about key partners who can facilitate market entry at country level, communication of demand forecasts refined from the current demand estimation model, and articulation of consumer preferences as identified in market research. Alongside lessened donor pressure on product price, this critical information will signal to manufacturers demand for their product, as well as opportunities and incentives for product innovation. As the HIVST market develops, the market manager may also facilitate information sharing for other market players such as distributors.

Go-to-Market Strategic Planning: The market manager should support go-to-market strategy development to introduce HIVST at scale in key markets. Strategic planning efforts in prioritized markets are not to be performed exclusively by the market manager, but instead, through the engagement of the relevant market players, as well as the implementing partners working in these markets who are likely to perform key market functions during the market's early development. A go-to-market strategy should identify the role of each market player and specify:

- Appropriate distribution strategies in public and private sectors;
- Refined demand estimates based on the market size estimation model;
- Collaboration with the WHO to support adoption of operational guidance on HIVST distribution, linkages to care, monitoring and evaluation, quality assurance, and waste disposal;
- Critical market research to inform marketing and behavior change strategies;
- Roles and strategies for demand creation and post-test linkage to care or counseling, including consumer segmentation; and
- Financing strategy for HIVST internally or through requests to funding agencies.

At a global level, the market manager should work with partners to provide technical support for go-to-market strategies including:

- Dissemination of market research from across implementation settings to inform marketing strategies across contexts;
- Targeted support to manufacturers with a strong product and interest in the HIVST market but limited experience in low and middle income country markets.

Regulatory Strategic Guidance Support: Manufacturers cited concerns about the unclear regulatory environment as a primary barrier to market investment. To increase clarity and facilitate market entry, technical support should be provided for the development of HIVST regulation in target markets. The STAR Project will generate a draft regulatory framework for HIVST. Regulatory stakeholders from Malawi, Zambia, and Zimbabwe will be trained on its use at the conference of African Science and Laboratory Medicine in 2016. This framework could be adapted for use across countries. Targeted training and mentorship for regulatory stakeholders, identified through landscaping in key target markets, should be provided. Such support has already been provided by STAR Project regulatory experts and these experts could be engaged to replicate this work in key markets. As regulatory frameworks are established, the market manager should

provide regular updates to manufacturers about the evolving regulatory environment in various markets and should engage support for manufacturer registration, where necessary.

Of course, regional harmonization of in-vitro diagnostics also offers a promising way to strengthen regulatory regimes while also decreasing costs and delays in approvals. A number of regional harmonization efforts including the Latin America IVD Alliance, the PAHWP, and the AHWP have been launched in recent years to address some of these weaknesses in regulatory regimes. The PAHWP is currently using HIV viral load and early infant diagnosis to pilot a common registration file.[45] While promising, regional harmonization is a long-term process that is likely to take several years. Under the STAR Project, HIVST will be placed on the agenda of the PAHWP, and the market manager should monitor harmonization efforts to ensure HIVST remains a key consideration of the working party. However, to ensure that HIVST contributes toward the 90-90-90 targets, country specific support will still be necessary while regional harmonization efforts progress forward. This includes support for governments establishing regulatory frameworks and manufacturers who need to navigate these frameworks.

Market Intelligence and Market Dynamics: The market manager should support market dynamics and market intelligence in a number of ways. First, the manager should continue to monitor global market trends in line with this report and the HIVST Technology Landscape 2nd Edition. Second, the market manager should build upon the market size estimation model and in-country landscaping and go-to-market planning efforts to develop global strategic demand forecasts based on concrete orders as well as advocacy efforts with donors and governments. The market manager should work in partnership with WHO to ensure that HIVST forecasting is linked into existing models and workstreams of the Diagnostics Forecasting Working Group. Third, the market manager should proactively identify market constraints as demand materializes. Particular attention will need to be paid to ensuring that supplier capacity can match demand increases. Finally, the market manager will need to ensure that policy and advocacy efforts facilitate the vision of a healthy market with multiple suppliers. In particular, the market manager should ensure that testing algorithms, policies, and strategies do not entrench a single supplier for HIVST screening products and that evidence generation opens the door to new entrants (See Recommendation #4). If new entrants fail to materialize and the price to donors proves to be a barrier, the market manager may be responsible for recommending appropriate market intervention, such as global access pricing or volume guarantee.

Recommendation #2: Conduct demonstration projects to understand the potential of specific distribution channels, especially through the private sector

How HIVST will fit into donor and government HIV strategies and what product innovation and implementation investment will be required to optimize public health impact will be dependent upon the channels through which HIVST is offered. Although significant work has been undertaken to understand community-based distribution of HIVST and secondary distribution of HIVST through ANC channels, much less is known about how HIVST can extend provider initiated HTS channels or the potential of new distribution channels, such as pharmacies. These immediate gaps, which are likely to affect decision-making of key stakeholders, including donors and national HIV testing program managers, should be addressed now to ensure they do not slow market development or the achievement of public health objectives.

Conduct a large-scale demonstration project in pharmacies: A private-sector market for HIVST is developing in many countries across Africa. However, without intervention, this market is likely to be heavily skewed towards low-quality products, could undermine public confidence in HIVST, and may adversely affect public health gains. Many of the countries with the largest potential markets for HIVST have weak regulatory systems that have not proven to be effective in restricting substandard products. Efforts should be made to build a private-sector market for quality-assured HIVST that crowds out low-quality products.

A robust private-sector market for quality-assured HIVST could address manufacturer constraints around lack of demand, inability to achieve appropriate product pricing, and a lack of incentives to innovate to improve consumer use. Such a market could be dynamic and sustainable, reach new users, and help shift some of the testing burden off of the existing public health infrastructure while diversifying funding for product and service delivery. HIVST available through the private sector could directly target users who have a willingness and ability to pay rather than relying solely on subsidized public health infrastructure.

The private sector also offers an opportunity to work towards long-term public health goals by strengthening other aspects of a healthy market. It increases the number of buyers and makes the market more sustainable and less reliant on the actions of one or two key donors.

Given this potential for the private sector landscaping conducted by the market manager, a large-scale, multi-country demonstration project should be conducted to evaluate the feasibility, acceptability, and impact of HIVST programs that directly target consumers through pharmacies. This will assist in determining the potential of the private-sector market to achieve public health impact by reaching existing and new testers to find new cases of HIV infection, increasing the frequency of testing amongst key populations, and/or reducing the burden on existing HIV testing infrastructure. It could also provide a roadmap for introducing HIV RDTs for self-testing in other private sector markets. Critically, the intervention evaluated should be aligned with how the current private-sector market functions to ensure that if proven effective, it can be easily scaled.

Primary outcomes in the study would answer the following questions:

- **Public Health Impact**: Can pharmacy distribution achieve public health impact as measured by accuracy of use, testing frequency, case finding and linkage to care?
- **Consumer Uptake**: Will pharmacies reach population segments unreached by current testing models? What level of uptake can be achieved through pharmacies?
- **Price**: What is the willingness to pay for HIVST among different target groups? Is there potential for differential pricing across channels and how does price impact uptake? Will subsidies be required?
- **Promotion**: How can demand be steered away from low quality and towards quality-assured products in the private sector? What efforts are needed to limit the sale of low-quality products?

The only existing effort to understand the potential of the private sector is a small study in Mombasa, Kenya (sample size less than 500) examining the feasibility, acceptability, and uptake of HIVST across five pharmacies. Preliminary results suggest the pharmacy channel is promising, but the study's scale, lack of randomization, and limited marketing investment make it unlikely that it will provide conclusive evidence of the public heath impact or potential demand volumes in this channel.

Conduct studies to understand the role of HIVST within PITC. There also remains a gap in understanding of how HIVST should interact with existing PITC. This includes how HIVST may be used within public health facilities to increase provider initiated testing by offering HIVST in overburdened public facilities, followed by a confirmatory test if the result is positive. Secondary distribution of HIVST by individuals recently diagnosed with HIV may also be considered as a means to facilitate partner notification, if clients are properly counseled, screened for risk of harm, and opt to bring a test home. If successful, HIVST use in such models has the potential to drastically expand the market size. Operational research to investigate these models should be targeted for funding in the next year to ensure that efforts to clarify demand in the public sector are not constrained by information gaps in the potential for HIVST in this market.

Recommendation #3: Fund research on HIVST service delivery costs and cost-effectiveness across various contexts

Beyond the gap in understanding the potential of certain distribution channels, limited data on the cost-effectiveness of HIVST across various geographic, epidemic and delivery contexts continues to limit donor and government investment. While published data suggest that the higher cost of HIV RDTs for self-testing is likely to be a key cost driver for HIVST implementation, researchers acknowledge that distribution models are likely to present significant cost savings.[46] Lack of data on delivery costs contributes to HIVST purchase price expectations from donors and governments that may not be consistent with the selling prices required by manufacturers to attract new entrants and incentivize product innovation. Generating data to facilitate investment and calibrate appropriate levels of price pressure from donors on manufacturers is of the utmost importance to HIVST market development.

Support cost-effectiveness studies in alternate geographic and epidemic contexts: Cost-effectiveness is likely to be the most critical information for donors and country government decision-making. Under the STAR project, a robust cost-effectiveness model will be fit to examine the incremental cost-effectiveness of HIVST in Zimbabwe. Although an important first step, there is urgent need for modeling in other resource-limited setting, particularly cost-effectiveness in settings with different underlying epidemiologies (e.g. concentrated epidemics), lower baseline HIV testing coverage, and a larger private sector. Additionally, cost-effectiveness models need to be designed to take into account the cost-effectiveness work include Nigeria, Kenya, and South Africa.

Better data on the costs of HIVST service delivery will be needed to support improved cost-effectiveness modeling. Costing of service delivery should be integrated into all HIVST studies to assess how a higher ex works price for an HIV RDT for self-testing may be offset by other savings in service delivery. Currently, costing data is available from one study in Malawi, and STAR will generate additional data for the models under evaluation (including community-based distribution, facility-based distribution, and distribution through peer educators). Costing for other models (private-sector and provider-initiated use of HIVST) should be prioritized, as should collection of costing data from more diverse geographic settings.

Evaluate the impact of product innovations: Cost-effectiveness modeling will be based on data from HIVST programs employing repurposed HIV RDTs for professional-use which do not meet many of the requirements contained in the TPP. Improvements in product design, resulting in better alignment with the TPP, may impact the cost-effectiveness of self-testing. Modeling should be undertaken to identify, at a high level, the impact of product changes that may improve sensitivity and specificity, reduce the need for demonstration or other support, or better facilitate linkages to care. If modeling demonstrates that such improvements would increase cost-effectiveness, it may incentivize innovation by making larger public-sector buyers willing to pay for such investments.

Additionally, if efforts to incentivize innovation are successful, or if studies into blood-based HIVST prove promising (see Recommendation #4), there will be need to switch products within national HIVST programs. Given that self-tests are designed for ease of use, costs of switching should be minimal. However, altering supply chains, re-acquainting users to a new test, and

gaining support for the product among healthcare professional may each disincentive switching. Understanding the likely barriers to product switching, and their relevant costs, will be critical to ensure a path to market for innovative products remains open and that barriers to switching can be easily addressed.

Recommendation #4: Facilitate market entry for blood-based HIVST

The vast majority of products in the pipeline are blood-based RDTs and their entry into the market could lower prices and increase competition, innovation, and supply security. To date, most research on self-testing in Sub-Saharan Africa has been conducted using the oral fluid Oraquick HIV Self-Test. Increasing competition and creating natural pressure on price will require entry of blood-based products. However, due to the dominance of Oraquick, there is little data about the accuracy, feasibility, and acceptability of blood-based products in the region. To accelerate the introduction of blood-based products, the following interventions are needed.

Fund research on blood-based products: A large research study should be conducted to evaluate the usability, feasibility, and acceptability of blood-based HIV self-tests in Sub-Saharan Africa. This work should include a comparison to oral fluid tests in order to identify the relative benefits of each specimen type and consumer preference. The research should develop solutions to specific stakeholder concerns related to blood-based HIVST, such as waste management. By addressing the specific concerns of country stakeholders, the research will reduce barriers to formal adoption of blood-based products and signal to companies and funders that a market for such products does exist in low and middle income countries.

The results of this research can be used to support market entry for blood-based HIVST products by generating the evidence required for WHO PQ and in-country regulatory approvals. Several such products are developed, or are in development, by smaller/less experienced manufacturers who tend to lack the resources and expertise in African markets. These manufacturers are likely to need partnerships to conduct the research needed for regulatory approvals.

This project should evaluate blood-based tests that are best positioned for market entry. Products should meet certain minimum criteria for inclusion in the study, including:

- Alignment with the TPP,
- Manufacturer investments in the development of products designed for self-test use,
- Estimated time to market if accuracy is established, and
- Manufacturer ability to deliver at scale.

If blood-based evaluations show poor product performance in Sub-Saharan African populations, additional investment may be needed to facilitate entry of a second oral fluid test or improve design of blood-based products. The market manager will need to monitor the results and engage with manufacturers accordingly.

In addition to usability studies with existing blood-based HIVST products, investments should also be made in the development of an HIVST that can detect acute HIV infection. Currently, the majority of HIVST products on the market, as well as the majority in the pipeline, are second generation tests that can detect HIV beginning 28 days after an exposure. A test with a shorter window period, especially one which could detect acute infection, will ensure that HIVST programs identify people living with HIV as early as possible. Furthermore, several stakeholders referenced the potential use of HIVST alongside the administration of PrEP to reduce the number of facility visits required of a PrEP user. Such a use of HIVST would require a test that could detect acute infections in order to detect breakthrough infections as early as possible.

A reliable 4th generation HIV self-test may be one means of achieving this goal. In order to determine whether investments in the development of a 4th generation test is necessary, a study should assess the feasibility of such a test and its relative benefits over current HIVST products. A small study of self-testing, employing prototypes of a 4th generation self-test, should assess user ability to run the test as well as quantify the risk of higher false-positives against the improvement in case detection relative to 2nd or 3rd generation HIVST. The study should assess use among lay users, for whom opportunities for training may be limited, and individuals on PrEP, for whom increased training is feasible given their more frequent touch points with the health system. The study findings will be key to determining whether a market for a 4th generation HIVST product exists or whether additional technological innovation is necessary to develop an HIVST that detects acute HIV infection. .

APPENDIX

Appendix 1: List of Stakeholders Interviewed

NAME	ORGANIZATION
Anna Heard	3IE
Stephanie Behel	CDC
Dr. Peter Preko	CDC, Swaziland
Frances Cowan	CeSHHAR
Seth Procter	CHAI
Seth McGovern	CHAI
Anna Osborne	CHAI
Simon Azariah	CIFF
Alvaro Bermejo	CIFF
Thato Chidarikire	DOH, South Africa
Bill Rodriguez	FIND
Ade Fakoya	Global Fund
Micky Urdea	Halteres
Liz Corbett	LSHTM
Miriam Taegetymeyer	LSHTM
Owen Mugurungi	MOH, Zimbabwe
Dr. Joyce Wamicwe	NASCOP Kenya
Dr. Martin Siregno	NASCOP Kenya
Lisa Nelson	OGAC
Elliot Cowan	Partners in Diagnostics
Roger Peck	PATH
Ian Boulton	TropMed Pharma Consulting
Martina Brostrom	UNAIDS
Michael Hahn	UNAIDS
Craig McClure	UNICEF
Carmen Perez Casas	UNITAID
Heather Ingold	UNITAID
Jared Baeten	University of Washington
Vincent Wong	USAID
Dr. Nobert Mubiru	USAID, Uganda
Rachel Baggaley	WHO
Cheryl Johnson	WHO
Francois Venter	Wits Institute
Mohammed Majam	Wits Institute

Appendix 2: List of Manufacturers Interviewed

NAME	ORGANIZATION
Chris Smit	Alere Medical Co. Ltd.
Joesph Oerson	Chembio Diagnostic Systems, Inc.
Michael Steele	Chembio Diagnostic Systems, Inc.
Andre Han	JAL Innovation
Bruce Marsh	Trinity Biotech Manufacturing Ltd.
Mícheál Roche	Trinity Biotech Manufacturing Ltd.
Guido Lippoli	Calypte Biomedical
Brian Reid	OraSure Technologies
Fabien Larue	AAZ Labs
Bridgette Bard	Biosure
Gary Carpenter	Biosure
Anna Wang	AtomoDiagnostics
Neil Mehta	Premier Medical Corporation Ltd.
Daniel Kim	Standard Diagnostics

Appendix 3: Technical Advisory Group Members

NAME	ORGANIZATION
Martin Chalkley	University of York
Brenda Waning	Global Drug Facility
Wouter Deelder	Dalberg Consulting
Prashant Yadav	William Davidson Institute

Appendix 4: Hiv Rdts for Self-Testing Currently in the Market

MANUFACTURER	PRODUCT NAME	SPECIMEN TYPE	SRA APPROVAL
AAZ-Labs (France)	Autotest VIH	fingerstick/whole-blood	CE
Biosure (United Kingdom)	Biosure HIV Self-test	fingerstick/whole-blood	CE
Orasure Technologies (USA)	Oraquick In-Home HIV Test	oral fluid	FDA, CE
bioLytical Laboratories Inc. (Canada)	INSTI HIV Self-test	Fingerstick/whole-blood	CE

Appendix 5: Manufacturers of HIV RDTs[x,xi]

COMPANY	PROFESSIONAL USE ASSAYS	GEN	SPECIMEN	DEVELOPING AN HIV RDT FOR SELF TESTING
ALERE A large multinational with a diverse product portfolio and more than $2B in revenue, Alere is a dominant player in the professional-use testing market in low and middle income countries with more than 85% market share. In 2013, Alere launched a 4th generation test that can detect p24 antigens beginning at 15 days post exposure.	• HIV Combo • Determine HIV-1/2 • ABON™ HIV 1/2/O Tri-Line • ImmunoComb® II HIV 1&2 BiSpot • SD Bioline HIV Ag/Ab Combo • SD BIOLINE HIV/Syphilis Duo • SD BIOLINE HIV-1/2 3.0	• 4th • 3rd • 2nd • 2nd • 4th • 2nd • 3rd	Fingerstick/ whole-blood	yes
ATOMO DIAGNOSTICS Launched in 2010, Atomo is a new company that secured US$6 million from the Global Health Investment Fund in 2015. Atomo's unique professional-use test kit is not yet WHO pre-qualified or approved for Global Fund procurement, but its fully integrated design makes it easy to use and particularly suitable for self-testing.	• AtomoRapid HIV1&2 - CE marked but not approved for use in donor-funded programs	• 3rd	Fingerstick/ whole-blood	yes
BEIJING WANTAI Beijing Wantai Biological Pharmacy is one of the largest Chinese manufacturers of in vitro diagnostic tests.	• Rapid Test for Antibody to HIV (Colloidal Gold Device)	• 2nd	Fingerstick/ whole-blood	Not reported
BIOLYTICAL LABORATORIES Incorporated in 2002, bioLytical markets an HIV RDT for professional-use that can provide highly accurate test results in as little as 60 seconds. The company has not been a significant player in low and middle income markets.	• INSTI HIV-1/HIV-2 Antibody Test	• 2nd	Fingerstick/ whole-blood	Not reported
BIOMÉRIEUX A large company with more than $2B in revenue, bioMerieux has not year reported developing an HIV RDT for self test use. BioMerieux developed a partnership with Chinese-based Shanghai Kehua Bio-engineering (KHB) which is a major player in Asian markets.	• VIKIA HIV 1/2	• 3rd	Fingerstick/ whole-blood	Not reported
BIO-RAD LABORATORIES A A large company with revenues of more than $2B, Bio-Rad's HIV test kits accounted for approximately <0.5% of the donor funded HIV RDT market in 2014.	• Genie Fast HIV ½	• 2nd	Fingerstick/ whole-blood	Not reported
BIOSURE A small company in the UK, in 2015, BioSure launched a private label self-test version of Chembio's Sure Check HIV1/2 test in the UK market.	• N/A	• 2nd	Fingerstick/ whole-blood	Launched in the UK in 2015

x Policy table represents the best information available at the time of publication. Information was sourced primarily from hivst.org

xi For the purposes of this report, 3rd generation tests were defined as those that can detect both IgG and IgM.

COMPANY	PROFESSIONAL USE ASSAYS	GEN	SPECIMEN	DEVELOPING AN HIV RDT FOR SELF TESTING
CHEMBIO A New York based company with $25M in annual revenue, Chembio's SureCheck HIV1&2 are sold as self-tests in the UK and France by BioSure and AAZ respectively.	• DPP® HIV 1/2 Assay • HIV 1/2 STAT-PAK® Dipstick • HIV 1/2 STAT-PAK™ • SURE CHECK® HIV 1/2 Assay	• 2nd • 2nd • 2nd • 2nd	Fingerstick/ whole-blood	Private-label versions available in UK and France via BioSure and AAZ.
DIALAB GMBH Based in Austria, Dialab GmbH markets sells a wide range of rapid tests for pregnancy, HIV and other infectious diseases.	• DIAQUICK HIV 1&2 Ab Cassette	• 3rd	Fingerstick/ whole-blood	Not reported
INTEC PRODUCTS In 2014, InTec accounted for approximately <0.5% of the donor funded HIV RDT market. Based in China.	• ONE STEP Anti-HIV(1&2) Test	• 3rd	Fingerstick/ whole-blood	Not reported
HUMAN GMBH Based in Germany, Human GMBH produces numerous CE market products, including a RDT for HIV.	• Hexagon HIV	• 3rd	Fingerstick/ whole-blood	Not reported
MP BIOMEDICALS A small company based in Switzerland, MP Biomedicals accounted for approximately 0.1% of the donor funded HIV RDT market in 2014.	• Multisure HIV Rapid Test		Fingerstick/ whole-blood	Not reported
ORASURE TECHNOLOGIES Orasure was the first company to enter the self-test market when it's OraQuick test received approval by the US FDA. Orasure has developed a lower cost version of the test which is used in operational studies throughout the world. The company earns approximately $120M annual revenue.	• OraQuick HIV 1/2 Rapid Antibody Test	• 2nd	Oral Fluid	Launched in the US in 2012
PREMIER MEDICAL CORPORATION Based in India, Premier Medical Corportation accounted for approximately 1% of the donor funded HIV RDT market in 2014. The company is a major player in the mRDT market.	• First Response™ HIV 1-2-0 Card Test		Fingerstick/ whole-blood	Not reported
TRINITY BIOTECH A company with approximately $100M in revenue, Trinity Biotech dominates the confirmatory test market in low and middle income countries and accounts for approximately 5% of HIV RDT sales.	• Uni-Gold™ HIV	• 2nd	Fingerstick/ whole-blood	Yes
TURK LAB Based in Turkey, Turk Lab accounted for approximately <0.5% of the donor funded HIV RDT market in 2014.	• Anti-HIV 1/2		Fingerstick/ whole-blood	Not reported

Appendix 6: PSI's Production to Use Matrix

MARKET FUNCTIONS		MANUFACTERERS	IMPORTERS	DISTRIBU-TORS/WHOLE-SALERS	PROVIDERS/ RETAILERS	CONSUMERS
CORE FUNCTIONS (DEMAND AND SUPPLY)	Product					
	Price					
	Place					
	Promotion					
SUPPORTING FUNCTIONS	Information					
	Coordination					
	Guidance					
	Quality					
	Financing					
	Labor Capicity					
RULES	Policy					
	Regulation					
	Taxes/tarrifs					

Appendix 7: HIVST Policy Landscape[xii]

COUNTRY	HIVST POLICY (NATIONAL TESTING GUIDELINES) STATUS	HIVST REGISTRATION STATUS AND AVAILABILITY
BOTSWANA	• HIVST is illegal under current policy, since September 2013 • MOH is currently evaluating revision of policy	• No test registered for sale or use
KENYA	• HIVST policy included in 2008 and 2015 Kenya national guidelines on HIV testing and services • Additional Implementation pilot and study underway	• No HIVST registered for sale and use • Pharmacists authorized to sell HIVST
MALAWI	• No HIVST in national guidelines • HIVST included in national strategic plan • Implementation pilot and study underwa	• No test registered for sale or use
MOZAMBIQUE	• No HIVST in national guidelines	• No test registered for sale or use
NAMIBIA	• No HIVST in national guidelines • HIVST policy currently being evaluated	• No test registered for sale or use • HIVST informally available since 2002
NIGERIA	• No HIVST in national guidelines • Implementation pilot and study scheduled for 2016	• No test registered for sale or use
RWANDA	• HIVST policy in place since October 2015	• No test registered for sale or use
SOUTH AFRICA	• South Africa has policy allowing HIVST and is planning to include HIVST in national strategic plan.	• No test registered for sale or use • Reportedly available informally OTC since 2007 • Since May 2015 legal for sale over internet, in pharmacies and some venues • Regulatory standards in development
TANZANIA	• No HIVST in national guidelines • Policy in development	• No test registered for sale or use • Legal for sale, but must be used in supervised clinical setting (authorized center with clinical personnel) • Regulatory standards in development
UGANDA	• No HIVST in national guidelines • HIVST potentially illegal under current policy • Implementation pilot and study underway	• No test registered for sale or use
ZAMBIA	• No HIVST in national guidelines • HIVST potentially illegal under current policy • Implementation pilot and study underway	• No test registered for sale or use
ZIMBABWE	• No HIVST in national guidelines • Implementation pilot and study underway	• No test registered for sale or use

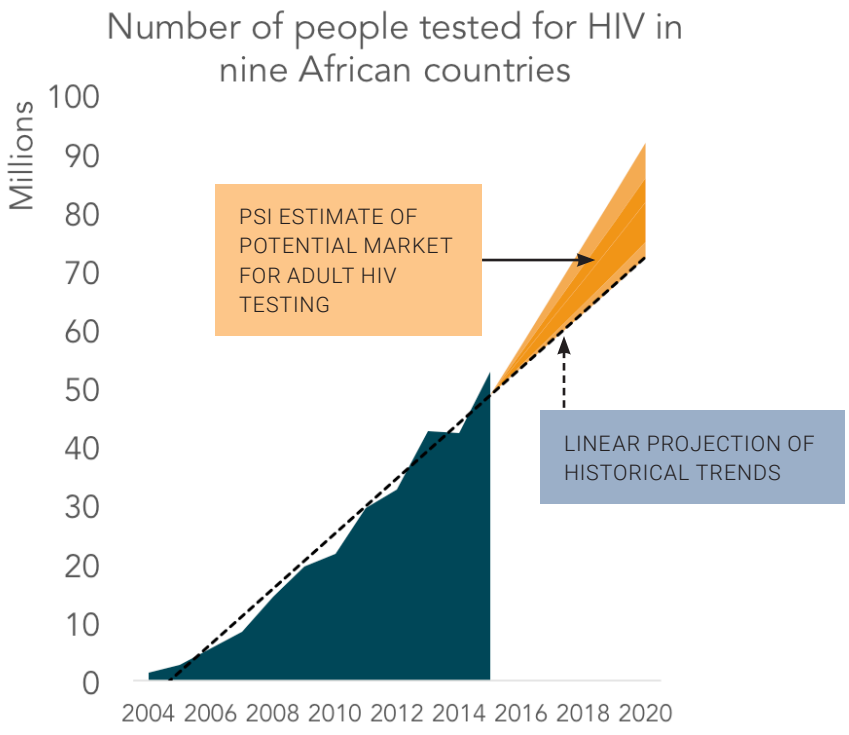
xii Information was sourced primarily from hivst.org.

Appendix 8: PSI Estimates of Adults Tested by Distribution Channel in 2015/2016

COUNTRY	ADULTS TESTED	ANC	FACILITY-BASED TESTING (EXCLUDING ANC)	COMMUNITY-BASED TESTING	YEAR
Kenya	5,909,012	1,233,462	3,080,000	1,600,000	2016
Mozambique	6,334,340	953,487	4,500,000	880,000	2016
Nigeria	7,791,257	2,610,889	3,230,000	1,950,000	2016
South Africa	10,089,051	1,028,311	6,030,000	3,026,715	2016
Tanzania	5,342,238	757,249	3,240,000	1,340,000	2015
Uganda	7,835,074	1,675,562	4,360,000	1,800,000	2015
Malawi	1,870,302	508,768	800,000	560,000	2016
Zambia	2,326,010	555,292	1,070,000	700,000	2016
Zimbabwe	1,155,459	94,918	830,000	230,000	2016
TOTAL	**48,652,744**	**9,417,938**	**27,140,000**	**12,090,000**	

Sources used in the analysis included:
1. National data as reported in FY 2015 & 2016 PEPFAR Country Operational Plan Strategic Direction Summaries available from http://www.pepfar.gov//countries/cop/
2. GARPR reporting
3. National strategies

Appendix 9: A Comparison of Potential Market to Actual HIV Testing Conducted in Target Markets[47]



Appendix 10: A Summary of Population and Testing Data for the Nine Countries Included in The Modeling Scope

COUNTRY	ADULTS (1)	ADULTS PLHIV (2)	ADULTS ON ART (2)	ART COVERAGE	ADULTS TESTED (3)	ADULTS DIAGNOSED (3)	YEAR (4)
Kenya	26,753,000	1,400,000	826,097	59%	5,909,012	197,064	2016
Mozambique	15,303,000	1,400,000	738,386	53%	6,334,340	446,020	2016
Nigeria	102,054,000	3,100,000	785,212	25%	7,791,257	263,370	2016
South Africa	38,559,000	6,700,000	3,384,160	51%	10,089,051	892,001	2016
Tanzania	29,304,000	1,400,000	688,604	49%	5,342,238	No data	2015
Uganda	20,260,000	1,400,000	774,902	55%	7,835,074	289,433	2015
Malawi	9,441,000	890,000	543,699	61%	1,870,302	111,219	2016
Zambia	8,768,000	1,100,000	706,743	64%	2,326,010	218,082	2016
Zimbabwe	9,112,000	1,300,000	817,397	63%	1,155,459	94,738	2016

Sources

1. United Nations, Department of Economic and Social Affairs, Population Division (2015). World Population Prospects: The 2015 Revision
2. UNAIDS AIDSInfo Database, http://aidsinfo.unaids.org/ accessed 10 August 2016
3. National data as reported in FY 2015 & 2016 PEPFAR Country Operational Plan Strategic Direction Summaries available from http://www.pepfar.gov//countries/cop/
4. Represents the Fiscal Year of the COP in which the testing and diagnosis data were reported.

Appendix 11: Channel Definitions and Assumptions for Conservative, Moderate and Aggressive Adoption Scenarios

DISTRIBUTION CHANNEL	CHANNEL DESCRIPTION
Community-based testing (existing channel)	HIVST is distributed through community health workers, mobile outreach, or workplace testing programs.
Facility-based testing (existing channel)	HIVST is distributed at a facility via prescription or sale and conducted at home. Alternatively, HIVST may be used within a facility to overcome capacity and personnel constraints.
Private-sector pharmacy channel (new channel)	HIVST is sold through private-sector pharmacies. HIVST sales have been reported in the US, Europe, Kenya, South Africa, Namibia, and China
Secondary distribution in ANC clinics (new channel)	HIVST is provided to a woman attending an ANC center to bring home to her partner(s).
Secondary distribution in facility-based channels (new channel)	HIVST is provided to an individual receiving an HIV-positive diagnosis in a facility-based PITC or CITC setting and the tests is taken home to test his or her sex partner.

CONSERVATIVE SCENARIO	MODERATE SCENARIO	AGGRESSIVE SCENARIO
HIVST is offered to 30% of users in community-based testing channels. Uptake is consistent with data from Malawi study.	HIVST is offered to 50% of users in community-based testing channels. Uptake is consistent with data from Malawi study.	HIVST is offered to 70% of users in community-based testing channels. Uptake is consistent with data from Malawi study.
HIVST is not offered through facility-based testing channels	10% of HIV tests conducted in facility-based settings are HIVST.	20% of HIV tests conducted in facility-based settings are HIVST.
None. Private -sector market is dominated by non quality-assured products.	Quality-assured HIVST products dominate the channel. Private-sector pharmacy sales account for 10% of all HIV tests conducted.	Quality-assured HIVST products dominate the channel. Private-sector pharmacy sales account for 20% of all HIV tests conducted.
HIVST is not offered through secondary distribution at ANC clinics. All partner testing remains referral to professional testing services.	HIVST is provided to 80% of women visiting ANC clinics in PEPFAR priority districts.	HIVST is provided to 80% of women visiting ANC clinics.
HIVST is not offered through secondary distribution in facility-based channels. All partner testing remains referral to professional testing services	HIVST is provided to 50% of people testing positive in facility-based channels in PEPFAR priority districts.	HIVST is provided to 80% of people people testing positive in facility-based channels

REFINEMENT	ASSUMPTIONS FOR ALL SCENARIOS
Testing frequency	PSI assumed that key populations would test between two to four times per year.
Scale-up	To account for uptake over time, PSI examined the increase in coverage of other global health technologies including single dose Tenofovir, triple fixed-dose combination therapy, malaria RDTs, and HIV RDTs for professional-use from 2006-2014. Based on this analysis, PSI segmented countries into early and late adopters and then assumed that once HIVST was introduced into a country, it would take approximately 6 years to scale.

Appendix 12: Key Market Size Modeling Assumptions

1. Potential Market:

Assumptions:

- Countries will adopt test-and-treat by 2020.
- Countries with more than 60% ART coverage in 2016 will meet their 90-90-90 targets in 2020. Countries with less than 60% ART coverage will achieve their targets in 2021. Nigeria will meet its 90-90-90 target in 2024 (in 2016 it had 30% ART coverage).
- Yield rates will change over time but will fall within a range of plausible values that can be modeled based on historical and underlying population and epidemiological data.

Data Sources:

- Population Data: United Nations, Department of Economic and Social Affairs, Population Division (2015). World Population Prospects: The 2015 Revision, custom data acquired via website accessed 18 August 2016.
- PLHIV and PLHIV on ART estimated in 2015: UNAIDS, AIDSInfo database (2015) accessed 10 August 2016.
- PLHIV and PLHIV on ART estimated in 2020 and 2021: SPECTRUM Avenir Health (2016). National Spectrum files 2015. Glastonbury, CT: Avenir Health.

2. Actual Market:

Assumptions:

- Approximately 48.6 million adults were tested for HIV in the nine countries during the most recent year for which there is data.
- The actual market will stay constant over time. Tests required that are beyond the actual market are considered new users and come from the gap.

Data Sources:

- Kenya FY 2016 COP. Strategic Direction Summary. May 25, 2016. Available from http://www.pepfar.gov/documents/organization/257644.pdf.
- Malawi FY 2016 COP. Strategic Direction Summary. July 1, 2016. Available from *http://www.pepfar.gov/documents/organization/257638.pdf*.
- Mozambique FY 2015 COP. Strategic Direction Summary. 2015. Available from *http://www.pepfar.gov/documents/organization/250296.pdf*.
- Nigeria FY 2016 COP. Strategic Direction Summary. June 10, 2016. Available from http://www.pepfar.gov/documents/organization/257635.pdf.
- South Africa FY 2016 COP. Strategic Direction Summary. April 14, 2016. Available from https://za.usembassy.gov/wp-content/uploads/sites/19/2016/04/Final-draft-SDS-South-Africa-COP-2016-public-version.pdf.
- Tanzania FY 2015 COP. Strategic Direction Summary. August 12, 2015. Available from http://www.pepfar.gov/documents/organization/250304.pdf.
- Uganda FY 2015 COP. Strategic Direction Summary. 2015. *http://www.pepfar.gov/documents/organization/250305.pdf*
- Zambia FY 2016 Country Operational Plan (COP). Strategic Direction Summary. June 14, 2016. Available from http://www.pepfar.gov/documents/organization/257644.pdf.
- Zimbabwe FY 2016 COP. Strategic Direction Summary. May 25, 2016. Available from *http://www.pepfar.gov/documents/organization/257623.pdf*.
- Kenya AIDS Indicator Survey 2012. Available from http://nacc.or.ke/kais-2012-final-report/
- Zimbabwe. Global AIDS Response Progress Report 2016. December 2015. Available from http://www.unaids.org/sites/default/files/country/documents/ZWE_narrative_report_2016.pdf
- Nigeria. Global AIDS Response Progress Report 2015. 2015. Available from http://www.unaids.org/sites/default/files/country/documents/MOZ_narrative_report_2016.pdf
- Zambia. Global AIDS Response Progress Report 2015. 2015. Available from http://www.unaids.org/sites/default/files/country/documents/ZMB_narrative_report_2015.pdf.

3. Adoption of HIVST:

Assumptions

- Acceptability rates of HIVST will be in line with those measured in the Malawi (Choko, et al) study of community-based HIVST distribution and in the Kenya study (Thirumurthy, et al) of secondary distribution in ANC facilities.
- Baseline 2016 channel volumes estimated by PSI analysis of PEPFAR COPS, National AIDS Indicator Surveys, and GARPR reporting.

Data Sources:

- Choko, AT, MacPherson, P, Webb, EL et al. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-

based prospective study. ***PLoS Med***. 2015; **12**: e1001873.

- Thirumurthy, H., Masters, S.H., Mavedzenge, S.N., Maman, S., Omanga, E., Agot, K. (2016). Promoting Male Partner HIV Testing and Safer Sexual Decision Making through Secondary Distribution of Self-tests by HIV-negative Female Sex Workers and Women Receiving Antenatal and Post-partum Carin in Kenya: A Cohort Study. The Lancet. 3(6): e226-e274. http://www.thelancet.com/pdfs/journals/lanhiv/PIIS2352-3018(16)00041-2.pdf

4. Enabling Environment:

Assumptions

- Malawi, Zambia, and Zimbabwe will introduce HIVST in 2016. Kenya will introduce HIVST in 2017. South Africa, Uganda, and Mozambique will introduce HIVST in 2018. Nigeria and Tanzania will introduce HIVST in 2019.

Data Sources:

- Interviews with PSI staff and affiliates in Kenya, Malawi, Mozambique, South Africa, Tanzania, Zambia, Zimbabwe.
- HIVST.org accessed September 2016.

REFERENCES

1. UNAIDS. (2016). Fact Sheet 2016. http://www.unaids.org/en/resources/fact-sheet
2. UNAIDS. (2014). 90-90-90, an ambitious treatment target to help end the AIDS epidemic. Geneva.
3. UNAIDS. (2014). A short technical update on self-testing for HIV. http://www.unaids.org/sites/default/files/media_asset/JC2603_self-testing_en_0.pdf
4. UNITAID and the World Health Organization. (2016). HIV Rapid Diagnostic Tests for Self-Testing. 2nd Edition. http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_rapid_diagnostic_tests_for_self-testing.pdf
5. Peck, R.B., Lim, J.M., Wellhausen, J.D., Lee, A.M., & Valdez, M.M. (2014). Target Product Profile: HIV Self-Test Version 4.1.: A White Paper on the Evaluation of Current HIV Rapid Tests and Development of Core Specifications for Next-Generation HIV Tests. Seattle, Washington: PATH. http://www.path.org/publications/files/TS_hiv_self_test_tpp.pdf
6. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000 Oct;32(4):1008-15.
7. Chambers J, Mullick S, Smith D. How to Choose the Right Forecasting Technique. Harvard Business Review 1971.
8. World Health Organization. Global Price Reporting Mechanism. Geneva. Available from http://apps.who.int/hiv/amds/price/hdd/ accessed 10 August 2016.
9. McNerney, R. & Peeling, R. (2015). Regulatory In-vitro Diagnostics Landscape in Africa: Update on Regional Activities. Clin Infect Dis., 61(suppl 3), S135-S140. http://dx.doi.org/10.1093/cid/civ553
10. The World Health Organization. (2015). Consolidated Guidelines on HIV Testing Services. Available at: http://apps.who.int/iris/bitstream/10665/179870/1/9789241508926_eng.pdf?ua=1&ua=1
11. Krause, J., Subklew-Sehume, F., &Colebunders, R. (2013). Acceptability of HIV self-testing: A Systematic Literature Review. ***BMC Public Helath. 13:735.*** http://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-13-735
12. Figueroa C, Johnson C, Verster A, Dalal S, and Baggaley R. (2016). Systematic Review on HIV Self-Testing (HIVST) Performance and Accuracy of Results. Presented at the 2016 International AIDS Conference, Durban South Africa, 18-22 July 2016, WEPEC207
13. Choko, A., MacPherson, P., Webb, E.L., Wiley, B.A., Feasy, H., Sambakunsi, A.M., Makonbe, S.D., Desmond, N., Hayes, R., Maheswaran, H., & Crobett, E.L. (2015). Uptake, Accuracy, Safety, and Linkage into Care over Two Years of Promoting Annual Self-Testing for HIV in Blantyre, Malawi: A Community-Based Prospective Study. ***PLOS Medicine.*** 12(9): e1001873. doi:10.1371/journal.pmed.1001873
14. Thirumurthy, H., Masters, S.H., Mavedzenge, S.N., Maman, S., Omanga, E., Agot, K. (2016). Promoting Male Partner HIV Testing and Safer Sexual Decision Making through Secondary Distribution of Self-tests by HIV-negative Female Sex Workers and Women Receiving Antenatal and Post-partum Carin in Kenya: A Cohort Study. ***The Lancet.*** 3(6): e226-e274. http://www.thelancet.com/pdfs/journals/lanhiv/PIIS2352-3018(16)00041-2.pdf
15. Cambian, V., Mavedzenge, S.N., and Phillips, A. (2014). Modelling the Potential Population Impact and Cost-effectiveness of Self-testing for HIV: Evaluation of Data Requirements. ***AIDS Behav.*** 18(4): 450-458. http://www.ncbi.nlm.nih.gov/pubmed/24957978
16. UNITAID and the World Health Organization. (2016). HIV Rapid Diagnostic Tests for Self-Testing. 2nd Edition. http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_rapid_diagnostic_tests_for_self-testing.pdf
17. UNITAID and the World Health Organization. (2016). HIV Rapid Diagnostic Tests for Self-Testing. 2nd Edition. http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_rapid_diagnostic_tests_for_self-testing.pdf
18. Global Price Reporting Mechanism (GPRM). World Health Organization. Geneva. http://who.int/hiv/amds/gprm/en/ accessed August 2016.
19. UNITAID and the World Health Organization. (2015). Landscape for HIV rapid diagnostic tests for HIV self-testing. UNITAID and The World Health Organization. http://unitaid.org/images/marketdynamics/publications/HIV_ST_Landscape_Nov_2015-_UNITAID_WHO.pdf.
20. Global Price Reporting Mechanism (GPRM). World Health Organization. Geneva. http://who.int/hiv/amds/gprm/en/ accessed August 2016.
21. Trinity Biotech. (2016). ***Your Diagnostic Partner May 2016***. [PowerPoint slides]. (http://www.trinitybiotech.com/wp-content/uploads/2015/01/Trinity-Biotech-Corporate-Presentation-May-2016.pdf, accessed 20 July 2016)
22. Personal communication Han, Andre. 1 July 2016
23. Peck, R.B., Lim, J.M., Wellhausen, J.D., Lee, A.M., & Valdez, M.M. (2014). Target Product Profile: HIV Self-Test Version 4.1.: A White Paper on the Evaluation of Current HIV Rapid Tests and Development of Core Specifications for Next-Generation HIV Tests. Seattle, Washington: PATH. http://www.path.org/publications/files/TS_hiv_self_test_tpp.pdf
24. UNITAID and the World Health Organization. (2016). Landscape for HIV rapid diagnostic tests for HIV self-testing. UNITAID Technology Landscape (2nd Edition).
25. UNITAID and the World Health Organization. (2016). Landscape for HIV rapid diagnostic tests for HIV self-testing. UNITAID Technology Landscape (2nd Edition).

26. United Nations, Department of Economic and Social Affairs, Population Division. (2015). World Population Prospects: The 2015 Revision, Key Findings and Advance Tables. Working Paper No. ESA/P/WP.241. https://esa.un.org/unpd/wpp/publications/files/key_findings_wpp_2015.pdf

27. UNAIDS. (2016). AIDS Info Database. http://aidsinfo.unaids.org/. accessed 10 August 2016.

28. PEPFAR. (2016). National Data as reported in FY 2015 & 2016. ***Country Operational Plan Strategic Direction Summaries.*** http://www.pepfar.gov//countries/cop/.

29. Population Services International. (2016). Analysis of National Testing Results. FY2015 and FY2016 PEPFAR Country Operational Plans.

30. PEPFAR. (2016). Analysis of Investment Profile by Program Areas and Procurement Profile for Key Commodities. ***Country Operational Plans***. http://www.pepfar.gov//countries/cop/.

31. PEPFAR. (2016). Analysis of Investment Profile by Program Areas and Procurement Profile for Key Commodities. ***Country Operational Plan***s. http://www.pepfar.gov//countries/cop/

32. PEPFAR. (2016). National Data. Country and Regional Program Results. https://data.pepfar.net/global.

33. UNITAID and the World Health Organization. (2015). Landscape for HIV rapid diagnostic tests for HIV self-testing. UNITAID and The World Health Organization. http://unitaid.org/images/marketdynamics/publications/HIV_ST_Landscape_Nov_2015-_UNITAID_WHO.pdf.

34. Clinton Health Access Initiative. (2016). Catalyzing the Market for Accurate Tuberculosis Testing in India's Extensive Private Sector through IPAQT. http://www.clintonhealthaccess.org/content/uploads/2016/06/Case-Study-India-IPAQT-June-2016.pdf.

35. World Bank. (2006).Africa Development Indicators 2006. Washington, DC: The World Bank, International Bank for Reconstruction and Development. http://siteresources.worldbank.org/INTSTATINAFR/Resources/ADI_2006_text.pdf

36. Nersesian, P., Hulsmann, M., Cloutier, S., and Chintalova-Dallas, R. (2013). Assessment of Over-the-Counter HIV Rapid Tests Kits in Namibia. Arlington, VA: USAID's AIDS Support and Technical Assistance Resources, AIDSTAR-One, Task Order 1. https://aidsfree.usaid.gov/resources/assessment-over-counter-hiv-rapid-test-kits-namibia.

37. Global Price Reporting Mechanism (GPRM). World Health Organization. Geneva. http://who.int/hiv/amds/gprm/en/ accessed August 2016.

38. UNITAID and the World Health Organization. (2016). HIV Rapid Diagnostic Tests for Self-Testing. 2nd Edition. http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_rapid_diagnostic_tests_for_self-testing.pdf

39. Cambiano, V., Ford, D., Mabugu, T., Mavedzenge, S. N., Miners, A., Mugurungi, O., Nakagawa, F., Revil, P., & Phillips, A. (2015). Assessment of the Potential Impact and Cost-effectiveness of Self-Testing for HIV in Low-Income Countries. ***J Infect Dis.*** doi: 10.1093/infdis/jiv040. http://jid.oxfordjournals.org/content/early/2015/03/10/infdis.jiv040.

40. STAR implementation

41. McNerney, R. & Peeling, R. (2015). Regulatory In-vitro Diagnostics Landscape in Africa: Update on Regional Activities. ***Clin Infect Dis.***, ***61***(suppl 3), S135-S140. http://dx.doi.org/10.1093/cid/civ553

42. McNerney, R. & Peeling, R. (2015). Regulatory In-vitro Diagnostics Landscape in Africa: Update on Regional Activities. Clin Infect Dis., 61(suppl 3), S135-S140. http://dx.doi.org/10.1093/cid/civ553

43. Personal Communication – Russ Dacombe; Miriam Taegtmeyer

44. Center for Accelerating Innovation and Impact. (2015). Idea to Impact: A Guide to Introduction and Scale of Global Health Interventions, ***United States Agency for International Development, Global Health***. Washington DC. https://www.usaid.gov/sites/default/files/documents/1864/Idea-to-Impact_Jan-2015-508.pdf.

45. Peeling, R. (2016). Update on Regional Harmonization of Diagnostic Regulation in Africa. ***PowerPoint slides***, Geneva.Personal communication McGovern, Seth. 30 June 2016.

46. Maheswaran, H., Petrou, S., MacPherson, P., Choko, A., Kumwenda, F., & Lalloo, D. et al. (2016). Cost and quality of life analysis of HIV self-testing and facility-based HIV testing and counselling in Blantyre, Malawi. ***BMC Medicine***, ***14***(1). http://dx.doi.org/10.1186/s12916-016-0577-7.

47. PEPFAR, Country and Regional Program Results, https://data. pepfar.net/global accessed September 7, 2016.

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